Submitted electronically via email to paperwork@hrsa.gov

April 27, 2026

Ms. Chantelle Britton
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 14W52
Rockville, MD 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

Dear Director Britton:

Hudson Headwaters, CH021790, appreciates the opportunity to provide comments on the estimated burden associated with the proposed 340B rebate model pilot program.

Hudson Headwaters is a mission-driven organization and the sole primary care provider for most of its 7,900-square-mile service region in rural Upstate New York. The Network cares for patients at 26 health centers and more than 90 total locations, including hospitals, nursing homes, workplaces, schools, and patient homes, across seven counties in the North Country, Adirondack Park, and Glens Falls areas. The Network's 1,000+ employees, including 220 physicians and advanced practice clinicians, provide care for more than 160,000 patients.

As a Federally Qualified Health Center (FQHC), the Network is an eligible covered entity for participation in the 340B Drug Pricing Program. Like many non-profit, safety-net providers, Hudson Headwaters relies on the 340B Program to offset the costs of providing high-quality health care to everyone who needs it, while ensuring financial sustainability, reinvestment in the community, and expansion of essential services and care.

The 340B Program was created by the federal government, with widespread bipartisan support, to require drug manufacturers to contribute to the cost of providing health care. Each year, Hudson Headwaters uses approximately $20 million in 340B savings to sustain operations and offset chronic under-reimbursement from government payers of core services including preventive health care, dental, pediatrics, obstetrics & gynecology, care management, behavioral health and much more. 340B savings also makes it possible to offer medication discounts and financial assistance programs for eligible patients. Since 2018, it's estimated that Hudson Headwaters has invested $68 million from 340B savings in

capital investments into the communities we serve, in addition to offsetting operational losses.

The 340B program has also enabled the Network to respond quickly and nimbly to community needs and crises. Recent examples include:

- When a private OB/GYN office closed, Hudson Headwaters became the sole provider of OB/GYN services at Glens Falls Hospital, keeping nearly 900 births in the region, despite a $2.4 million annual operating deficit.
- When a private pediatric office closed in Plattsburgh, the Network expanded services, quickly opening a new center to absorb approximately 6,000 children. (Cost: $4.24 million)
- The Network opened Salem Family Health in 2025, a new 14,000+ square foot primary care health center in Washington County, with on-site lab services operated by Glens Falls Hospital. (Cost: $11.46 million)
- Malone Family Health opened in March 2026, located on the Alice Hyde Medical Center campus of UVM Health. (Cost: $12 million)

Lastly, Hudson Headwaters previously operated a third-party administrator (TPA), Hudson Headwaters 340B, that the Network sold in 2024. As both a covered entity and former TPA owner, Hudson Headwaters has unique insight into the administrative and operational impact of the proposed rebate model.

Executive Summary of Position

Hudson Headwaters opposes a rebate model as it does not align with the original intent of the program and would increase administrative burden, financial risk and operational fragility without advancing statutory objectives. The administrative and financial impact will be paralyzing to both small and large covered entities. Adverse impacts include dramatically increasing drug expenditures, reducing cash on hand and disrupting cash flow predictability, creating significant barriers for covered entities that rely on the 340B Program to meet regional health care needs.

In terms of the administrative burden anticipated with a rebate model, the five hours a week that HRSA estimates per covered entity is extremely low. Based on our experience as both a covered entity and a former TPA owner, Hudson Headwaters estimates the rebate model would add at least an additional 40 hours a week of administrative work and one FTE to handle the data submission requirements, including troubleshooting and reconciliation. This level of additional staffing would be necessary given the number of contract pharmacies we partner with, and the prescription volume associated with serving a large, rural region—where we care for a significant proportion of the population.

Ultimately, a rebate model will harm the very people the 340B Drug Pricing Program is intended to help: the vulnerable communities and patients that depend upon covered entities like Hudson Headwaters for essential health care services.

If a rebate model is implemented, Hudson Headwaters urges HRSA to carefully consider the unique operational and financial realities and challenges of community health centers. Pending legislation (e.g., the Community Health Center Drug Pricing Protection Act proposed by Reps. Bergman and Auchincloss) would exempt FQHCs from any 340B rebate framework and highlights bipartisan support for this approach. Additionally, HRSA should consider a neutral clearinghouse to support program integrity (e.g., duplicate discount prevention and patient definition compliance) without allowing manufacturers to redefine 340B requirements through unilateral criteria or processes.

Current Upfront 340B Discount Model

In the past year, Hudson Headwaters captured 84,139 eligible dispenses into our 340B program. Hudson Headwaters ensures that the maximum 340B savings are reinvested for the benefit of our patients and communities—not intermediaries. For our gross 340B savings, 13% was allocated to contracted pharmacies, 38% to drug costs, and 5% to TPA services, with the remaining 44% retained by the Network to support patient care and access. The Network carefully negotiates all contracts, executing agreements with terms that reflect fair market value for dispensing and administrative fees.

In addition to the costs noted above, the increasing number of manufacturer restrictions and the resulting administrative burden have created significant financial implications for the Network.

Since 2020, when pharmaceutical companies began denying or limiting access to 340B contract pharmacy savings, Hudson Headwaters' 340B savings have steadily declined, resulting in $13.7 million lost in 2024 and $15 million in projected losses for 2025. A recent analysis of claims excluded by our contracted pharmacies due to manufacturer policy restrictions from April 2022 to March 2025, shows that Hudson Headwaters did not capture an estimated $39.5M in 340B savings. This figure of lost savings continues to grow as more restrictions have been added. For example, in February 2026 the Network received a letter from Pfizer announcing that its restrictions now apply to FQHCs, which will have an additional $760K financial impact to the Network. Pfizer and many other pharmaceutical companies routinely issue similar letters on their own accord and without warning. These companies have also not decreased the price of drugs thereby retaining 340B funds for their record-setting profitability.

Current contract pharmacy restrictions have also severely curtailed the Network's abilities to fully leverage the 340B program as intended and meet our region's growing demand for high-quality health care close to home. The intent of the program to expand access is undermined when identifying only one pharmacy per health center site or for the entire Network, as Hudson Headwaters' 7,900+ square mile service region is too large to support a single site designation. Allowing only one designated pharmacy across the entire Network does not reflect the realities of rural care delivery or support timely, local access to medications.

The Network has responded to these impacts by devoting significant time and resources to navigate these restrictions. The Network has actively set up committees and taskforces to expand operational efficiencies, as well as significantly slowing or pausing growth and provider recruitment strategies, in response to the financial challenges due to decreased 340B savings. In most cases, we have consolidated and not backfilled leadership positions to better assure long-term organizational sustainability. Additional changes in staffing may be required due to frequent, additional or unexpected manufacturer policy changes.

A rebate model is anticipated to exacerbate these manufacturer restriction challenges and further limit the Network's ability to respond to urgent community needs. Overall, the changes would result in the Network using time, energy and resources to address the many obstacles inherent in a rebate model. These are resources better spent on providing care for the thousands of patients who depend upon us and reinvesting dollars into operational and capital needs.

Adverse Impacts Under a Potential 340B Rebate Model

A rebate model would significantly harm the Network, and ultimately patients, by dramatically increasing drug expenditures, reducing cash on hand, and disrupting cash-flow predictability. As a direct result, Hudson Headwaters would experience significant and ongoing cost increases.

The tables below estimate the rebate model's financial impact on the Network using the NACHC/FQHC Compliance Tool[1]. The estimates focus on MFP drugs because they would be the first to be subject to the proposed rebate model framework. If a rebate model implemented and expanded beyond MFP drugs, these already significant estimates would

[1] The costs were calculated using the NACHC/FQHC Compliance Tool which uses 2025 purchase data and Q1 pricing data to estimate the effect on maximum fair price (MFP) drugs if transitioned to a rebate model: https://www.nachc.org/policy-advocacy/policy-priorities/340b-drug-pricing-program/340b-rebate-model-pilot-program/

be astronomically more. The estimates in Table 1 also assume a 20% rebate denial rate based on Hudson Headwaters current experience with incorrect manufacturer denials (a rebate model is anticipated to increase this problem and contribute to additional costs).

Table 1

	Annual Rebate Opportunity Cost (Loss of Cost Minus + 20% Rebate Denials)	Increased Upfront Annual Drug Spend (WAC-340B AAC)	% Increase in Upfront Inventory Spend
Projected Rebate Model Impact on MFP Drugs in 2026	$ 2,113,437	$ 10,437,741	523171%
Projected Rebate Model Impact on MFP Drugs in 2027	$ 5,303,205	$ 25,441,199	345159%
Projected Rebate Model Impact on MFP Drugs in 2028	$ 6,411,424	$ 30,572,871	896156%

The first column of Table 1 depicts the loss of cost savings due to the fact that a rebate model would break our distributor agreements, reduce our discount across the board (as it is currently based on purchase volume), and eliminate the discount cost for purchases at Wholesaler Acquisition Cost (WAC). In 2026, the Network estimates this loss at $2.1 million; by 2028, a total $13.8 million loss (the sum of the first column in Table 1) is anticipated as more MFP drugs become subject to the rebate model.

A rebate model would also require initial purchase at WAC pricing which would create a financial hurdle that will reduce patient access by straining our distributors' lines of credit, ultimately reducing patient inventory. The second and third columns of Table 1 reflect the immense increase in upfront inventory spend that would be required due to WAC pricing.

Additionally, because the Network currently pays its distributor based on 15-day terms, a rebate model would increase our need for additional cash on hand. Based on the Network's 2025 purchase data and the growing number of impacted MFP drugs each year, the potential annual increased costs will be:

Table 2

	Average Increase in Inventory Costs Pending Rebate Payments - 45-Day Cash on Hand Impact
Projected Rebate Model Impact on MFP Drugs in 2026	$ 1,282,855
Projected Rebate Model Impact on MFP Drugs in 2027	$ 3,103,458
Projected Rebate Model Impact on MFP Drugs in 2028	$ 3,723,511

For example, in 2026, the Network would need to keep an additional $1.2 million in cash on hand in order to cover the rebate model's upfront inventory purchase requirement. By 2028, the Network would need an additional $3.7 million in cash on hand. As a consequence, the Network's financial resources would need to be shifted to accommodate the increased inventory cost of a rebate model. This would negatively impact the Network's ability to nimbly respond to our patient and communities' growing needs. As just one example, these are resources that currently allow the Network to step in when crucial health care services would have otherwise been lost, such as operating the sole OBGYN practice with delivering privileges at Glens Falls Hospital, a service that currently operates at a $2.6 million loss.

In order to manage the additional administrative and operational tasks required of a rebate model, the Network anticipates at least one additional staff member will be required to help with:

- Submitting new data submission requirements.
- Managing dual accumulation systems.
- Monitoring manufacturer-specific requirements.
- Managing denials and dispute processes.
- Managing and reconciling rebates across 100+ contract pharmacies.
- Completing increased compliance and reporting activities.

According to an internal NACHC assessment, 47% of responding CHCs estimate needing to hire 0.5 to 1 full-time equivalent (FTE), 36% estimate needing 1 to 2 FTEs, and 7% project needing more than two FTEs to meet the anticipated demand of reporting 340B rebate claims This would cost Hudson Headwaters an additional $80,000 to $100,000 a year per FTE.

If a rebate model is implemented, these additional costs and financial implications will make it increasingly difficult to support underfunded programs, such as OB/GYN and behavioral health, make much-needed capital investments or address critical community needs and priorities such as the recruitment and retention of rural health care providers.

Preventing Adverse Impacts of a Potential Rebate Model

The Network opposes the transition away from the current upfront discount model. However, if a rebate model is implemented, and whether community health centers are ultimately exempt or not, we provide the following recommendations based on our experience as both a covered entity and former TPA owner. To ensure the integrity of 340B,

prevent increased costs and reduce administrative burden under a rebate model framework, we encourage HRSA to:

Utilize a neutral "clearinghouse" IT platform or authority: The current framework allows manufacturers to act as the sole arbiter, creating an uncertain environment that results in direct financial harm. As part of any rebate model, Hudson Headwaters recommends ensuring that the company overseeing the rebate model is assured as a neutral authority to help prevent individual manufacturers from requiring varying processes, platforms and/or systems and, as a result, prevent additional costs for covered entities. The framework proposed in the previously proposed 340B Rebate Pilot allows manufacturers to deny rebate claims based on vague or ambiguous reasons, such as "duplicate rebate" or "MFP deduplication," without providing the data or documentation CHCs need to understand or contest those decisions. HRSA should require that any rebate model operates under uniform national standards that limit manufacturer discretion and costly delays, hold manufacturers accountable, and protect covered entities from financial harm.

Require unlimited contract pharmacy use: The Network suggests HRSA add language to the 340B rebate pilot stating that restrictions or designations on the number of contracted pharmacies are not allowed, ensuring a covered entity, as registered on OPAIS, can use any contracted pharmacy. This is an especially important protection for rural communities and covered entities responsible for large geographies.

Provide additional details and assurances on the transition plan for accumulations: Based on the Network's experience with pharmaceutical manufacturers' contracted pharmacy restrictions, there is concern about the pace of the significant changes and limited insight into the steps required to ensure a seamless transition. The Network operates 340B replenishment models across all our contract pharmacies, clinically administered drugs, and our entity-owned pharmacy. It is unclear in rebate model plans how covered entities will transmit appropriate data from new to old accumulations. Dispenses in old accumulations may be outside of the 45-day requirement and remain unreplenished. The Network recommends that HRSA outline assurances in a transition plan for accumulation models to ensure a seamless transition without disruptions for patients or missed savings for covered entities.

Increase timeframe for claim submission and uniformity: The Network suggests expanding the 45-day window to 90 or 180 days. Along with a clear, uniform process, this expanded timeframe will help ensure rebates are not denied due to issues with timely claim submission, patient definition, or other technical concerns. HRSA should accept rebate claims as valid unless the manufacturer demonstrates otherwise under statutorily defined duplication of discount prevention terms (i.e., 340B with Medicaid Drug Rebate Program or

Medicare Drug Price Negotiation Program); HRSA should require uniformity among eligible manufacturers to mitigate potential administrative and financial burdens associated with receiving timely and appropriate 340B rebates. A lack of standardization and likely varying requirements across manufacturers will force CHCs to use multiple internal systems to manage and report the same data, thereby increasing costs and operational burdens.

Require rebates based on units, including wasted units: Base rebates on dispensed/administered units rather than package size, and include wasted units where partial packages cannot be fully used by eligible patients—this is critical given high upfront costs under WAC purchasing.

Example: Package size = 100 tablets; three 30-day (30-tablet) prescriptions dispensed; remaining 10 tablets cannot be matched to eligible patients. Absent a unit-level rebate, covered entities cannot be made whole and must absorb these costs, often for increasingly expensive medications.

Pilot with a limited, incremental, or voluntary source of covered entities: Begin with a small volunteer cohort of covered entities to identify and remediate operational issues before broader rollout. Also note pending legislation (e.g., the Community Health Center Drug Pricing Protection Act proposed by Reps. Bergman and Auchincloss) that would exempt FQHCs from any 340B rebate framework.

Promote Negotiation of Terms and Conditions and BAAs: Require pilot vendors to hold harmless covered entities, restrict data use to MFP and duplicate discount prevention, and execute covered entities' Business Associate Agreements (BAAs). HRSA should clearly state the company's terms and conditions and outline requirements consistent with the Health Insurance Portability and Accountability Act of 1996.

Finality of Payment and Manufacturer Appeals: Once a rebate is paid, treat it as final unless a covered entity reverses it. If a manufacturer disputes payment, establish a clear, time-bound appeal process, modeled on the Medicaid rebate program—not unilateral claw backs. It should be clarified that a manufacturer must bear the burden of establishing that no rebate is owed rather than the covered entity establishing that it is due.

Create a refund dispute or appeal process: The current Administrative Dispute Resolution (ADR) process has not been an effective way to resolve issues or concerns and often involves lengthy timelines. For example, the Network has submitted three ADR cases in July 2024 (Sanofi), September 2024 (Lilly), and May 2025 (Biogen) and all are still awaiting resolution. Given the substantial financial resources required to participate in the proposed rebate model, the Network recommends a resolution process with clearly defined and enforced timelines to address disputes promptly.

Remove Payer BIN/PCN from Required Data: BIN/PCN data is not universally available to covered entities (particularly for clinically administered drugs outside NCPDP formats) and is not necessary to validate MFP duplication or covered entity inclusion.

Conclusion: 340B Program Integrity

It is written in the Federal Register that the intent of the 340B Drug Pricing Program is to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). A rebate model compromises the program's intent by crippling providers both administratively and financially, creating limited access through adverse impacts to the covered entity. Ultimately, this model threatens the Network's ability to continue providing a comprehensive array of services, while also limiting its capacity to adequately or rapidly respond to emerging needs and changes in the health care landscape.

We appreciate this opportunity to provide comments. Please do not hesitate to contact us with any additional follow-up questions.

Respectfully,

Tucker Slingerland, M.D.
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Hudson Headwaters Health Network, CH021790
9 Carey Road
Queensbury, NY 12804

April 27th, 2026

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

Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of **Wirt County Health Service Association INC d/b/a Coplin Health Systems,** 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, Coplin Health Systems again requests that CHCs be exempted from the pilot program.**

Coplin Health Systems in a Federally Qualified Health Center that has locations in Jackson, Wood, and Wirt Counties in West Virginia and Meigs County Ohio. We have over 19,000 patients with many of them relying on the 340B program to access medications.

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 **over 19,000** 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: Coplin Health Systems** anticipates needing **at least 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, **Coplin Health Systems** will face an increased administrative burden to monitor rebate claims and payments. **Approxiemately 20 hours a week** will be required to report and reconcile 340B rebate claims to a third-party platform.
- **External Vendor Costs: Coplin Health Systems** anticipates an additional **$25,000 -50,000 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.

The In-House Pharmacy: The Burden of IT Integration

Coplin Health Systems operates 3 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. **Our software vendor will have to create reporting mechanism that they are unfamiliar with to navigate the rebate model**
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools. **This is estimated to be $20,000**
- **Ongoing Resource Diversion:** Staff who currently manage clinical pharmacy services will be forced to spend **20** hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

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

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 25 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 **25** 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 rural West Virginia 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] We anticipate the burden to be severe enough that we will not utilize 340B medications for clinic administered drugs, creating a financial burden for our organization.

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

Coplin Health Systems 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. **On a daily basis, we have sliding fee patients that tell us how fortunate they are to have us here and they would not be able to afford their medications without us. The rebate model is a threat to this. Without the upfront discounts, it makes it difficult to assure these patients will have access to their medications because the financial impacts to our organization of fronting the money for the medications will be devastating.**

Conclusion

Coplin Health Systems 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

[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

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

Coplin Health Systems 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 **Scott Price, Chief Pharmacy Officer at scottp@coplinhealth.com**

Sincerely,

Rob Dudley, President & CEO
Coplin Health Systems

April 27, 2025

Chantelle Britton
Director
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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 **Lowell 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, Lowell Community Health Center again requests that CHCs be exempted from the pilot program.**

Lowell Community Health Center, established in 1970, is the healthcare home of choice for 38932 individuals in Greater Lowell. Guided by The Power to Care, we provide comprehensive, high-quality services that help people stay healthy and connected to care, ensuring every patient is welcomed, understood, and supported. We help patients get the care they need, regardless of ability to pay. If cost is a concern, we can guide patients through applying for insurance or checking if they qualify for our sliding fee scale.

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 **38932** 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 Lowell Community Health Center** anticipates needing **2.1** 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, **Lowell Community Health Center** will face an increased administrative burden to monitor rebate claims and payments. **10 hours** will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **Lowell Community Health Center** anticipates an additional **$130,000** 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.

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

- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees **approximately $7500 each month** to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves **38,932** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at **$260,000** annually.

The In-House Pharmacy: The Burden of IT Integration

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

System Interoperability: Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure. This would require us to manually add AAC price files in order to submit 340B net acquisition cost to certain Medicaid claims.

- **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 **10** hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with 16 Contract 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 **17** 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 Middlesex County**,** this would leave patients with no affordable medication options. Over 17 percent of the U.S. population already lives in a pharmacy desert.[2]

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHCs are designed cost-effectively to reflect the nuances of CHC billing. Implementing a rebate model for CADs would also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[3] **Lowell Community Health Center** estimates it will take 15 **hours and cost $50,000** to upload records related to CADs. For a primary care clinic implementing **Epic Willow** to monitor clinic-administered drugs mainly involves building a streamlined, closed-loop workflow that

[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

connects ordering, administration, inventory, and billing. The integration starts with configuring a limited formulary of commonly administered medications (e.g., vaccines, injections) and mapping each to the correct NDCs, billing codes, and charge logic. From there, the system is set up so that when a provider places an order, it routes appropriately for clinic staff, ties into the electronic medication administration record (eMAR), and documents administration in a way that automatically decrements inventory and triggers charges. Inventory management is typically lighter but still requires setting up stock locations, lot and expiration tracking, and basic replenishment rules. The build also includes ensuring accurate billing through J-code mapping and charge triggers, defining user roles and permissions for nurses and staff, and thoroughly testing the full workflow from order to administration to charge capture. Overall, the focus is on creating a simple, reliable system that maintains medication safety, ensures accurate inventory tracking, and captures revenue correctly without adding unnecessary complexity to clinic workflows.

II. Patient Impact

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

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

III. Financial Challenges

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

- **Purchasing Drugs at the WAC Price Upfront:** Under the proposed model, CHCs would be required to purchase drugs at the WAC. CHCs will have to wait to receive their rebate payment *after* providing medications to their patients, forcing difficult decisions about how to allocate limited financial resources, including cutting essential services and reducing

[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)

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. **Lowell Community Health Center** pharmacy helps make medications more affordable by combining discounted purchasing, clinical collaboration, and patient support services. Through the 340B Drug Pricing Program, Lowell Community Health Center pharmacists work closely with clinicians to optimize cost-effective therapy by selecting generics, using therapeutic alternatives, and following evidence-based formularies that prioritize high-value medications. In addition, Lowell Community Health Center Pharmacy assists patients with enrolling in insurance or medication assistance programs, help navigate prior authorizations, and offer adherence services such as medication synchronization and counseling**.**

Conclusion

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

Lowell Community Health Center appreciates the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact **Amy Sullivan PharmD RPh, Senior Director of Pharmacy Services at AmySu@lchealth.org.**

Sincerely, Diane Martin

Diane Martin, RPh, 340B Program Manager
Lowell Community 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

Community Care of West Virginia

PO Box 217 · Rock Cave, WV 26234 · (304) 924-6262 · www.CCWV.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:

Community Care of West Virginia began operations in 1979 with a single medical clinic, envisioned by a group of community leaders who wanted to meet the needs of their small rural Appalachian community by providing access to medical care. This community, through donations of materials and volunteers, built a medical clinic and hired a primary care doctor to address unmet medical needs, which became "Tri-County Health Clinic." Between 1993 and 2011, the organization expanded by opening six primary care clinics and four school-based wellness centers across five counties: Upshur, Clay, Pocahontas, Randolph, and Harrison. In 2005, Tri-County Health Clinic was among the first WV health centers to implement an Electronic Health Record management system, enhancing accountability and patient care procedures. In 2010, Tri-County Health Clinic and Primary Care Services in Clay County, West Virginia, merged to become Community Care of West Virginia, Inc. From a single healthcare clinic in Rock Cave, WV, CCWV now employs 600+ employees, operates twenty (20) health center locations with integrated behavioral health and addiction services, forty-eight (48) school-based wellness sites, one (1) dental clinic, ten (10) in-house 340B pharmacies and one (1) mobile unit. CCWV serves 54,584 (2025 UDS) patients from 34 West Virginia counties. CCWV currently utilizes twenty-six (26) contract pharmacies within our health center footprint, providing our patients access to affordable 340B medications they wouldn't otherwise have due to the significant travel distance and lack of public transportation.

The mission of CCWV is to help our communities live the healthiest lives possible by meeting their immediate and long-term healthcare needs. This

mission is accomplished by providing high-quality, accessible, comprehensive, cost-effective healthcare services, by serving as a true, complete medical home for our patients and communities.

On behalf of Community Care of West 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, Community Care of West Virginia 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 **54,584** 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.

<u>Workforce Impact:</u>

- **Staffing Impact**: **Community Care of West Virginia** will add 2 FTE's totaling $130,605.00-one FT Pharmacy Admin Employee, 70,305.00 and one FTE compliance employee 60,299
- **Number of Hours:** Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, Community Care of West Virginia, will face an increased administrative burden to monitor rebate claims and payments. With uploading daily dispensing data for 10 In-house pharmacies, estimating 1 hour per day (20 business days in a typical month), tracking progress, and reconciling refunds, on the low end, 45 hours a month. This does not take into consideration whether issues and further research are needed. This will be

required to report 340B rebate claims to a third-party platform, assuming all adhere to the nine drug manufacturers' plans. The lack of standardization and likely varying requirements across manufacturers will force CHCs to use multiple internal systems to manage and report the same data, thereby increasing costs and operational burdens.

- **External Vendor Costs**: **Community Care of West Virginia, One-Time Implementation Costs:** We added Central Office to our pharmacy software system to consolidate in-house data and streamline reporting. While this addition has been helpful in some areas, we discovered that several reports still need to be generated at the individual store level. The software purchase totaled **$18,628.00**, and we are charged an annual **fee of $26,244.00** for server access.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees to maintain these complex rebate-tracking features. These are permanent, recurring costs that diminish our 340B savings.
- **Ongoing Resource Diversion:** It is estimated that staff who will manage clinical pharmacy services will be forced to spend **[10-15]** hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price. CCWV clinical pharmacy is estimated to be established in 2028.
- **Total Cost:** For our CHC, which serves 54500 patients, the total projected increase in expenses, including labor, IT, and carrying costs—is estimated at 450K annually

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. Community Care of West Virginia currently partners with 27 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 in-house and 27 contract 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. This would leave our patients unable to obtain life-saving medications outside CCWV's in-house pharmacies during evenings and weekends, potentially increasing emergency room utilization and hospitalizations. 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 to be cost-effective and 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

Community Care of West Virginia 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. **Community Care of West Virginia, in particular, means it will impact over the course of a year: 20,867 340B patients receiving 145,827 340B-eligible prescriptions, 3,262 of which come from contract pharmacies. Additionally, Community Care of West Virginia passes on over $647,000 in 340B savings directly to patients via some 29,360 'at-cost' cash prescriptions. We**

also have 340B-based copay assistance, which saves our patients over $529,000 across more than 2,400 prescriptions annually.

Conclusion

Community Care of West Virginia 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. **Community Care of West Virginia** believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHCs and other safety net providers.

Community Care of West Virginia 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 Patricia Collett, CEO: trish.collett@ccwv.org

Sincerely,

Patricia Collett
Community Care of West Virginia

April 27, 2026

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

RE: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-XXXX

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

Dear Director Britton:

On behalf of Careteam Plus, Inc., I would like to thank the Health Resources and Services Administration (HRSA) for extending the comment deadline to April 27, 2026. This extension has been vital in enabling our organization to conduct a deep-dive analysis of the operational and financial risks to CHC /FQHC Look-a-likes posed by the proposed rebate model. The 340B program is foundational to CHC /FQHC Look-a-like'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 /FQHC Look-a-like pharmacy operations nationwide. Based on national assessments from NA CHC /FQHC Look-a-like, we know that CHC /FQHC Look-a-likes are facing staggering impacts:

- **Financial Losses: Careteam Plus, Inc.** anticipates an average loss of **$1.5 million** from entity-owned pharmacy operations and **30% reduction in savings** for contract pharmacy arrangements due to the administrative hurdles of manual reconciliation
- **Projected Cost Increases:** CHC /FQHC Look-a-likes anticipate significant increases in operational costs. National data shows that a single mid-sized CHC /FQHC Look-a-like expects to incur over $3 million in additional costs **annually** to manage the pilot.
    - **Rural Health Center Breakdown:** For rural CHC /FQHC Look-a-likes, these costs are even more devastating. Rural centers invest nearly **one-quarter (25%)** of their 340B savings in rural-specific infrastructure, such as mobile clinics and telehealth.

The impact of implementing the 340B pilot program will significantly affect Careteam Plus, Inc. as we are an FQHC look-a-like who does not receive 330 funding.

I. We Strongly Urge HRSA To Exempt CHC /FQHC Look-a-likes from the 340B Rebate Model Pilot Program.

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

congressional intent made clear, the program was created to help safety-net providers "stretch scarce Federal resources as far as possible." The proposed rebate model undermines this by placing an immense financial burden on CHC /FQHC Look-a-likes.

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

- **6500 patients over all programs**
- **Increase administrative costs by $1 million**
- **Decrease access for vulnerable Ryan White patients**

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

II. Patient Impact

Most importantly, a 340B rebate model poses a direct and serious threat to medication access for the vulnerable patients that CHC /FQHC Look-a-likes serve. For uninsured and underinsured patients who rely on the affordability that the 340B program provides, this model could render critical medications financially out of reach. Patients may be forced to make tough decisions in transitioning to other medications, due to cost or lack of availability, as a direct result of a 340B rebate pilot program. These forced therapeutic interchanges introduce real clinical risk, including medication nonadherence, treatment delays, and adverse outcomes, particularly for patients managing multiple chronic conditions who have limited alternatives and no other pharmacies close by.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

III. Administrative Complexities and Financial Challenges for CHC /FQHC Look-a-likes

The proposed 340B Rebate Model Pilot Program is not only a financial threat to CHC /FQHC Look-a-likes but also a duplicative and unnecessary administrative burden. HRSA should exempt CHC /FQHC Look-a-likes from the 340B Rebate Model Pilot because they will incur additional workforce and IT costs to comply with multiple manufacturer rebate requirements. A recent NA CHC /FQHC Look-a-like assessment illustrates that CHC /FQHC Look-a-likes will incur additional workforce and IT costs to maintain compliance with multiple manufacturer rebate requirements, increasing the burden associated with this rebate pilot program. Similar to navigating manufacturers' existing contract pharmacy restrictions, CHC /FQHC Look-a-likes will need to invest in IT infrastructure upgrades and hire or reassign staff to manage new complexities, including varying data submission requirements and timelines, payment reconciliations, and dispute processes for denied rebates. Depending on the volume of prescriptions a pharmacy fills for the selected drugs, CHC /FQHC Look-a-likes will face an increased administrative burden in monitoring rebate claims and payments.

340B Rebate Model Operational & Administrative Cost Calculator Description

To support CHC /FQHC Look-a-likes in assessing the **financial and operational impact** of current manufacturer restrictions and an anticipated rebate model, NACHC worked with their consultant, FQHC 340B Compliance, to create an **Operational & Administrative Cost Calculator.** The tool aggregates program savings, UDS financial data, staffing, external consulting costs, dispensing/capture activity, and clinic-administered drug tracking models to support operational cost forecasting.

CHC /FQHC Look-a-likes have already experienced steep increases in operational costs given the multitude of manufacturer restrictions, which have now been extended to clinic-administered drugs and entity-owned pharmacies. A refund model will require a significant increase in already-strained operational capabilities.

- **Sliding Fee Discount**: **Careteam Plus, Inc.** provided **$517,948** in sliding fee discounts, provided through discounted medications and medical services. We anticipate that our ability to offer sliding fee discounts will decrease significantly under a rebate model.
- **Staffing Impact**: **Careteam Plus, Inc.** anticipates needing **up to 2** additional FTEs to account for the increase in regulatory, operational, administrative, and compliance burden created by a rebate model.
- **External Vendor Costs**: Given increased complexity, **Careteam Plus, Inc.** anticipates an increase of **$350,000** to costs for external support vendors. These vendors may include 340B consultants, legal counsel, program coordination, third-party administrators, electronic medical records, pharmacy software, and reconciliation services.

Workforce Impact

Below is specific data on the administrative costs that CHC /FQHC Look-a-likes anticipate, based on thorough planning, review of current business practices, and the costs of implementing new systems and processes.

- According to an internal NACHC assessment, 47% of responding CHC /FQHC Look-a-likes estimated needing to hire 0.5 to 1 full-time equivalent (FTE), 36% estimate needing 1 to 2 FTEs, and 7% project needing more than two FTEs to meet the anticipated demand of reporting 340B rebate claims.[7] **Careteam Plus, Inc. anticipates 1 to 2 FTEs to meet the demand**
- Additionally, several CHC /FQHC Look-a-likes estimate the cost to hire additional staff to be between $30,000 to $200,000 annually.[8] One midwestern CHC /FQHC Look-a-like, serving approximately 12,000 unique patients last year, anticipates annual costs exceeding $3 million, including upfront costs for purchasing drugs in this pilot program, increased labor costs, carrying costs, and potential losses on discounted or expired drugs without rebate recovery. CHC /FQHC Look-a-likes operate on razor-thin margins, and these additional costs are not an option for many entities. **Careteam Plus, Inc. estimates the cumulative costs to reach upwards of $1.5 million to accommodate this rebate model.**
- Depending on the volume of prescriptions a pharmacy fills for the 10 selected drugs, CHC /FQHC Look-a-likes will face an increased administrative burden in terms of monitoring rebate claims and payments. **Careteam Plus, Inc. estimates 10 hours per week** will be required to report 340B rebate claims to a third-party platform, assuming all adhere to the nine drug manufacturers' plans. The lack of standardization and likely varying requirements across manufacturers will force CHC /FQHC Look-a-likes to use multiple internal systems to manage and report the same data, thereby increasing costs and operational burdens. **Careteam Plus, Inc. urges HRSA to require uniformity among eligible manufacturers to mitigate potential administrative and financial burdens associated with receiving timely and appropriate 340B rebates.**

Pharmacy Software & Third-Party Administration Changes

Navigating this pilot requires more than just staff; it requires significant changes to pharmacy software and Third-Party Administrator (TPA) workflows. We encourage HRSA to consider the increased compliance burdens when manufacturers have the flexibility to require varying data submission standards and elements. Additionally, if manufacturers are allowed to select different software platforms, as they currently do with contract pharmacy policies, the administrative burden on CHC /FQHC Look-a-likes 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. $45,000 will be required simply to reach the baseline of compliance before a single rebate is ever received.
- **Ongoing Operational Fees**: Beyond implementation, our TPA and software vendors will likely charge ongoing service fees to maintain these complex rebate-tracking features. These are permanent, recurring costs that diminish our 340B savings.
- **Total Cost:** For our CHC /FQHC Look-a-like, which serves 6500 patients, the total projected increase in expenses—including labor, IT, and carrying costs—is estimated at $500,000+ annually.

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

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

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

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

For CHC /FQHC Look-a-like contract pharmacy partners, the rebate model introduces a new complexity that threatens the very existence of these arrangements. My CHC /FQHC Look-a-like 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:** Because this model shifts the financial risk to the pharmacy, we fear our contract partners will opt out of the 340B program entirely rather than manage the administrative headache. In our region, this would leave patients in **Horry, Georgetown, and Williamsburg Counties** with no affordable medication options. Over 17 percent of the U.S. population lives in a pharmacy desert already,[9] and the closings of pharmacies have only exacerbated this, with nearly 30 percent of pharmacies that had been open from 2010 to 2021 closing by 2021.[10]

Clinic Administered Drugs: The Burden of New Systems Required

Clinic-administered drug (CAD) operations and record-keeping in CHC /FQHC Look-a-likes are designed in a cost-effective manner that reflects the nuances of CHC /FQHC Look-a-like billing. Implementing a rebate model for CADs would also require new software, system integration, and staff training. NACHC estimates these costs would range from $30,000 to $50,000 annually and could be much higher, depending on the software.[11]

- **Bundled Payments:** The majority of clinic-administered drugs are bundled into the prospective payment system (PPS) billing when administered to patients by CHC /FQHC Look-a-likes. Because PPS visits are paid at a flat rate, the medications administered in CHC /FQHC Look-a-likes are often not included on claims billed to payers.

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

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

[11] Internal NACHC survey data

- **Simplified Records:** Because CHC /FQHC Look-a-likes maintain limited inventories of CADs and they are typically not separately billed on claims, it is still common for administration and inventory logs to be maintained on paper, with text documentation in patient visit notes describing what was administered. While the CHC /FQHC Look-a-likes maintain perpetual inventories and complete administrative records, the fact that the records are often paper imposes the added burden of converting them to electronic data before submitting for rebate. Very few CHC /FQHC Look-a-like records include electronic medication administration records (eMARs), which are common in hospital electronic medical records (EMRs). Where eMARs are available, they incur an additional cost and often require CHC /FQHC Look-a-like to pay for a standalone software system.
- **Minimal Risk of Duplicate Discounts:** CHC /FQHC Look-a-likes primarily bill under Medicare Part A, which is not statutorily included in the Medicare Drug Price Negotiation Program (MDPNP). Maximum Fair Prices (MFP) are only applicable to Medicare Part D claims in 2026 & 2027 and then expand to include Medicare Part B claims in 2028. Regarding Medicaid, each state already has mechanisms in place to address duplicate discounts.
- **HRSA should explicitly exclude CADs from any 340B rebate model pilot.** At a minimum, such drugs should remain excluded unless and until they are billed as discrete claims by CHC /FQHC Look-a-likes and a demonstrated duplicate discount risk exists that cannot be addressed through existing statutory mechanisms. Including CADs in a rebate pilot at this stage would impose disproportionate administrative costs, software expenses, and compliance risks on CHC /FQHC Look-a-likes without corresponding benefits to program integrity or federal oversight.

A. Financial Challenges

Under the proposed 340B Rebate Model Pilot, CHC /FQHC Look-a-likes would be required to purchase drugs at full retail price, also known as the Wholesale Acquisition Cost (WAC). This departure from over 30 years of precedent would drastically diminish CHC /FQHC Look-a-likes' ability to purchase drugs, as the uncertainty of waiting for a manufacturer to approve a rebate would constrain cash flow. CHC /FQHC Look-a-likes will have to wait to receive their rebate payment ***after*** providing medications to their patients. This change will force CHC /FQHC Look-a-likes to make difficult decisions about how to allocate their limited financial resources, including cutting essential health services, reducing operating hours, or discontinuing services that support patients' health outcomes.

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

A rebate model also creates substantial uncertainty about CHC /FQHC Look-a-likes' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHC /FQHC Look-a-likes are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of the project.[12] In line with their mission, CHC /FQHC Look-a-likes offer flat or sliding-scale discounts on prescription drugs to make them more affordable for low-income individuals.[13] A CHC /FQHC Look-a-like can adjust the cost of health care services, including medications, based on a patient's income and family size. **Careteam Plus, Inc. will therefore incur more substantial losses on our sliding fee patients.**

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

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

Lack of access to upfront 340B discounts, along with the high IT/infrastructure costs, will disproportionately impact CHC /FQHC Look-a-likes and trickle down to patients. It is important

[12] HRSA FAQ

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

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

to note that many CHC /FQHC Look-a-likes are currently under financial strain. Nearly half of CHC /FQHC Look-a-likes operate with fewer than 90 days of cash on hand, and one in four reports approximately negative five percent (-5%) operating margins. Below, you will find specific data demonstrating the significant increase in financial costs CHC /FQHC Look-a-likes will incur under a 340B Rebate Model.

340B Rebate Drug Cost Impact Calculator Description

To support CHC /FQHC Look-a-likes in assessing the financial impact of purchasing drugs at the full WAC price, NA CHC /FQHC Look-a-like worked with its consultant, FQHC 340B Compliance, to create another calculator for all CHC /FQHC Look-a-likes. Financial data and projections are based on a 340B Rebate Drug Cost Impact Calculator, which utilizes CHC /FQHC Look-a-like-specific purchasing data, 340B[15] and WAC pricing data for the first quarter of 2026 (Q1 2026), and the CMS list of MDPNP selected drugs by NDC.[16] For individual MDPNP Price Applicability Years, the calculator evaluates:

- **Increase Upfront Annual Drug Spend**: WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026. WAC and 340B prices applied for the overall annual program volume to determine the annual increase in initial drug spend.
- **Cash Flow Impact**: WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026 WAC and 340B prices to give overall annual program increase in initial spend reflected at intervals of 30, 45, 60, & 90 days. Represents potential WAC purchase to 340B rebate payment cycles. Inventory models, frequency of data submission, and manual processes for referral claim capture can all influence Covered Entities' (CEs) intervals between purchasing a drug at WAC and receiving the Manufacturer Rebate to 340B Ceiling Price.
- **Rebate-Related Opportunity Costs**: Based on percentages of loss of prompt pay, purchase volume, and subceiling discounts and anticipated rebate denials as a portion of annual WAC spend (described above).
- **Increase Upfront Drug Spend** WAC – 340B for 2025 purchases by NDC & volume, reflected in Q1 2026, calculated by NDC, then aggregated at the MDPNP selected drug, manufacturer, and MDPNP Price Applicability Year levels.
- **WAC Purchase to 340B Rebate Payment "Wait" Period:** CHC /FQHC Look-a-likes must wait to receive a rebate payment after purchasing and dispensing medication to the patient. This delay forces difficult decisions about allocating limited financial resources.

Based on our organization's data, we estimate it would cost **$585,000** to purchase these 10 drugs under the proposed rebate model. Currently, our organization spends **$24,000** to purchase these same drugs at the 340B ceiling price. This represents a **2300%** increase in upfront capital required for procurement.

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

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

- **Essential Clinical Services:** To offset the upfront cost of drugs, we would be forced to scale back non-revenue-generating but essential services, such as **our mobile health unit that provides immunizations to rural school districts, medication therapy management (MTM) program for complex diabetic patients, transportation, community health workers, and more.**
- **Workforce & Staffing:** The administrative burden of this pilot requires us to divert funds away from clinical staff. For every "Rebate Coordinator" we are forced to hire, we lose the ability to fund **much needed clinical and support staff.**
- **Patient Financial Assistance:** Our ability to provide medications at "zero-pay" or deeply discounted rates under our sliding fee scale will be compromised. If the cash is not in our accounts because it is being held by a manufacturer, we cannot provide the "bridge" support that prevents our **840** uninsured patients from rationing their insulin or heart medication.
-

B. Wholesaler Implications

Another concern is that purchasing drugs at full WAC will potentially lead the organizations to exceed wholesaler credit limits, halting their ability to order medications until payments are submitted. For example, some CHC /FQHC Look-a-likes have suggested that paying for medications upfront at WAC prices would require dipping into limited financial reserves or taking out loans, thereby defeating the purpose and intent of the 340B program.

Careteam Plus, Inc. asserts that taking out a loan or an extended line of credit to fund drug procurement is a high-risk strategy that places our organization in a state of "financial limbo." This approach fundamentally defeats the purpose and intent of the 340B program—to "stretch" scarce federal resources—by diverting patient-care funds toward interest payments, origination fees, and debt service. Relying on credit to "float" manufacturer rebates is particularly dangerous at a time when all other major revenue sources are unstable.

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

- **Wholesaler Credit Limits:** Purchasing drugs at full WAC will potentially lead organizations to exceed wholesaler credit limits, halting our ability to order medications until payments are submitted. At present, many CHC /FQHC Look-a-likes are forced to pay invoices before their due dates to remain within their credit limits. Given that CHC /FQHC Look-a-likes typically operate with extremely limited financial margins, they are often perceived as having higher credit risks, making increases to credit limits difficult or impractical.
- **Discounts:** CHC /FQHC Look-a-likes often receive prompt pay, purchase volume, and sub-ceiling discounts on their drug purchases. Forcing a WAC-upfront model threatens our ability to meet these terms, potentially resulting in the loss of these essential discounts. Due to contractual confidentiality requirements, CHC /FQHC Look-a-likes are unable to disclose their

exact prompt-pay discount. However, **Careteam Plus, Inc.** estimates its 2027 Annual Rebate Opportunity Cost to be approximately **$203,000+.** This cost aggregates the estimated financial impact of rebate denials and loss of purchase discounts.

- **Careteam Plus, Inc.** estimates that purchasing the 10 selected drugs at WAC instead of 340B ceiling prices will increase our upfront monthly drug spend by **$48,750+**. **This increases to $107,500+ monthly to include the 2027 MFP Drugs, and balloons to $480,000+ monthly to include the 2028 MFP Drugs. This rebate model would prove devastating to all programs at Careteam Plus, Inc.**

Every dollar we pay upfront at WAC is a dollar that remains "frozen" in the manufacturer's reconciliation system. While we wait for rebates, we lose the liquidity necessary to respond to immediate public health crises or facility emergencies. To navigate the rebate model, our organization may be forced to **take out a line of credit and utilize limited financial reserves.** This is not a sustainable solution. Forcing CHC /FQHC Look-a-likes into debt to maintain their drug supply creates an environment of clinical instability. In our region, where patients have no choice but to rely on **Careteam Plus, Inc.**, the risk of our credit limit being reached or our reserves being depleted is a direct threat to the community's safety net, which again was and is the intent of the 340B program. If we are forced into financial limbo, the "trickle-down" effect is immediate: longer wait times, reduced service availability, and a weakened ability to provide the steeply discounted medications that our 52 million patients across the country depend on.

a. Financial Impact of Rebate Denials and Delays

Careteam Plus, Inc. urges HRSA to recognize that without rigorous, non-discretionary safeguards, the rebate model is not a "pricing mechanism" but a significant financial liability. The current framework allows manufacturers to act as the sole arbiter of a CHC /FQHC Look-a-like's statutory savings, creating an uncertain environment that results in direct financial harm. The framework proposed in the previously proposed 340B Rebate Pilot allowed manufacturers to deny rebate claims based on vague or ambiguous reasons, such as "duplicate rebate" or "MFP deduplication," without providing the data or documentation CHC /FQHC Look-a-likes need to understand or contest those decisions.[17]

If a rebate is denied, the CHC /FQHC Look-a-like takes a net loss on the transaction, having already paid the full WAC price to the wholesaler and provided the drug to the patient at a steep discount. Given our current volume of the 10 selected drugs, even a conservative **15%** denial rate would result in a net annual loss of **$90,000+.** This is a sum our CHC /FQHC Look-a-like cannot absorb, as it represents a direct extraction of resources from our safety net budget. Any reduction in financial resources will directly affect our ability to fulfill the CHC /FQHC Look-a-like mission of serving all patients, regardless of their ability to pay.

The financial harm is compounded by the fact that the 340B price is no longer reflected in the wholesaler's price catalog or the pharmacy software at the time of purchase. This forces CHC /FQHC Look-a-likes to "estimate" rebate amounts, creating unpredictable financial losses and the

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

potential to undercharge or overcharge patients. Additionally, the lack of real-time 340B pricing presents challenges for compliance with 340B actual acquisition cost (AAC) billing in fee-for-service Medicaid. This may lead to increased Medicaid costs and potential state-level claw-backs, creating a second layer of financial liability for the CHC /FQHC Look-a-like. Without a standardized, transparent, and neutral dispute resolution process, the 340B Rebate Model Pilot functions as an interest-free loan from safety-net providers to multi-billion-dollar manufacturers. These unpredictable denials and delays create serious cash flow issues for CHC /FQHC Look-a-likes operating on thin margins, which depend on timely reimbursement to sustain services for medically underserved populations.

IV. Reconciliation and Rebate Denials Operational Challenges

If HRSA proceeds with a rebate-based pricing model, the program must include clear, enforceable operational guardrails to prevent the systematic shifting of financial and administrative risk to covered entities. **HRSA must require that any rebate model operate under uniform national standards that limit manufacturer discretion, hold manufacturers accountable, and protect covered entities from financial harm.** Recommendations around guardrails include:

- A presumption that rebate claims are valid unless the manufacturer demonstrates otherwise under statutorily sanctioned duplication of discount prevention (i.e., 340B with MDRP or MDPNP);
- Standardized, publicly defined denial categories with claim-level documentation;
- Rebate payment timing requirements must apply to both initial and corrected determinations. If HRSA adopts a 10-day payment requirement, that requirement must run from both the initial determination and any subsequent corrected determination to prevent manufacturers from using dispute processes as a delay mechanism;
- A clear enforcement framework, including consequences for repeated late payments or improper denials by manufacturers;
- Manufacturers must bear the burden of establishing that a rebate is not owed;
- Rebate determinations must align with statutory patient definition: HRSA should explicitly prohibit rebate denial methodologies that rely on manufacturer-defined patient eligibility standards or undisclosed validation criteria.
- OPA should establish a stakeholder advisory panel to ensure that the feedback and concerns of covered entities are formally and consistently addressed. This panel should include pharmacists with the necessary subject-matter expertise to understand the complexities of pharmacy software, billing, and data components.

V. Existing CHC /FQHC Look-a-like Compliance Actions

CHC /FQHC Look-a-likes already operate under a comprehensive regulatory framework established through the Health Center Program and the 340B statute to make medications affordable for patients.

- In alignment with Section 330 of the Public Health Service Act, they utilize a sliding fee discount that adjusts costs based on a patient's income and household size, ensuring that no one is denied services due to an inability to pay.
- CHC /FQHC Look-a-likes also establish systems for eligibility determination and offer full discounts to individuals at or below 100% of the Federal Poverty Level (FPL). These

services would not be possible without the savings generated from the 340B program, intended for patient care.

- CHC /FQHC Look-a-likes participate in regular Operational Site Visits (OSVs) to verify Health Center Program compliance, and also follow strict 340B compliance protocols, including internal audits, training, and external oversight.
- CHC /FQHC Look-a-likes participating in the 340B program are required to report 340B-related information annually through the Uniform Data System (UDS). This includes data on 340B-purchased drugs, associated costs and revenues, and detailed information about the patients served by the program.

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

VI. Establishing a National, Neutral Claims Clearinghouse

We recommend OPA use a Neutral Claims Clearinghouse, which would produce more accurate deduplication at a tiny fraction of the cost and administrative burden of a rebate model. Compared to HRSA's proposed rebate model, the NCC approach would:

- **Avoid cash-flow and borrowing challenges** for CEs by preserving the upfront 340B discount.
- **Substantially reduce administrative burden on CEs** by significantly reducing the need for them to build and maintain complex rebate compliance systems, and the staff time needed to track and reconcile claims and to manage cashflow issues.
- **Provide manufacturers with the necessary deduplication data within the same 45-day timeframe.**
- **Improve rebate accuracy**, reducing the time and effort manufacturers and CEs must spend correcting errors.
- **Preserve the longstanding upfront discount structure** that has defined the 340B program for more than three decades and is essential to most CHC /FQHC Look-a-likes' participation in the program.
- **Protect patient access to affordable MFP drugs.** If a rebate model were implemented, the resulting cash-flow pressures could force many CHC /FQHC Look-a-likes to stop purchasing or dispensing MFP drugs altogether.
- **Identify Medicaid Duplicate discounts in Medicaid.** An NCC could provide a standardized national approach to preventing duplicate Medicaid discounts by collecting CEs' 340B claims data for Medicaid prescriptions and making it available to states.

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

Conclusion

Careteam Plus, Inc. strongly urges HRSA to exempt CHC /FQHC Look-a-likes 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 CHC /FQHC Look-a-likes to make difficult decisions about staffing, services, and the range of drugs they can afford to stock. Additionally, CHC /FQHC Look-a-likes 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. **Careteam Plus, Inc.** believes that a 340B rebate pilot would cause disproportionate harm to patients served by CHC /FQHC Look-a-likes and other safety net providers.

Careteam Plus, Inc. appreciates the opportunity to respond to this Request for Information on the 340B Rebate Model Pilot, and we look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact:
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or Donna Fiorentino, PC (dfiorentino@careteamplus.org).

Sincerely,

Donna Fiorentino on behalf of
Johanna Haynes, CEO
Careteam Plus, Inc.

Ryan White Clinics for 340B Access

April 27, 2026

SUBMITTED ELECTRONICALLY VIA PAPERWORK@HRSA.GOV

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RE: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation Information Collection Request Federal Register Notice

Dear Director Miller:

Ryan White Clinics for 340B Access (RWC-340B) appreciates the opportunity to submit comments to the Health Resources and Services Administration (HRSA) in response to the above-referenced information collection request (ICR) Federal Register Notice (FRN) dated February 26, 2026.[1] The purpose of this comment is to express RWC-340B's alarm that HRSA is proposing a rebate model in the ICR that is unnecessary and highly burdensome. In the FRN, HRSA drastically underestimates the burden of such a collection, and fails to consider less burdensome alternatives that would enhance the information collected.

RWC-340B is a national association of HIV/AIDS health care providers that receive funding under the Ryan White CARE Act and participate as covered entities in the federal 340B drug discount program. Ryan White Clinics (RWCs) are dedicated to caring for low-income and vulnerable patients living with HIV/AIDS. Our members are on the frontlines of the battle against the HIV/AIDS epidemic, supporting patients living with HIV/AIDS by providing primary care, case management, testing and behavioral health, and other support services that are proven to keep medically vulnerable individuals engaged in their healthcare. The 340B program allows RWCs to stretch their scarce resources to support the full continuum of care that their patients require, including testing, linkage to care, treatment, retention, case management, and medication adherence. Services funded by 340B savings enable RWCs to achieve high viral suppression rates for their patients, helping to improve their health, reduce costs and protect against new incidence of HIV.

A rebate model would impose a tremendous administrative and financial burden on RWCs and other covered entities, as well as on RWC patients. Any rebate model would completely upend RWC technology systems and workflows, pose substantial implementation and managements

[1] 91 Fed. Reg. 9632 (Feb. 26, 2026).

costs, and do nothing to improve 340B compliance or operations. HRSA has not adequately accounted for the substantial burden that a rebate model would impose on covered entities. We respectfully urge HRSA to refrain from implementing a rebate model and instead collaborate with the Centers for Medicare & Medicaid Services (CMS) to develop an alternative approach that protects manufacturers from providing covered entities with both the 340B ceiling price and a maximum fair price (MFP) on the same drug.

HRSA's Rebate Model Proposal is Unnecessary and Untenable

I. A Rebate Model Would Place a Tremendous Administrative Burden on RWCs

For the last 30 years, RWCs and their vendor partners have developed sophisticated technologies and workflows to manage the complexities of 340B compliance and operations. These carefully crafted systems are built on the premise that RWCs receive 340B ceiling prices as upfront discounts. Converting 340B into a rebate program would completely upend these systems, pose substantial implementation and managements costs, and do nothing to improve 340B compliance or operations. RWCs would have to make significant upfront and ongoing financial investments in technology, staff, and workflow redesign to accommodate a rebate model. Importantly, these investments would diminish RWCs' ability to care for their patients.

Many RWCs qualify for and participate in the 340B program as federally qualified health centers (FQHCs). The administrative burden of a rebate model would be even worse for RWCs that are enrolled in 340B as FQHCs and have subgrantees. HRSA currently assigns an FQHC and its subgrantees the same 340B ID, forcing the FQHC and its subgrantees to act as one entity when uploading data to manufacturer platforms. If HRSA were to advance its rebate model, FQHCs and their subgrantees would face an onerous process to discern which purchases, dispenses, and rebate payments belong to which 340B ID holder.

II. The Additional Burden and Costs Imposed on RWCs Would Hinder the Ability of RWCs to Care for Their Patients

The comprehensive services that RWCs provide range from free or discounted medications to critical wrap-around support services for people living with HIV, including case management, dental and behavioral health, and food and housing assistance. Because RWCs often receive no insurance payments for these services and given that Congress has level-funded the Ryan White program in recent years, they depend on the 340B program to underwrite the cost of providing these critical services to their patients. Importantly, the 340B program allows RWCs to provide these expanded services without any cost to taxpayers. The 340B program enables RWCs to maximize their resources to support the full HIV/AIDS care continuum, from diagnosis, to linkage to care, to medication adherence and viral suppression.

RWCs rely on upfront 340B discounts to provide patient care that is uncompensated or undercompensated. By delaying and complicating RWCs' access to 340B discounts, a rebate model would erode the 340B savings available to RWCs to cover the cost of care to the uninsured and underinsured. A rebate model would make the comprehensive care that RWCs' patients need less accessible and more expensive, an outcome that is completely contrary to congressional intent in enacting the 340B program. Increased financial and administrative costs to RWCs from the rebate model would reduce the resources on which RWCs rely, both to care for existing patients and to identify additional patients in need of care. These burdens directly contradict the purpose of the 340B program – to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[2]

Additionally, contract pharmacies may be less willing to distribute 340B drugs to patients on behalf of covered entities due to the cumbersome and financially challenging rebate process. If contract pharmacies refuse to enter into agreements with RWCs, access to medications will be limited for Ryan White patients, many of whom are already difficult to treat due to barriers such as housing instability, food insecurity, unemployment, and mental health conditions. For RWCs, adherence to prescribed treatment regimens is an essential component of controlling the HIV/AIDS epidemic, and RWCs' efforts to encourage patient adherence are significantly compromised if individuals living with HIV/AIDS do not have consistent and convenient access to the prescription drugs they need. Simply put, implementation of a rebate model would set back this nation's fight to end the AIDS epidemic.

III. A Rebate Model Would Create a Slippery Slope for More Manufacturer Restrictions

A rebate model would be a "gift" to manufacturers. Even a narrowly constructed pilot would provide the foundation and blueprint for more restrictive manufacturer rebate models in the future. For years, manufacturers have attempted to shrink the size and scope of the 340B program, first through contract pharmacy restrictions and most recently through manufacturer-initiated rebate programs. The rebate model would give credibility to manufacturers' unfounded claims that the 340B program is flawed and in need of reform. The rebate model would inappropriately shift decision-making power into the hands of manufacturers to determine whether a covered entity purchase is eligible for the statutorily mandated 340B ceiling price. Giving manufacturers control over whether 340B discounts are paid will lead to fewer 340B discounts because these discounts come directly from manufacturers' bottom lines.

For many years, covered entities have contended with pharmacy benefit managers (PBMs) using 340B claims data and knowledge of entities' program participation to target them for lower, discriminatory reimbursement rates. These payment policies erode covered entities' 340B savings and, in turn, undermine their ability to care for patients. Covered entities have advocated

[2] H.R. Rep. No. 102-384, pt. 2, at 12.

for dozens of state laws prohibiting such policies and blocking requirements that covered entities share 340B claims data with PBMs. HRSA should not recreate this same problem by ceding control over 340B discounts to manufacturers or granting them access to data to which they are not entitled.

Pharmacy claims data is proprietary information. Manufacturers can use such data to fuel their marketing campaigns, whether directed at patients, providers, or both. Even worse, they can use the data to support their advocacy efforts to attack and shrink the 340B program. Manufacturers have a long history of publishing pseudo-scientific studies that allegedly document misuse of the 340B program. A rebate model would give them new data to expand their misinformation campaigns.

HRSA's Burden Estimate Fails to Account for All Costs

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

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

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

HRSA's assumption that the data will be comparable to information that covered entities already collect is inaccurate and results in HRSA's low burden estimate. The only covered entity burden estimate that HRSA included in the FRN is a 5-hour per week burden for reporting claims data to a third party platform. For ease of reference, we have reproduced that estimate in the table below.

Annual Covered Entity Burden for Rebate Processing:

	Number of Claims/Year	Time Estimate per Claim
Time Spent Reporting Rebate Claims	52	5

To help HRSA adequately evaluate the rebate model costs, below is our estimate of the impact that a rebate model would have on one of RWC's member organizations.

Annual Covered Entity Burden for Rebate Processing:

	Number of Claims/Year	Time Estimate per Claim
Time Spent on Rebate Claim Reporting, Denial Management, and Payment Disbursement	4,316	4

Start-Up Cost for Rebate Model Implementation

Cash on Hand for Upfront Drug Acquisition Costs	$310,000
Purchase of Additional Equipment	$46,000
Hiring and Training of Additional Staff	$30,000

Category of Employee Acting (E.g., Executive, Administrative Assistant, Pharmacist)	Number of Hours Spent	Hourly Wage Rate	Total Cost (number of hours multiplied by rate)
Director of Pharmacy	104	$114	$11,856
Pharmacy Operations Manager	208	$57	$11,856
Associate Director of Pharmacy Operations	104	$74	$7,696
Financial Coordinator	8	$35	$280
Inventory Coordinator	52	$35	$1,820
Information Technology Specialist	26	$110	$2,860
Financial Analyst	52	$62	$3,224
Chief Financial Officer	52	$135	$7,020
Total			$46,612

HRSA Failed to Consider a More Efficient Rebate Model Alternative: a Neutral Clearinghouse

Instead of proceeding with a rebate model, RWC-340B respectfully asks that HRSA work with CMS to develop a neutral clearinghouse run by the federal government or a government contractor, to which covered entities, third-party administrators, and/or contract pharmacies retrospectively submit 340B claims data to prevent 340B-MFP duplicate discounts. The clearinghouse would remove 340B claims from Medicare drug claims and share the non-340B claims with manufacturers for MFP rebate payments. Since manufacturers would only pay rebates on non-340B claims, duplicate discounts would be prevented. This approach is not without precedent. CMS already plans to test a voluntary clearinghouse-like model that the

agency is calling a "340B repository" to prevent 340B-MFP duplicate discounts. A clearinghouse approach could also be used to prevent 340B-Medicaid rebate duplicate discounts.

* * *

We appreciate HRSA's consideration of our comments. For further information, please contact me at ceo@cempa.org or 423-648-9911.

Sincerely,

Shannon Burger, MBA, CPA
President
Ryan White Clinics for 340B Access

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April 27, 2026

VIA ELECTRONIC FILING – http://www.regulations.gov

Thomas J. Engels
Administrator
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 14W52
Rockville, MD 20857

Re: Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW

Dear Administrator Engels:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to submit comments on this Information Collection Request (ICR) for the 340B Rebate Model Pilot Program (Rebate Pilot) Application, Implementation, and Evaluation.

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. PhRMA member companies have invested more than $850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.[1]

For the reasons described in our response[2] to the Health Resources and Services Administration's (HRSA) "Request for Information: 340B Rebate Model Pilot Program" (RFI),[3] PhRMA strongly supports HRSA's RFI as a positive step toward developing and carrying out an urgently needed 340B rebate model. A rebate model would serve as a rapid verification of 340B claims and would be a commonsense solution to inject transparency and accountability into the program.

The ICR describes information to be collected in connection with a potential Rebate Pilot,[4] including qualifying manufacturers' proposed rebate model plans, the ongoing collection of sales data from manufacturers to allow the Office of Pharmacy Affairs (OPA) to evaluate a future pilot program and

[1] PhRMA. (July 2025). 2025 PhRMA Annual Membership Survey. Available at: https://cdn.aglty.io/phrma/Report%20-%20PhRMA%202025%20Annual%20Membership%20Survey%20-%20July%202025.pdf.
[2] PhRMA. (April 2026). Response to the Health Resources and Services Administration request for information on a potential 340B Rebate Model Pilot Program (HRSA–2026–03042). Available at: https://phrma.org/resources/request-for-information-340b-rebate-model-pilot-program.
[3] 91 Fed. Reg. 7287 (February 17, 2026).
[4] As stated in prior correspondence with the agency, PhRMA maintains that as a matter of law, HRSA preapproval of manufacturers' 340B rebate models is not required. 42 U.S.C. § 256b(a)(1).

enhance 340B Program integrity and compliance monitoring, and the collection of data submitted by covered entities to manufacturers to request a rebate.

Our comments, which we provide in more detail below, are summarized as follows:

- HRSA should consider the full range of benefits and expand the rebate model under consideration to include all drugs to address 340B integrity beyond MFP deduplication.
- Appropriate data collection from manufacturers will allow HRSA to evaluate program integrity, provide greater transparency, and demonstrate the benefits of a rebate model.
- Only HRSA should receive submission of rebate pilot data, and only HRSA and other government partners should evaluate a rebate model.
- Covered entities will not be unduly burdened by information collection.
- A rebate model with standardized data elements will further simplify data submissions.

I. HRSA Should Consider the Full Range of Benefits and Expand the Rebate Model Under Consideration to Include All Drugs to Address 340B Integrity Beyond MFP Deduplication

As described in detail in our RFI response, a rebate model would serve as a rapid verification of 340B claims and is a commonsense means to detect and prevent violations. A rebate model would also provide 340B covered entities with the 340B price on eligible patient prescriptions in an efficient, effective and timely manner. The ICR states that the scope of the potential 340B Rebate Model Pilot Program will be limited to manufacturers with maximum fair price (MFP) agreements with the Centers for Medicare & Medicaid Services (CMS) for initial price applicability years 2026 and 2027. Given the strong promise of a 340B rebate model to address current program integrity challenges, a rebate model should be an option for all drugs immediately, without first limiting implementation to a pilot.

However, if HRSA elects to begin with a pilot, it should, at minimum, include all units of all selected drugs under the IRA once they are announced to allow for sufficient preparation in the rollout of a rebate. We also urge HRSA to consider the far-reaching benefits of a rebate model—and their applicability to broader circumstances—as soon as possible following launch to allow for prompt expansion of a pilot. Looking ahead, HRSA should work toward a broader rebate model that goes beyond IRA selected drugs as operational and program integrity benefits of such a rebate approach apply broadly across the 340B program.

II. Robust Data Collection from Manufacturers Will Allow HRSA to Evaluate Program Integrity, Provide Greater Transparency, and Demonstrate the Benefits of a Rebate Model

Robust data collection is necessary for evaluation of both a rebate model and the 340B Program's integrity more broadly. To that end, PhRMA supports the submission of data by manufacturers on a monthly basis. We recommend that HRSA require manufacturers to report the data elements listed in Appendix A, which largely align with the elements HRSA listed in the 2025 Rebate Pilot ICR. These data elements would provide HRSA with empirical information on the use of rebates to effectuate the 340B

ceiling price, which the agency could use both to assess manufacturer and covered entity compliance with a rebate model and to evaluate its effectiveness.

HRSA should publicly share the following data in aggregate form across all drugs (or as an average, as indicated below for certain of the data elements): 1) total purchases by covered entity type (in dollars at the 340B ceiling price and at WAC); 2) average days from clean claim submission to rebate payment; 3) number of rebates paid within 10 days of clean claims submission (out of specified number of total rebate claims, so that an average can be calculated); 4) number of rebates denied, with reasons (out of specified number of total rebate claims, so that average can be calculated); and 5) number of claims where an MFP refund was denied due to a 340B discount being paid.

We believe that transparency of non-proprietary data will assist all 340B stakeholders in understanding how well a rebate model is performing and help in identifying ways to improve and expand the model over time. Publicly reported data could also be useful to policymakers, taxpayers, employers and other stakeholders to make informed decisions about program-related activities.

340B ceiling prices, or data that could be used to calculate the 340B ceiling price, are confidential and proprietary and therefore should not be publicly released.[5] We recommend that HRSA confirm that not only will this information be secure, but that it will also be kept confidential, by HRSA as well as any agency or entity working with HRSA or on its behalf.

III. Only HRSA Should Receive Submission of Rebate Pilot Data, and Only HRSA and Other Government Partners Should Evaluate a Rebate Model

The ICR states that manufacturers will be required to "submit data to the 340B Prime Vendor monthly to evaluate program integrity and to provide greater transparency in the 340B Program." While, as noted above, we support the frequency and use of manufacturer-reported data for these purposes, a requirement to submit the data to the Prime Vendor is problematic given this organization's well-known conflicts of interest. As highlighted in a *New York Times* investigation published in early 2025, the current Prime Vendor compensation model creates an incentive for Apexus to "supercharge" the 340B program.[6] Apexus is also the subject of an ongoing investigation by the Chairman of the Senate Health, Education, Labor, and Pensions (HELP) Committee scrutinizing (among other things) how "Apexus has expanded its business beyond its core role as the 340B prime vendor . . . to increase its profits."[7] Apexus is a subsidiary of a company owned by hospitals, further contributing to conflicts of interest.[8] As such, we have serious concerns that the Prime Vendor will not remain impartial and, therefore, should not be

[5] This information may be protected from disclosure under Exemption 4 of the Freedom of Information Act (FOIA) and, the Trade Secrets Act (18 U.S.C. § 1905), and the PPA (which states that "[i]nformation disclosed by the Manufacturer in connection with the [PPA], except as otherwise required by law, will not be disclosed by the Secretary or his designee in a form which reveals the Manufacturer," except as necessary to carry out section 340B or permit review by the Comptroller General). Pharmaceutical Pricing Agreement. Available at https://www.hrsa.gov/sites/default/files/hrsa/opa/manufacturer-ppa.pdf.
[6] Gabler E. (January 2025). How a Company Makes Millions Off a Hospital Program Meant to Help the Poor. *NY Times*.
[7] HELP Committee. (February 2, 2026). Chair Cassidy Continues Investigation into 340B Drug Program, Seeks Information from 340B Prime Vendor. Available at: https://www.help.senate.gov/rep/newsroom/press/chair-cassidy-continues-investigation-into-340b-drug-program-seeks-information-from-340b-prime-vendor-1. *See also* Gabler E. (February 2026). Senate Questions Health Care Firm for Profiting Off Program Meant for Poor. *NY Times*. Available at: https://www.nytimes.com/2026/02/12/us/health-care-apexus-340b.html.
[8] Gabler E. (January 2025). How a Company Makes Millions Off a Hospital Program Meant to Help the Poor. *NY Times*.

involved in evaluating a rebate model nor should it have access to any confidential or sensitive data related to the pilot. For these reasons, we urge HRSA to specify that OPA—not the Prime Vendor—will receive data from manufacturers.

Furthermore, only HRSA and other government partners should evaluate a model. We urge HRSA to work with the Department of Health and Human Services OIG and with groups across CMS to establish objective, transparent, and measurable criteria that will be used when evaluating a rebate model and in considering any potential changes to such a model. OIG will provide valuable insight based on their past recommendations for program improvements.[9] Within CMS, the Center for Program Integrity should be involved in any assessment of a rebate model given its expertise in preventing and reducing waste, fraud, and abuse. CMS' Medicare Drug Rebate and Negotiations Group and the Center for Medicaid and CHIP Services should also be part of any evaluation to determine how well a rebate model helps ensure compliance with the IRA and Medicaid nonduplication requirements, respectively.

IV. Covered Entities Will Not Be Unduly Burdened by the Information Collection

In comments on the 2025 Rebate Pilot and the 2025 Rebate Pilot ICR, various covered entities and organizations representing them claimed that a rebate model would have imposed substantial costs on covered entities, in part because obtaining and submitting the claims data required under the 2025 Rebate Pilot would be a burdensome new task. This is incorrect.

Instead, as HRSA recognizes in this ICR, the burden associated with a rebate model "may not be significant" if covered entities are required to submit data that is "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."[10]

A rebate model would readily leverage existing data collection and retention requirements, which would minimize incremental costs and burdens associated with covered entity participation in the pilot, to the extent there are any. We therefore urge HRSA to look with skepticism on unsupported or conclusory claims by covered entities that the requirements of a rebate model would cause them to incur substantial new costs or burdens. For example, in its comments on the 2025 Rebate Pilot ICR, the American Hospital Association (AHA) argued – without reliable justification – that hospitals would require "up to two full-time equivalents to manage the entire rebate model process," resulting in approximately 4,160 hours per hospital annually, or 11.2 million burden hours across all 340B hospitals.[11] This assertion disregards several important and relevant facts.

First and most importantly, the data elements and reporting requirements included in the 2025 Rebate Pilot align with information already captured and retained by covered entities for 340B compliance and other purposes, and therefore would not lead to significant new administrative burdens. Specifically, most

[9] OIG. (June 2016). State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates. Available at: https://oig.hhs.gov/reports/all/2016/state-efforts-to-exclude-340b-drugs-from-medicaid-managed-care-rebates/.
[10] 91 Fed. Reg. at 9633.
[11] Golder C. (September 2025). AHA Comments to HRSA Re: The 340B Rebate Model Pilot Program. *AHA*. Available at: https://www.aha.org/system/files/media/file/2025/09/aha-letter-to-hrsa-on-the-340b-rebate-model-pilot-program-9-30-2025.pdf.

of these data elements[12] are (1) already captured in electronic health records,[13] (2) necessary to comply with 340B audit requirements,[14] (3) submitted to manufacturers in connection with certain contract pharmacy policies,[15] or (4) necessary for billing both private and government insurance payers,[16] and inventory management.

Given that covered entities already routinely compile and transmit to third parties claims data that is similar to what we propose HRSA adopt for a future rebate model, transmitting the data to a 340B rebate vendor should not require significant additional labor. In light of the existing data submission and transmission requirements that already apply to covered entities, which presumably are performed by current covered entity employees, it is extraordinarily unlikely that each covered entity will need two additional full-time employees working year-round to compile and submit fundamentally the same data. A rebate model would not impose a novel data collection burden for covered entities already in compliance with applicable requirements. In the lead up to the 2025 Rebate Pilot, some TPAs confirmed they were able to provide the support necessary to implement the rebate model without changes to covered entity software.[17] Given the crowded field of for-profit companies offering services in the 340B space,[18] we are confident that market competition will drive down any additional TPA costs associated with the Rebate Model.

In their response to HRSA's 2026 Rebate Model RFI, some opponents of the rebate model demonstrated a fundamental misunderstanding of current MFP/340B deduplication efforts compared to a rebate model. Among their most cited concerns is that the process for reconciling 340B claims is costly and time-consuming, but the foundation for this complaint is their experience navigating rebate alternatives currently utilized by manufacturers to deduplicate MFP.[19] After the 2025 Rebate Pilot was blocked by litigation in late December, manufacturers were forced to quickly adapt in an effort to try to avoid unauthorized duplicate MFP/340B price concessions. With limited options, manufacturers were, and still are, left to piece together incomplete and flawed information from a variety of sources.[20] These imperfect

[12] The data elements we propose here are the same elements that HRSA included in the 2025 Rebate Pilot, plus a limited number of data elements to verify that the covered entity actually purchased the drug and the price at which it made the purchase.
[13] *See, e.g.,* United States Core Data for Interoperability (USCDI) data elements maintained by the Office of the National Coordinator for Health Information Technology. Available at: https://isp.healthit.gov/united-states-core-data-interoperability-uscdi#uscdi-v6. The USCDI defines the standardized classes and individual data elements that certified EHR systems must be able to capture and exchange.
[14] *See, e.g.,* Section 3(C), Sample HRSA 340B Audit Data Request List (DRL) for Covered Entities. Available at: https://www.340bpvp.com/Documents/Public/340B%20Tools/sample-hrsa-340b-audit-data-request-for-covered-entities.pdf.
[15] *See* 340B ESP, Data Submissions FAQ 9. Available at: https://help.340besp.com/en/articles/8808065-frequently-asked-questions-faqs#h_a1adc6cecc.
[16] For example, covered entities are required to provide many of the data fields HRSA contemplated in the 2025 Rebate Pilot as part of the 837P form required for providers to bill Medicare for separately payable drugs covered under Part B and as part of the D.0 electronic telecommunication standard utilized for pharmacy billing.
[17] *See, e.g.,* The Craneware Group press release, "95% of 340B processes remain unchanged…TCG confirmed that its customers can participate in the 340B Rebate Pilot without procuring additional software or new vendor contracts. The rebate workflow is demo-ready today." The Craneware Group. (October 2025). The Craneware Group Hosts 340B Rebate Forum, Confirms No New Vendor Needed for Pilot. Available at: https://www.kxan.com/business/press-releases/cision/20251031FL12663/the-craneware-group-hosts-340b-rebate-forum-confirms-no-new-vendor-needed-for-pilot/.
[18] Nikpay S, Halvorson L. (2023). Growing administrative complexity in the 340B program and the rise of third-party administrators. *Health affairs scholar*, *1*(5), qxad052. Available at: https://doi.org/10.1093/haschl/qxad052.
[19] American Hospital Association. (April 2026). Response to HRSA request for information regarding a potential 340B rebate model pilot program (HRSA–2026–03042). Available at: https://www.aha.org/system/files/media/file/2026/04/aha-response-to-hrsa-request-for-information-re-a-potential-340b-rebate-model-pilot-program-letter-4-20-2026.pdf
[20] Such as Part D claims data received from the Medicare Transaction Facilitator Data Module and wholesaler purchase and chargeback data for 340B drugs purchased by the covered entity.

alternatives can result in inefficiencies in covered entity receipt of MFP refund payments on claims for IRA selected drugs when a manufacturer's reasonable belief of 340B eligibility is at odds with the covered entity's determination.

Overall, these alternative approaches are less accurate, less efficient and involve more steps for everyone involved—including covered entities and pharmacies. If the covered entity instead confirmed 340B eligibility for each unit at the time a claim is submitted for payer reimbursement, as would be expected to occur under a 340B rebate model, many of the complaints outlined in some covered entities' responses would be mitigated. A rebate model would be a more efficient and effective way to mitigate duplicate discounts for all parties.

In this ICR, HRSA estimates that each covered entity would prepare and submit 52 annual responses (weekly submissions) at an average of 5 hours per response.[21] This estimate, too, is inflated. It assumes five hours of labor per weekly submission is needed even after initial setup and testing has been completed. This ignores:

- Data elements likely to be necessary and appropriate are elements that covered entities already collect and maintain for other purposes;
- Modern pharmacy systems can automate data extraction and formatting;
- Electronic submissions to standardized platforms require minimal manual intervention once initially configured;
- Batch processing capabilities allow submission of multiple claims simultaneously; and
- Most "submission time" consists of automated system-to-system data transfer.

Accordingly, HRSA should update, correct, and significantly reduce its burden estimate for covered entities. In doing so, HRSA should evaluate the actual burden for *recurring* weekly submissions—*after* initial system configuration. Its assessment should be that these recurring submissions will require just minutes, not hours, of human labor per week. Even 2 hours per week—HRSA's estimate in the 2025 Rebate Pilot ICR—is unrealistic under the circumstances proposed. While 2 hours per week may be a reasonable estimate for initial setup and testing, it is not a credible estimate for routine ongoing submissions.

To the extent that some of these administrative costs relate to ensuring compliance with program requirements and maintaining auditable records, that is entirely appropriate given that covered entity participation in the 340B program is optional and covered entities and their for-profit partners earn nearly $65 billion from the program.[22] Indeed, all payers, both private and government, implement requirements that create some compliance costs for providers. For example, hospitals' costs to comply with Medicaid and Medicare participation and billing requirements likely dwarf what they spend to manage their 340B compliance.[23]

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[21] 91 Fed. Reg. at 9633.
[22] Blalock E., Ferritto M., Taylor, J. (January 2025). The Pharmaceutical Supply Chain, 2013–2023. *Berkeley Research Group*. Available at: https://cdn.aglty.io/phrma/global/blog/import/pdfs/PhRMA_Supply-Chain-2013-2023_White-Paper_V484.pdf.
[23] AHA. (September 2024). Skyrocketing Hospital Administrative Costs, Burdensome Commercial Insurer Policies are Impacting Patient Care. Available at: https://www.aha.org/guidesreports/2024-09-10-skyrocketing-hospital-administrative-costs-burdensome-commercial-insurer-policies-are-impacting?utm.

V. A Rebate Model with Standardized Data Elements Will Further Simplify Data Submissions

We support an approach that minimizes burden on covered entities by relying largely on data elements they already collect and maintain and a consistent set of required data elements across drugs and manufacturers, and we believe the data elements we recommend in Appendix B to this letter are consistent with this approach and objective for purposes of a rebate pilot. If these data are included, it would not be necessary, for purposes of a rebate pilot, for HRSA to allow manufacturers to add additional data elements for their products.

It is important that any rebate model require the submission of data to confirm that the covered entity requesting the rebate made a physical purchase and the price at which the drug was purchased. While the purchase data were not listed by HRSA in the 2025 Rebate Pilot, we strongly believe these data are critical to a rebate model running efficiently and effectively for manufacturers. These data will allow manufacturers to verify that the covered entity seeking the rebate actually purchased the supply of the drug dispensed or administered—the most basic statutory requirement for a covered entity to obtain 340B pricing. Requiring covered entities to report purchase data is no different from the common practice of requiring consumers to show proof of purchase, such as a receipt, to earn cash back. Purchase data is also needed to validate the covered entity's purchase price.[24]

If HRSA does not allow for collection of that data in connection with the Rebate Pilot under consideration, we ask that HRSA clearly state that covered entities subject to a rebate model are required to make all purchases of selected drugs dispensed, administered, or furnished (or to be dispensed, administered, or furnished) to patients under the 340B program through their wholesaler 340B account that manufacturers participating in the pilot load with WAC pricing.

VI. A Rebate Model Will Not Negatively Impact Patients' Access to Medicines

While PhRMA has advocated for 340B covered entities to use the program to provide discounted medicines to low income commercially insured and uninsured patients,[25] covered entities have been transparent in their belief that the program was not meant to directly benefit patients through access to lower cost medicines.[26] As a result, patient costs at the pharmacy counter are not impacted by the prescription's 340B status and, therefore, providing the 340B price via a rebate rather than an upfront discount will have no impact on patients' access to medicine. In fact, evidence shows that there is no consistent improvement in patient out-of-pocket costs or abandonment when covered entities are able to collect 340B prices on more prescriptions at external pharmacies.[27]

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[24] In some cases, covered entities purchase at a manufacturer-offered price other than WAC, and even if the covered entity purchases at the then-current WAC, WAC changes periodically.

[25] "All hospitals in the program and their contract pharmacies should be required to pass through 340B discounts to lower the cost of medicines for vulnerable patients." PhRMA. (July 2023). Today's 340B program leaves patients behind. Available at: https://phrma.org/blog/phrma-responds-to-senate-todays-340b-program-leaves-patients-behind-phrma.

[26] *See, e.g.,* Bon Secours Mercy Health in the HELP Majority Staff 340B Report, "Directly reducing patients' drug expenses is not the purpose of the 340B Program…" U.S. Senate Committee on Health, Education, Labor, and Pensions, Majority Staff. (2024). The 340B Drug Pricing Program: Background, Ongoing Challenges, and Policy Considerations. Available at: https://www.help.senate.gov/imo/media/doc/final_340b_majority_staff_reportpdf1.pdf.

[27] Community Access National Network (CANN). (January 2026). State 340B mandates do not improve patient access or affordability. Available at: https://www.tiicann.org/pdf-docs/2026_January_Policy-Brief_State-340B-Mandates-Do-Not-Improve-Patient-Access.pdf.

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PhRMA appreciates the opportunity to comment on this important issue and looks forward to continued dialogue with the Administration to ensure the prompt launch, success, and then expeditious expansion of a rebate model. As HRSA evaluates next steps following what we anticipate will be a successful pilot, it should work towards a broader rebate model that goes beyond IRA selected drugs as operational and program integrity benefits of such a rebate approach broadly across the 340B Program. Please do not hesitate to reach out to Sylvia Yu (syu@phrma.org) and Karyn Schwartz (kschwartz@phrma.org) with any additional questions.

Sincerely,

/s/

Karyn Schwartz

Senior Vice President, Policy & Research

/s/

Sylvia Yu

Senior Vice President, Law

Appendix A:
HRSA should require manufacturers to report the following data elements

- Claim submission date
- 340B ID
- NDC-11 and quantity purchased
- Unit WAC, 340B Ceiling, and MFP
- Rebate amount and date paid
- Rejection reason (if applicable)
- Aggregated sales by covered entity type
- Average days from claim submission to rebate payment
- Number of rebates paid in 10 days of clean claims submission
- Number of rebates denied, with reasons
- Number of claims where an MFP refund was denied due to a 340B discount being paid

Appendix B:
Data elements needed to accurately implement a rebate model

Pharmacy Claims Data	**Medical Claims Data**
• Date of service • Date prescribed • Rx number • Fill number • 11 digit National Drug Code (NDC) • Quantity Dispensed • Prescriber ID • Service provider ID • 340B ID • Rx Bank Identification Number (BIN) • Rx Processor Control Number (PCN)	• 11 digit NDC • Quantity • Date of service • 340B ID • Service provider ID • Claim number (analogous to Rx number) • Health plan ID & health plan name (analogous to Rx BIN & Rx PCN) • Rendering physician ID (analogous to Prescriber ID) • Claim line number • Unit of measure
Purchase data elements (for retail and medical claims)	
• Wholesaler Name • Wholesaler Account Number • Invoice Date • Invoice number • Ship-to pharmacy NPI ▪ 11-digit NDC ▪ Package units ▪ 340B ID	

April 20, 2026

SUBMITTED ELECTRONICALLY VIA PAPERWORK@HRSA.GOV

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

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

Dear Director Miller:

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

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

As a Ryan White grantee 340B provider, we are deeply concerned with the proposed rebate model. We do not own an inhouse pharmacy so rely on contract pharmacies to participate in the 340B program and reinvest all savings in to supportive services for our program participants. A rebate model will reduce our 340B savings we can reinvest to serve the people who need it most. As a nonprofit CBO, we are also concerned with the cashflow constraints that would be caused by a rebate program.

Alliance for Positive Change is a leading multiservice organization providing low-income New Yorkers living with HIV and other chronic conditions access to quality health care, housing, behavioral health, coaching, and training and job placement programs that cultivate leadership and economic mobility. Alliance for Positive Change is a Ryan White program grantee and are a 340B covered entities as designated by the federal Health Resources and Services Administration (HRSA) through classification as Ryan White grantees. Alliance uses the 340B benefit to ensure that low-income New Yorkers living with HIV, HCV, substance use disorder, and other chronic conditions have access to life-saving medications, adhere to medication regimens, and achieve improved health. Alliance's dedicated treatment adherence program serves over 800 low-income New Yorkers living with HIV each year, and we provide counseling, support groups, direct observation therapy (DOT), navigation to medical care, and other support services for over 5,000 program participants.

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

The comprehensive services that Ryan White clinics like our organization provide range from free or discounted medications to critical wrap-around support services for people living with HIV, including case management, dental and behavioral health, and housing assistance. Because Ryan White clinics often receive no insurance payments for these services, they depend on the 340B program to underwrite the cost of providing this care to their patients. Importantly, the 340B program allows Ryan White clinics to provide these expanded services without any cost to taxpayers. The 340B program enables Ryan White clinics to maximize their resources to support the full HIV/AIDS care continuum, from diagnosis, to linkage to care, to medication adherence and viral suppression.

A Rebate Model Pilot would have an inevitable adverse impact on our patients. Increased financial and administrative costs from the Rebate Model Pilot will reduce the resources on which we rely both to care for existing patients and to identify additional patients in need of care. We rely on upfront 340B discounts to provide patient care that is uncompensated or undercompensated. By delaying and complicating covered entities' access to 340B discounts, the Rebate Model Pilot will erode our 340B savings available to us to cover the cost of care to the uninsured and underinsured. These burdens directly contradict the purpose of the 340B program -- to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

Additionally, contract pharmacies may be less willing to distribute drugs to patients on behalf of covered entities due to the cumbersome and financially straining rebate process. If contract pharmacies refuse to enter into agreements with entities, access to medications will be limited for their patients, many of whom are already difficult to treat due to barriers such as housing instability, food insecurity, unemployment, and addiction. For Ryan White clinics like ours, adherence to prescribed treatment regimens is an essential component of controlling the HIV/AIDS epidemic, and the ability to do so wanes when individuals with HIV/AIDS do not have consistent and convenient access to the prescription drugs they need. Simply put, implementation of the Rebate Model Pilot will set back this nation's fight to end the AIDS epidemic.

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

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

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

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

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

Annual Covered Entity Burden for Rebate Processing:

	Number of Claims/Year	Time Estimate per Claim
Time Spent Reporting Rebate Claims	1322	10

HRSA Failed to Consider More Efficient Rebate Model Alternatives

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

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

The clearinghouse would remove 340B claims from Medicare drug claims and share the non-340B claims with manufacturers for MFP rebate payments. Since manufacturers would only pay rebates on non-340B claims, duplicate discounts would be prevented. This approach is not without precedent. CMS already plans to test a clearinghouse-like model that the agency is calling a "340B repository" to prevent 340B-Medicare Part D inflation rebate duplicate discounts. A clearinghouse approach could also be used to prevent 340B-Medicaid rebate duplicate discounts.

* * *

We appreciate HRSA's consideration of our comments. For further information, please contact Brooke Montes, CSAO, (212) 645-0875, x303..

Sincerely,

Brooke Montes
Chief Strategy & Advancement Officer
Alliance for Positive Change

CARING HEALTH CENTER

"Health is the Heart of Our Community"

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 No. 0906-NEW)
Submitted via paperwork@hrsa.gov

Dear Director Britton:

On behalf of **Caring Health Center, Inc.**, a federally qualified health center serving **Springfield, Massachusetts. A population that is predominantly low-income, racially and ethnically diverse, and medically underserved, with high rates of poverty and significant social determinant of health needs.** 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 **Caring Health Center**, we dispense approximately **48,000 prescriptions annually** across **75 pharmacy locations**. The program generates approximately **$1 million annually**, which is reinvested into essential patient services including **free medication delivery, patient navigators, clinical pharmacists, interpreters, 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 **$575k**, requiring additional working capital of **$2.3 million** to sustain operations. For organizations like ours operating on thin margins and serving **22,000 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 **2 additional FTEs** dedicated to rebate tracking and reconciliation, and an increase of **$225,000 annually** in administrative costs. We also anticipate **$90,000 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 **1,200 hours and approximately $180k 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 HRSA Section 330 funding and sliding fee scale programs, which require CHCs to provide affordable access to medications based on family size and patient income. **Caring Health Center 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, **Caring Health 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.

As Caring Health Center is operating on extremely tight cash flow margins and constrained budgets—and already managing an operating deficit—the shift to a rebate-based model would require us to front substantial medication costs without timely reimbursement. This creates an unsustainable financial burden and would make it extremely difficult to absorb or support any additional financial strain. Ultimately, this introduces real risk to our ability to maintain consistent access to essential medications and services for our patients.

We appreciate the opportunity to provide comments and welcome continued engagement on this critical issue. If you have any questions, please contact **Tania M. Barber, President & Chief Executive Officer at tmbarber@caringhealth.org.**

Sincerely,

Tania M. Barber
President & Chief Executive Officer
Caring Health Center, Inc.
tmbarber@caringhealth.org
(413) 693-1007

April 20, 2026

SUBMITTED ELECTRONICALLY VIA PAPERWORK@HRSA.GOV

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

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

Dear Director Miller:

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

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

How changes in 340B will change the ability to keep staff, help clients with transportation, housing, medication, co-pays, and food assistant.

At Northland Cares, we take pride in delivering a full spectrum of outpatient services for individuals living with HIV/AIDS and providing essential prevention services for those at risk in northern Arizona.

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

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

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

HRSA failed to appreciate the disruptive nature of the rebate model estimating that each covered entity would spend an average of 260 hours per year on complying with Rebate Model Pilot Program

requirements. In the FRN, HRSA justifies its low burden estimate for the Rebate Model Pilot Program by stating that the covered entity data:

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

HRSA's assumption that the data will be comparable to information that covered entities already collect is inaccurate and results in HRSA's low burden estimate.

* * *

We appreciate HRSA’s consideration of our comments. For further information, please contact Nick Adams, Executive Director 928-642-7700.

Sincerely,

Nicholas Adams
Executive Director
Northland Cares

April 20, 2026

SUBMITTED ELECTRONICALLY VIA PAPERWORK@HRSA.GOV

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

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

Dear Director Miller:

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

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

The proposed 340B Rebate Model Pilot Program is a direct threat to Trillium Health's core mission and a significant departure from the original purpose of the 340B Drug Pricing Program. For over 20 years, the 340B program has allowed Trillium Health to purchase outpatient medications at significantly reduced prices, allowing us to provide comprehensive services and affordable medications to thousands of low-income, uninsured, and underinsured patients. As congressional intent made clear, the program was created to help safety-net providers "stretch scarce federal resources as far as possible." Instead, the proposed rebate model would place an immense financial burden on Trillium Health, which would have to pay an additional $22 million a year to purchase drugs upfront at the WAC price and hope to get reimbursed at the 340B price later. The upfront cost, combined with additional expenses that we would incur, would deplete our cash-on-hand, and it would directly affect our ability to serve the 14,500 vulnerable patients who rely on us for care.

Trillium Health was founded as an HIV/AIDS clinic in 1989 during the height of the AIDS crisis. We became eligible for the 340B Prescription Drug Discount Program as a Ryan White Grantee (Parts B and C) and we maintained our eligibility when we became an FQHC Look-Alike in 2016 and a fully funded FQHC in 2025. Trillium Health uses 340B savings to provide discounted medications to patients; care management services (such as food, housing, and transportation); assistance with insurance eligibility and enrollment; support for HIV programming; peer navigation; clinical pharmacists to help manage chronic diseases; and to close the gap between operational costs and reimbursement. The 340B

Prescription Drug Discount Program has allowed us to serve more low-income, vulnerable patients and expand access to care in a medically underserved area.

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

Financial Impact of Increased Drug Acquisition Costs

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

Implementation and Administrative Burden

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

Some RWCs are also federally qualified health centers (FQHCs) and participate in 340B as FQHCs. The administrative burden of a rebate model would be even worse for RWCs that are enrolled in 340B as FQHCs and have subgrantees. HRSA currently assigns an FQHC and its subgrantees the same 340B ID, forcing the FQHC and its subgrantees to act as one entity when uploading data to manufacturer platforms. If HRSA were to advance its rebate model, FQHCs and their subgrantees would face an onerous process to discern which purchases, dispenses, and rebate payments belong to which 340B ID holder.

Patient Harm

The comprehensive services that Ryan White clinics like our organization provide range from free or discounted medications to critical wrap-around support services for people living with HIV, including case management, dental and behavioral health, and housing assistance. Because Ryan White clinics often receive no insurance payments for these services, they depend on the 340B program to underwrite the cost of providing this care to their patients. Importantly, the 340B program allows Ryan White clinics to provide these expanded services without any cost to taxpayers. The 340B program enables Ryan White clinics to maximize their resources to support the full HIV/AIDS care continuum, from diagnosis, to linkage to care, to medication adherence and viral suppression.

A Rebate Model Pilot would have an inevitable adverse impact on our patients. Increased financial and administrative costs from the Rebate Model Pilot will reduce the resources on which we rely both to care for existing patients and to identify additional patients in need of care. We rely on upfront 340B discounts to provide patient care that is uncompensated or undercompensated. By delaying and complicating covered entities' access to 340B discounts, the Rebate Model Pilot will erode our 340B savings available to us to cover the cost of care to the uninsured and underinsured. These burdens directly contradict the purpose of the 340B program -- to enable covered entities "to stretch scarce

Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

Additionally, contract pharmacies may be less willing to distribute drugs to patients on behalf of covered entities due to the cumbersome and financially straining rebate process. If contract pharmacies refuse to enter into agreements with entities, access to medications will be limited for their patients, many of whom are already difficult to treat due to barriers such as housing instability, food insecurity, unemployment, and addiction. For Ryan White clinics like ours, adherence to prescribed treatment regimens is an essential component of controlling the HIV/AIDS epidemic, and the ability to do so wanes when individuals with HIV/AIDS do not have consistent and convenient access to the prescription drugs they need. Simply put, implementation of the Rebate Model Pilot will set back this nation's fight to end the AIDS epidemic.

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

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

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

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

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

Annual Covered Entity Burden for Rebate Processing:

	Number of Claims/Year	Time Estimate per Claim
Time Spent Reporting Rebate Claims	40,000	4.95 minutes per claim, which is 3300 hours per year

HRSA Failed to Consider More Efficient Rebate Model Alternatives

Listing all Viable Alternatives

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

Neutral Clearinghouse as an Alternative

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

The clearinghouse would remove 340B claims from Medicare drug claims and share the non-340B claims with manufacturers for MFP rebate payments. Since manufacturers would only pay rebates on non-340B claims, duplicate discounts would be prevented. This approach is not without precedent. CMS already plans to test a clearinghouse-like model that the agency is calling a "340B repository" to prevent 340B-Medicare Part D inflation rebate duplicate discounts. A clearinghouse approach could also be used to prevent 340B-Medicaid rebate duplicate discounts.

* * *

We appreciate HRSA's consideration of our comments. For further information, please contact Christopher Woodring, Chief Pharmacy Officer, cwoodring@trilliumhealth.org.

Sincerely,

Jason Barnecut-Kearns
President and CEO
Trillium Health

April 20, 2026

SUBMITTED ELECTRONICALLY VIA PAPERWORK@HRSA.GOV

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

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

Dear Director Miller:

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

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

Continued assistance for treatment for HIV and STI's is a significant burden particularly for uninsured and underinsured. Lab costs are not covered and 340B provides funding to assist with these cost. As a non-profit current structure of a rebate model would cause a significant issue in the amount of medication NOVUS Health could provide in any given month, thus limited the number of people we could serve and effect access to medication in a timely manner. The continued administrative burden for submission for claims, not from the pharmacy but the entity itself having to do this requires additional staffing and again pulls funding that impact clinical care and treatment.

NOVUS Health provided multiple health services and is a primary sexual health clinic with a specialty in HIV care. NOVUS maintains a full patient clinic of nearly 2,000 patients and has a walk-in STI clinic that sees an additional 100 patients per month. NOVUS Health is a 340BSTI entity and a 340B Ryan White HIV site.

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

The comprehensive services that Ryan White clinics like our organization provide range from free or discounted medications to critical wrap-around support services for people living with HIV, including case management, dental and behavioral health, and housing assistance. Because Ryan White clinics

often receive no insurance payments for these services, they depend on the 340B program to underwrite the cost of providing this care to their patients. Importantly, the 340B program allows Ryan White clinics to provide these expanded services without any cost to taxpayers. The 340B program enables Ryan White clinics to maximize their resources to support the full HIV/AIDS care continuum, from diagnosis, to linkage to care, to medication adherence and viral suppression.

A Rebate Model Pilot would have an inevitable adverse impact on our patients. Increased financial and administrative costs from the Rebate Model Pilot will reduce the resources on which we rely both to care for existing patients and to identify additional patients in need of care. We rely on upfront 340B discounts to provide patient care that is uncompensated or undercompensated. By delaying and complicating covered entities' access to 340B discounts, the Rebate Model Pilot will erode our 340B savings available to us to cover the cost of care to the uninsured and underinsured. These burdens directly contradict the purpose of the 340B program -- to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

Additionally, contract pharmacies may be less willing to distribute drugs to patients on behalf of covered entities due to the cumbersome and financially straining rebate process. If contract pharmacies refuse to enter into agreements with entities, access to medications will be limited for their patients, many of whom are already difficult to treat due to barriers such as housing instability, food insecurity, unemployment, and addiction. For Ryan White clinics like ours, adherence to prescribed treatment regimens is an essential component of controlling the HIV/AIDS epidemic, and the ability to do so wanes when individuals with HIV/AIDS do not have consistent and convenient access to the prescription drugs they need. Simply put, implementation of the Rebate Model Pilot will set back this nation's fight to end the AIDS epidemic.

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

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

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

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

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

Annual Covered Entity Burden for Rebate Processing:

	Number of Claims/Year	Time Estimate per Claim
Time Spent Reporting Rebate Claims	456	6 hrs

* * *

We appreciate HRSA's consideration of our comments. For further information, please contact Dale R. Wrigley, CEP 314-779-8466.

Sincerely,

Dale R. Wrigley
CEO
NOVUS Health

COMMUNITYCARE
HEALTH CENTERS

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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 Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW

Dear Director Britton:

We would like to thank the Health Resources and Services Administration (HRSA) for providing this opportunity to share our estimated burden on compliance with the proposed 340B Rebate Model Pilot Program. CommUnityCare is one of the largest networks of community health centers in the country, with more than 30 clinic locations in and around Austin, Texas. The federal 340B program is foundational to our ability to provide primary care and preventive health services to patients who would not otherwise have access to care. We continue to have significant concerns that the proposed rebate pilot shifts risk from for-profit drug manufacturers to non-profit safety-net providers, jeopardizing patient access to care.

Under the proposed pilot, CommUnityCare anticipates financial losses of more than $3.4 million in the first year, increasing to approximately $3.85 million in 2028, with additional costs in future years related to carrying costs, new administrative expenses, and lost rebates. Lower-income, uninsured, and under-insured patients will ultimately bear these costs through reduced access to affordable medications and reduced

access to other services including transportation assistance, community health worker programs, and other supportive services that facilitate access to care.

CommUnityCare provided written comments in response to federal requests for information regarding proposed 340B rebate pilots in August 2025 and November 2025. We appreciate this additional opportunity to reiterate our concerns, which remain significant, and to provide further detail regarding the operational and financial risks the proposed 340B Rebate Model Pilot Program would pose to CommUnityCare and other community health centers across the country.

We strongly urge HRSA to exempt community health centers from this proposed 340B Rebate Model Pilot Program to protect the financial stability of safety-net providers and ensure continued access to care for the most vulnerable patients. This letter summarizes our concerns, outlines the operational and financial risks posed by a rebate model, and highlights the downstream impact of those risks on our patients and community.

About CommUnityCare

CommUnityCare is a critical part of our community's safety-net healthcare system, providing access to care for lower-income, uninsured, and under-insured patients. As a Federally Qualified Health Center, CommUnityCare Health Centers operates more than 30 clinical sites in Travis County and surrounding counties, offering a full range of services, including primary care, specialty care, dental care, and behavioral healthcare. We have four in-house pharmacies, and we partner with nearly 150 contract pharmacies to provide patients with access to affordable medications through the 340B program.

In 2025, CommUnityCare served more than 148,000 unique patients. More than two-thirds of our patients reported incomes at or below 100% of the federal poverty level (FPL), which is approximately $33,000 for a family of four. Of those who reported incomes, 98% reported incomes at or below 200% FPL. More than half of our patients were uninsured, over one-third were children, and more than 5,200 patients we served were experiencing homelessness at the time of care. We serve as our community's healthcare safety net.

About our 340B Program

The federal 340B program, in its current form, is foundational to the ability of community health centers such as CommUnityCare to provide comprehensive, high-quality

healthcare services in an increasingly challenging financial environment. The program enables us to offer patients access to medications they can afford while also supporting broader investments in care delivery.

Through roughly 260,000 claims last year, CommUnityCare realized approximately $34 million in 340B savings, all of which were reinvested into our community. In addition to providing low-cost medications, these savings supported home delivery of medications for housebound patients, patient transportation assistance, vaccination pop-up clinics, and community health worker and pharmacy programs – services that would not have been financially viable without 340B.

Today, under mounting financial pressures, 340B savings are more essential to community health centers than ever. In 2024, CommUnityCare delivered $20 million in uncompensated care to uninsured patients, and inflation continues to escalate the cost of care. Rising pharmacy supply costs alone resulted in a $2.5 million loss in 2024 and a $4 million loss in 2025.

Access to upfront 340B discounts has been critical to the financial viability of community health centers. We respectfully request that HRSA exempt community health centers from the proposed 340B Rebate Model Pilot Program.

Financial Losses

CommUnityCare anticipates a combined loss of $7,300,000 in years 2027 and 2028 due to upfront carrying costs, lost rebates, and additional administrative costs. This includes approximately $5 million in unrecovered upfront carrying costs by 2028, driven by the requirement to purchase MFP drugs introduced in years 2026, 2027, and 2028 at WAC. These costs reflect a permanent working capital obligation while awaiting manufacturer rebates. The rebate model would also create approximately $350,000 annually in new administrative costs, driven by additional staffing, compliance activities, and third-party software support not required under the current upfront discount model. CommUnityCare estimates an additional $1 million annual loss attributed to denied rebate claims, by 2028. Many of these losses are structural to the design of the rebate model and are outside the operational control of covered entities.

- **Carrying Costs due to Increased Upfront Drug Spend:** Based on CommUnityCare's annual drug spend data, we estimate that it would cost $2,535,574 to purchase 90 days of drugs in the proposed rebate pilot at the WAC price in 2027, compared to the

$285,402 we would spend to purchase those drugs at the 340B ceiling price without a pilot. This is an expense that we would need to carry indefinitely, tying up capital that would otherwise be used to fund services for patients in need. We project that the carrying costs will grow another $2.5 million in 2028, for a total of $5 million in carrying costs for the rebate model drugs, as we continue to serve more patients, and as more medications are added to the rebate pilot program.

- Annual Staffing Impact: CommUnityCare anticipates the need for two additional full-time equivalent (FTE) positions to manage the increased regulatory, operational, administrative, and compliance burdens associated with a rebate model. We estimate the annual cost of these positions at approximately $100,000 per FTE, including fringe benefits, for a total additional annual staffing cost of $200,000.
- Other Annual Operational Expenses: Due to increased operational complexity, CommUnityCare expects approximately $150,000 per year in additional vendor expenses. This expense covers a new module with one of our existing vendors that will help automate the process for monitoring rebate payments.
- Lost Rebates Due to Administrative Infeasibility: CommUnityCare projects approximately $500,000 in annual drug costs under the proposed 340B Rebate Model Pilot Program due to 340B-eligible claims that will never be qualified on the back end for administrative reasons. This represents 5% of the $10 million in WAC purchases CommUnityCare will spend on rebate model drugs annually by 2027. A $1,000,000 loss in 2028 is estimated at 5% of the $20 million in WAC purchases CommUnityCare will spend on rebate model drugs in 2028.
- One-Time Implementation Expenses: The annual costs outlined above do not include one-time implementation costs. CommUnityCare anticipates at least $100,000 in upfront costs to modify pharmacy software, develop custom dashboards, and design new internal workflows necessary to achieve baseline compliance before any rebates are received.
- Total Financial Losses: The total financial losses that CommUnityCare will incur under the proposed 340B Model Pilot Program include one-time implementation expenses of $100,000, more than $2,500,000 in annual carrying costs by 2027, an additional $2,500,000 in annual carrying costs in 2028, $500,000 in lost rebates in 2027, $1,000,000 in lost rebates in 2028, and an estimated $350,000 per year in additional staffing and other operating expenses, for a total of $3,450,000 in 2027 and $3,850,000 in 2028. The total anticipated financial losses for CommUnityCare in years 2027 and 2028 are $7,300,000.

Other Operational and Financial Risks

A 340B rebate model inherently shifts risk from for-profit drug manufacturers to non-profit safety-net providers, threatening financial sustainability and patient access to care.

- Capital Tie-Up due to Carrying Costs: There are risks associated with the significant carrying costs required under a 340B rebate model, including capital tie-up and related working capital gaps. These risks have the potential to limit health center expansion at a time when Americans are losing access to health coverage and threaten the financial sustainability of community health centers.
- Cash Flow Challenges due to Disputes and other Rebate Delays: While we appreciate HRSA's proactive effort to mitigate concerns about cash flow by requiring drug manufacturers to issue rebates within ten days, there are still opportunities outside of the ten-day window for rebates to be delayed. For example, disputes between covered entities and drug manufacturers may lead to rebate delays.
- Missed Rebates due to Challenges with Claims Submission: A restricted window to submit rebate claims puts major risk on covered entities that may not be ready to submit claims within that window. CommUnityCare has found that our in-house pharmacies often need more than 45 days to dispense an entire package of a drug, and a 45-day window for 340B drug claim submission is often too short of a timeframe, in our experience with contract pharmacy partners' replenishment timelines. Under a rebate model with a restricted window for submitting claims, there is a structural barrier that will prevent us from receiving rebates we are legally owed.
- Losses due to Misaligned Discounts and Rebates: Under a 340B rebate model, covered entities do not receive discounts on drugs until after they have charged the patient. This means rebate amounts may not match patient sliding fee discounts or reimbursement amounts. Community health centers will essentially have to make guesses about rebate amounts ahead of time, to determine what to charge their patients for drugs, opening the door for unpredictable losses if discounts and rebate amounts do not ultimately align.
- Missed Rebates for Drugs Dispensed by Contract Pharmacies: The proposed 340B Rebate Model Pilot Program does not fully account for the operational realities of contract pharmacy arrangements and may result in missed rebates for community health centers that rely on contract pharmacies to administer sliding fee

programs. Because patient discounts are applied at the point of dispensing—before replenishment occurs—sliding fee discounts may be applied to WAC-purchased drugs that never subsequently qualify for 340B pricing. Contract pharmacies control purchasing processes, package size requirements, and the timing of replenishment, leaving community health centers unable to ensure that 340B-eligible claims are replenished within the 45-day timeframe required under the rebate pilot. When replenishment does not occur within that window, rebates are permanently forfeited, undermining the financial integrity of sliding fee programs. This concern is particularly acute for CommUnityCare due to our nearly 150 contract pharmacy partners and our extensive use of sliding fee programs to support patient access. Absent any adjustments to the replenishment or rebate timing requirements for contract pharmacy arrangements, the pilot risks unintentionally disadvantaging health centers that rely on these models to serve lower-income patients.

- Clinic Administered Drugs (CADs): The proposed 340B Rebate Model Pilot Program poses a risk of additional unpredictable financial losses, including unanticipated one-time and ongoing operational expenses. For example, if the rebate model applies to clinic-administered drugs (CADs)—which frequently include high-cost injectable therapies—covered entities may incur new implementation costs related to software, system integration, workflow redesign, and staff training to support rebate eligibility, tracking, and reconciliation. In addition, the requirement to purchase these drugs at WAC and seek post-administration rebates introduces heightened cash flow exposure due to the high acquisition costs associated with CADs.
- Other Unpredictable Financial Losses: The rebate model also creates heightened risk of unpredictable financial losses for community health centers, such as CommUnityCare, that rely on contract pharmacies. Navigating manufacturers' varying rebate and data requirements across multiple contract pharmacy arrangements requires significant third-party administrator (TPA) intervention, and TPAs may pass through the costs of developing and maintaining rebate-tracking modules through increased per-claim or administrative fees. These costs are difficult to predict or control and may further erode the financial resources available to support patient care.

Patient Impact

Lower-income, uninsured, and under-insured patients will ultimately face the consequences of the proposed 340B Rebate Model Pilot Program through reduced access to affordable medications, as well as through reduced access to other services that have traditionally been supported by 340B cost savings.

- **Reduced Access to Contract Pharmacies:** CommUnityCare utilizes nearly 150 contract pharmacies to expand access to pharmacy services for our patients, including for patients who lack consistent access to transportation. Contract pharmacies may be hesitant to participate in a rebate model given the uncertainty around rebates and the operationalization of replenishment inventory accounting systems. We have already received communications from some of our contract pharmacy partners that they will not be ready to participate in the proposed 340B Rebate Model Pilot Program. If these contract pharmacies leave our network, our patients may need to travel further to access critical and life-saving medication.
- **Drug Shortages or Delays:** Under a rebate model, covered entities must purchase drugs at the full WAC price, which is substantially higher than the 340B ceiling price. CommUnityCare operates a large 340B program – with roughly 260,000 claims last year – requiring it to purchase a large supply of drugs at one time. Given the quantity of drugs that CommUnityCare must stock, there is risk that higher WAC prices will cause us to reach or exceed our wholesaler credit limits, halting our ability to order critical medications until payments are submitted to the wholesaler. This could prevent patients from accessing critical and life-saving medications in a timely fashion.
- **Fewer Sliding Fee Discounts:** In 2025 CommUnityCare provided $74 million in sliding fee discounts, provided through discounted medications and medical services. We anticipate that our ability to offer sliding fee discounts will decrease significantly under a rebate model, given the costs and risks outlined above. This is problematic given that the vast majority of our patients are lower-income, and more than half of our patients are uninsured.
- **Reduced Access to Care:** Community health centers reinvest 340B savings into patient-focused programs that expand access to care beyond core grant-funded services. Last year, through approximately 260,000 340B-eligible claims, CommUnityCare generated roughly $34 million in savings. After providing deeply discounted medications to patients in need, these savings were used to fund services such as home delivery of medications for housebound patients, patient transportation assistance, vaccination pop-up clinics, and community health worker

and pharmacy programs. These programs are directly supported by 340B savings and would not otherwise be financially sustainable. Financial losses and increased uncertainty associated with the proposed 340B Rebate Model Pilot Program would require CommUnityCare to scale back or eliminate these services, directly reducing patient access to care.

In closing, CommUnityCare respectfully urges HRSA to reconsider the proposed 340B Model Pilot Program and to exempt community health centers from participation. The current 340B program enables safety-net providers to stretch scarce federal resources, stabilize operations, and reinvest savings directly into patient care, consistent with congressional intent. A rebate-based model would undermine these outcomes by shifting significant financial and operational risks onto community health centers and, ultimately, the vulnerable patients they serve. We appreciate the opportunity to provide these comments and welcome continued dialogue with HRSA to ensure that any program changes preserve access to care for patients most in need.

Sincerely,

Cristie Pellegrini, BSPharm, MHA
Chief Pharmacy Officer

April 17, 2026

SUBMITTED ELECTRONICALLY VIA PAPERWORK@HRSA.GOV

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

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

Dear Director Miller:

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

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

The proposed 340B rebate model introduces significant financial, operational, and patient access risks that are not resolved by "prompt pay" assurances. Requiring covered entities to purchase drugs at full cost and await rebates shifts working capital burden to safety-net providers, creating ongoing cash flow exposure and financial volatility. The model also imposes substantial new administrative requirements, including claim-level tracking, reconciliation across manufacturers, denial management, and new IT infrastructure, all of which divert limited resources away from patient care. For Ryan White and HIV providers, these changes threaten the stability of programs that rely on 340B savings to fund comprehensive, integrated care. Disruptions to contract pharmacy arrangements and increased operational complexity risk limiting medication access, delaying treatment, and undermining adherence and viral suppression outcomes. Additionally, the rebate model does not address root causes of program integrity concerns, such as payer-side data limitations, and instead adds duplicative reporting burdens to entities that are already among the most highly regulated in healthcare. Critically, weakening the current 340B structure will not eliminate program value but will redirect it away from mission-driven providers to intermediaries, including pharmacy benefit managers, that have no statutory obligation to serve vulnerable populations. The cumulative effect is reduced access, increased administrative cost, and misalignment with the program's intent.

Cempa Community Care is a federally qualified health center look-alike and Ryan White–funded provider delivering comprehensive, integrated care to medically underserved populations, including individuals living with HIV. As a 340B covered entity, Cempa operates under extensive federal oversight,

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

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

Financial Impact of Increased Drug Acquisition Costs

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

Implementation and Administrative Burden

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

Some RWCs are also federally qualified health centers (FQHCs) and participate in 340B as FQHCs. The administrative burden of a rebate model would be even worse for RWCs that are enrolled in 340B as FQHCs and have subgrantees. HRSA currently assigns an FQHC and its subgrantees the same 340B ID, forcing the FQHC and its subgrantees to act as one entity when uploading data to manufacturer platforms. If HRSA were to advance its rebate model, FQHCs and their subgrantees would face an onerous process to discern which purchases, dispenses, and rebate payments belong to which 340B ID holder.

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

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

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

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

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

Annual Covered Entity Burden for Rebate Processing:

	Number of Claims/Year	**Time Estimate per Claim**
Time Spent Reporting Rebate Claims	48,000	.25

HRSA Failed to Consider More Efficient Rebate Model Alternatives

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

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

The clearinghouse would remove 340B claims from Medicare drug claims and share the non-340B claims with manufacturers for MFP rebate payments. Since manufacturers would only pay rebates on non-340B claims, duplicate discounts would be prevented. This approach is not without precedent. CMS already plans to test a clearinghouse-like model that the agency is calling a “340B repository” to prevent 340B-Medicare Part D inflation rebate duplicate discounts. A clearinghouse approach could also be used to prevent 340B-Medicaid rebate duplicate discounts.

* * *

We appreciate HRSA’s consideration of our comments. For further information, please contact Shannon Burger, Chief Executive Officer, 423-648-9911.

Sincerely,

Shannon Burger, DSc, MBA, CPA
Chief Executive Officer
Cempa Community Care

April 20, 2026

SUBMITTED ELECTRONICALLY VIA PAPERWORK@HRSA.GOV

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

RE: Matthew 25 AIDS Services, Inc. Comments in Response to: "340B Rebate Model Pilot Program Application, Implementation, and Evaluation" Information Collection Request Federal Register Notice

Dear Director Miller:

Matthew 25 AIDS Services, Inc. appreciates the opportunity to submit comments to the Health Resources and Services Administration (HRSA) in response to the above-referenced information collection request (ICR) Federal Register Notice ("FRN") dated February 26, 2026. The purpose of this comment is to express our alarm that HRSA is proposing a rebate model in the ICR that is unnecessary and so highly burdensome. In the FRN and in its previous Rebate Model Pilot Program ICR, HRSA drastically underestimates the burden of such a collection, and fails to consider less burdensome alternatives that would enhance the collected information.

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

The proposed 340B rebate model raises significant concerns related to patient harm, financial sustainability, and administrative burden. Under this model, our organization would be required to purchase medications at full wholesale acquisition cost and wait extended periods—often 60 days or more—for reimbursement. This creates a substantial financing gap, requiring us to front nearly $1 million per month in drug costs, which is not sustainable given our current resources. 340B drug pricing program savings are critical to our operations and are reinvested directly into patient care, including medication access and essential support services such as transportation, care coordination, and outreach. Delays or reductions in these savings would force difficult decisions about reducing services, particularly in a rural setting where patients already face significant barriers to care. This would increase the risk of treatment interruptions, loss of viral suppression, and worsening health outcomes. In addition, the rebate model introduces a significant and ongoing administrative burden. Based on our current experience with Medicare rebate processes, managing claims across multiple manufacturer platforms, resolving frequent errors, and tracking and reconciling payments requires substantial staff time—far exceeding federal estimates. This burden would require additional staffing and divert resources away from direct patient care. Overall, the rebate model shifts financial risk and administrative complexity onto covered entities without improving patient care and poses a direct threat to the sustainability of services supported by 340B drug pricing program savings.

Matthew 25 Clinic is a nonprofit healthcare provider serving individuals living with HIV as well as patients in need of STD testing, treatment, and prevention services in a largely rural region. As a Ryan

White–funded program and safety-net provider, the clinic qualifies for the 340B Drug Pricing Program and uses 340B drug pricing program savings to expand access to medications and comprehensive care for low-income, uninsured, and underinsured patients. These savings are reinvested directly into patient services, including medication access, case management, transportation assistance, mental health services, and outreach, enabling the clinic to deliver integrated, patient-centered care and maintain strong health outcomes, including high rates of viral suppression.

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

Financial Impact of Increased Drug Acquisition Costs

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

Implementation and Administrative Burden

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

Some RWCs are also federally qualified health centers (FQHCs) and participate in 340B as FQHCs. The administrative burden of a rebate model would be even worse for RWCs that are enrolled in 340B as FQHCs and have subgrantees. HRSA currently assigns an FQHC and its subgrantees the same 340B ID, forcing the FQHC and its subgrantees to act as one entity when uploading data to manufacturer platforms. If HRSA were to advance its rebate model, FQHCs and their subgrantees would face an onerous process to discern which purchases, dispenses, and rebate payments belong to which 340B ID holder.

Patient Harm

The comprehensive services that Ryan White clinics like our organization provide range from free or discounted medications to critical wrap-around support services for people living with HIV, including case management, dental and behavioral health, and housing assistance. Because Ryan White clinics often receive no insurance payments for these services, they depend on the 340B program to underwrite the cost of providing this care to their patients. Importantly, the 340B program allows Ryan White clinics to provide these expanded services without any cost to taxpayers. The 340B program enables Ryan White clinics to maximize their resources to support the full HIV/AIDS care continuum, from diagnosis, to linkage to care, to medication adherence and viral suppression.

A Rebate Model Pilot would have an inevitable adverse impact on our patients. Increased financial and administrative costs from the Rebate Model Pilot will reduce the resources on which we rely both to care for existing patients and to identify additional patients in need of care. We rely on upfront 340B

discounts to provide patient care that is uncompensated or undercompensated. By delaying and complicating covered entities' access to 340B discounts, the Rebate Model Pilot will erode our 340B savings available to us to cover the cost of care to the uninsured and underinsured. These burdens directly contradict the purpose of the 340B program -- to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

Additionally, contract pharmacies may be less willing to distribute drugs to patients on behalf of covered entities due to the cumbersome and financially straining rebate process. If contract pharmacies refuse to enter into agreements with entities, access to medications will be limited for their patients, many of whom are already difficult to treat due to barriers such as housing instability, food insecurity, unemployment, and addiction. For Ryan White clinics like ours, adherence to prescribed treatment regimens is an essential component of controlling the HIV/AIDS epidemic, and the ability to do so wanes when individuals with HIV/AIDS do not have consistent and convenient access to the prescription drugs they need. Simply put, implementation of the Rebate Model Pilot will set back this nation's fight to end the AIDS epidemic.

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

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

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

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

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

Annual Covered Entity Burden for Rebate Processing:

	Number of Claims/Year	Time Estimate per Claim
Time Spent Reporting Rebate Claims	1000	1.5-2
Time Spent Disbursing Rebate Payments to Correct Covered Entity	1000	.25-.5

Time Spent Disputing Rebate Claim Denials	1000	.1-.2

Start-Up Cost for Rebate Model Implementation:

Cash on Hand for Upfront Drug Acquisition Costs	1970000
Purchase of Additional Equipment	10000
Hiring and Training of Additional Staff	85000-120000

Annual Lost Wages for Rebate Model Implementation:

Category of Employee	Number of Hours Spent	Hourly Wage Rate	Total Cost
pharmacist	1000	50	$50000.00
finance/admin	500	35	$17500.00
340b program	580	45	$26100.00
		Total	**$93600.00**

HRSA Failed to Consider More Efficient Rebate Model Alternatives

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

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

The clearinghouse would remove 340B claims from Medicare drug claims and share the non-340B claims with manufacturers for MFP rebate payments. Since manufacturers would only pay rebates on non-340B claims, duplicate discounts would be prevented. This approach is not without precedent. CMS already plans to test a clearinghouse-like model that the agency is calling a “340B repository” to prevent 340B-Medicare Part D inflation rebate duplicate discounts. A clearinghouse approach could also be used to prevent 340B-Medicaid rebate duplicate discounts.

* * *

We appreciate HRSA’s consideration of our comments. For further information, please contact Courtney Woolfork, Chief Executive Officer, 270-826-0200.

Sincerely,

Courtney Woolforkq
Chief Executive Officer
Matthew 25 AIDS Services, Inc.

HALL RENDER
KILLIAN HEATH & LYMAN

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T. James Junger
(414) 721-0922
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April 27, 2026

VIA EMAIL TO PAPERWORK@HRSA.GOV

Ms. Samantha Miller
Health Resources and Services Administration
Information Collection Clearance Officer
5600 Fishers Lane, Room 13N82
Rockville, MD 20857

RE: Public Comment Response to HRSA's Request for Information Collection under OMB Number 0906-XXXX

Dear Ms. Miller:

On behalf of the Hall Render Pharmacy & 340B Collaborative, we respectfully submit this comment regarding the proposed collection of information described in *340B Rebate Model Pilot Program Application, Implementation, and Evaluation under OMB Number 0906-XXXX* ("**Proposed ICR**").[1] Through the Collaborative, we provide guidance on regulatory compliance, program implementation, and advocacy for best practices in 340B operations to more than 100 independent hospitals, health systems, and grantee networks, representing thousands of safety-net care locations across the country. We appreciate the opportunity to provide feedback during the 60-day comment period.

We believe that the Proposed ICR is materially deficient for submission to OMB and should be reconsidered and reissued because i) HRSA has failed to demonstrate that the information the Proposed ICR seeks has practical utility in the absence of a proposed 2026 340B Rebate Model Pilot Program; ii) HRSA did not draft the Proposed ICR in an unambiguous or an understandable manner because it provides no meaningful guidance regarding what information Covered Entities shall submit; iii) HRSA has materially understated the administrative burden by relying on a multiplier rather than accounting for the increased complexity of a Rebate Model and Covered Entities' need to implement new software to comply; and iv) to the extent the Proposed ICR is intended to replace the prior emergency Collection of Information, OMB No. 0906-0111-Extension ("**Proposed CoI**"),[2] HRSA has not addressed the substantive concerns raised in our previous letter, which remain unresolved and are incorporated by reference, as reflected in the enclosed prior submission.

[1] 91 Fed. Reg. 9632 (Feb. 26, 2026).
[2] 90 Fed. Reg. 44,197 (Sept. 12, 2025).

I. Legal Framework

Under the Paperwork Reduction Act of 1995 ("**PRA**")[3] and its attendant regulations,[4] an agency may not collect information from the public, or sponsor such collection, without approval from the Office of Management and Budget ("**OMB**"). The PRA and OMB's regulations include procedural requirements, including a 60-day public comment period.[5] The agency must solicit comments on: (i) whether the proposed Collection of Information is necessary and has ***practical utility***; (ii) whether the agency accurately estimated the burden of the proposed Collection of Information; (iii) whether the quality, utility, and clarity of the information to be collected can be improved; and (iv) whether the burden on respondents can be reduced.[6]

II. The Proposed ICR Violates the PRA and Should Not be Submitted to the OMB Because it is Fatally Ambiguous

The Proposed ICR violates the PRA's implementing regulations because it is neither unambiguous nor understandable. An agency must certify that any proposed collection of information is "written using plain, coherent, and unambiguous terminology and is understandable to those who are to respond."[7] The Proposed ICR does not contain definitions that describe the specific data elements that Covered Entities would be required to submit, nor does it identify any standardized format or scope for such submissions. This lack of clarity is particularly problematic because HRSA has not approved, reviewed, nor even received any manufacturer rebate model proposals, and therefore cannot articulate what information would actually be required under a future rebate model. Instead, the Proposed ICR states that it only "expects" Covered Entity data to be "comparable to data currently maintained through third-party vendors or previously provided to manufacturers under unrelated pharmacy or claims programs."[8] This expectation is entirely speculative and ambiguous. Any assumption that future rebate models may resemble existing manufacturer policies does not satisfy the PRA regulatory requirement that collection requests must be understandable and unambiguous.

The Proposed ICR also rests on the incorrect assumption that the anticipated data are already available and affirmatively maintained by Covered Entities or their software vendors. In practice, several of the data elements HRSA "expects" to be submitted as "data currently maintained through third-party vendors," are not currently compiled or readily available in the manner implied by the Proposed ICR.[9] For example, the "claim line number" fields that HRSA proposed in 2025 were so ill-informed that manufacturers instructed Covered Entities to make them up. This disconnect emphasizes the fundamental problem that Covered Entities do not know what they are being asked to respond to. HRSA is seeking approval for a collection before

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[3] *See generally* 44 U.S.C. § 3501 *et seq.*
[4] *See generally* 5 C.F.R. § 1320.
[5] 5 C.F.R. § 1320.8(d)(1).
[6] *See* 5 C.F.R. § 1320.8(d)(1)(i-iv) (emphasis added).
[7] 44 U.S.C. § 3506(c)(3)(D).
[8] 91 Fed. Reg. 9632.
[9] *Id*.

determining whether the data exists or what systems would be required to produce them.

Further, the Proposed ICR does not account for Covered Entities that enrolled in the 340B Program after the vacatur of the 2025 Rebate Model Pilot Program. For these entities, there is no regulatory or programmatic context against which to interpret the information being requested. Absent a proposed rebate model or defined data requirements, newly enrolled Covered Entities would have no meaningful basis for understanding what information they are expected submit, underscoring the ICR's failure to provide unambiguous and understandable guidance to all of its respondents.

III. The Proposed ICR Violates the PRA and Should Not be Submitted to OMB Because it Lacks Practical Utility, Leading to Stakeholder Confusion.

The Proposed ICR is materially insufficient also because it does not collect information that has practical utility. Under the PRA, an agency must ensure that information collected in its ICR has "practical utility,"[10] meaning that the collected information must have "actual, not theoretical or potential, usefulness to the agency's functions."[11] Here, the Proposed ICR seeks approval to collect data from Covered Entities for purposes of requesting manufacturer rebates in connection with a potential 340B Rebate Model Pilot Program, yet no rebate model is currently proposed for 2026.

Critically, the Proposed CoI was tethered to the 2025 Rebate Model Pilot Program. Therefore, despite the concerns that were at issue in the Proposed CoI, Covered Entities were at least able to better predict the type and volume of data they would have had to submit. This Proposed ICR, however, stands alone from any operative or proposed rebate framework. As a result, Covered Entities are left without any meaningful understanding of what information will be collected, or how their information will be used. Absent a defined rebate model, HRSA cannot demonstrate that the information it seeks will serve an actual agency purpose rather than a theoretical one. Collecting data now for a rebate model that may take an entirely different form, or may never be implemented at all, fails the PRA's statutory requirement that an agency must ensure that its collections yield practical utility.

IV. The Proposed ICR Is More Burdensome Than Necessary

HRSA is further required to ensure that "each collection of information," offers "an estimate…of the average burden of the collection."[12] HRSA is also specifically required both to certify to the OMB that the proposed collection "reduces to the extent practicable and appropriate the burden on persons who shall provide information to of for the agency..."[13]

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[10] 5 C.F.R. § 1320(d)(1)(i).
[11] 5 C.F.R. § 1320(l).
[12] 5 C.F.R. § 1320.8(b)(iii)
[13] 44 U.S.C. § 3506(c)(3)(C).

In this instance, HRSA has not offered an accurate estimate of the average burden upon Covered Entities, nor has it demonstrated that it has selected the least burdensome means of collecting covered entities' information. The current burden estimate for the Proposed ICR is that Covered Entities will have to spend 3,796,000 hours in total to comply with data submission requirements. In the Proposed CoI, that total time burden was 1,518,760 hours. It seems that HRSA calculated the burden solely by taking the Proposed CoI burden estimate and multiplying that number by 2.5 to account for 25 drugs in the 2026 Rebate Model Pilot Program rather than 10 in its 2025 counterpart. This is a rough and unacceptable method to calculate burden. Burden should not only be quantified through the sheer volume of drugs to be included in the Rebate Model Pilot Program, but should include a substantive analysis of the complexity it takes to comply with data submission requirements for each different drug.

By calculating burden for each drug as the same amount of time, HRSA is assuming that each drug in the Rebate Model Pilot Program is to be dispensed and purchased at the same or extremely similar rate, which is especially unpredictable here in the absence of a defined rebate model and standardized data submission requirements. Therefore, by relying on a mechanical multiplier rather than a substantive analysis, HRSA materially understates the true burden this Proposed ICR would impose on Covered Entities.

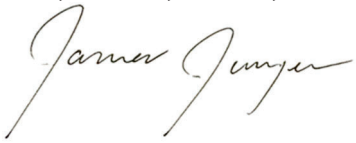
HRSA's burden estimate also fails to account for the substantial technological limitations Covered Entities face and therefore places further unnecessary burden upon Covered Entities. We have anecdotal evidence from clients within our Collaborative attesting that they currently lack access to the software infrastructure necessary to comply with the full range of anticipated claims-level data requests contemplated under manufacturer claims policies. As a result, compliance would require not only additional staff time, but also the implementation of new software systems, an undertaking that will be time-intensive. By ignoring the need for Covered Entities to acquire and operationalize new software, HRSA has materially understated the burden associated with the Proposed ICR. This oversight also further reflects that HRSA did not attempt to find a method that reduces burden upon its respondents.

V. Conclusion

We urge HRSA to revise and reissue the Proposed ICR to address the serious infirmities described above before submission to OMB. We appreciate your consideration of these comments and remain available to discuss practical alternatives to reduce burden and improve clarity consistent with the Paperwork Reduction Act.

Respectfully submitted,

Hall, Render, Killian, Heath & Lyman, P.C.



T. James Junger

CC: Todd A. Nova, Esq.

Enclosures:
(1) Hall Render's Previous Comment in Response to HRSA's Emergency Clearance regarding the 340B Rebate Model Pilot Program Application, Implementation, and Evaluation (OMB No. 0906-0111-Extension).

Attachment 1

HALL RENDER
KILLIAN HEATH & LYMAN

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T. James Junger
(414) 721-0922
jjunger@hallrender.com

November 12, 2025

VIA EMAIL TO PAPERWORK@HRSA.GOV

Ms. Samantha Miller
Health Resources and Services Administration
Information Collection Clearance Officer
5600 Fishers Lane, Room 14NWH04
Rockville, MD 20857

RE: Public Comment Response to HRSA's Request for Information Collection under OMB Number 0906-0111-Extension

Dear Ms. Miller:

On behalf of the Hall Render Pharmacy & 340B Collaborative, we respectfully submit this comment regarding the proposed collection of information described in *340B Rebate Model Pilot Program Application, Implementation, and Evaluation under OMB Number 0906-0111-Extension* ("**Proposed CoI**").[1] Through the Collaborative, we provide guidance on regulatory compliance, program implementation, and advocacy for best practices in 340B operations to over 100 independent hospitals, health systems, and grantee networks, representing thousands of safety-net care locations across the country. We appreciate the opportunity to provide feedback during the 60-day comment period.

We have significant concerns regarding the Proposed CoI and HRSA's September 12 Extension Notice ("**Extension Notice**"). The Extension Notice fails to meet the requirements under the Paperwork Reduction Act because it does not describe all the information collected from covered entities. Furthermore, the Extension Notice fails to properly address crucial patient privacy concerns inherent in the Proposed CoI. As to the Proposed CoI itself, it is not the least burdensome means of collecting the information needed to effectuate the 340B Rebate Pilot Program. Finally, if approved, the Proposed CoI will lead to unlawful overcharges for 340B Covered Outpatient Drugs.

I. Legal Framework

Under Paperwork Reduction Act of 1995 ("**PRA**")[2] and its attendant regulations,[3] an agency may not collect information from the public, or sponsor such collection, without approval

[1] 90 Fed. Reg. 44,197 (Sep. 12, 2025).
[2] 44 U.S.C. § 3501 *et seq.*
[3] 5 C.F.R. Part 1320.

from the Office of Management and Budget ("**OMB**"). The PRA and OMB's regulations include procedural requirements, including a 60-day public comment period.[4] The agency must solicit comments on: (i) whether the proposed Collection of Information is necessary and has practical utility: (ii) whether the agency accurately estimated the burden of the proposed Collection of Information; (iii) whether the quality, utility, and clarity of the information to be collected can be improved; and (iv) whether the burden on respondents can be reduced.[5]

II. The Extension Notice Does Not Accurately Describe the Collection of Information, Leading to Understated Burden Estimates and Serious Constitutional Issues.

With respect to the 340B Rebate Model Pilot Program, HRSA has taken the position that manufacturers or their agent, Beacon Channel Management,[6] will engage in a regulated Collection of Information when they require 340B covered entities to submit pharmacy claims data to obtain a 340B rebate. We agree. The act of collecting and submitting data to the Beacon platform is clearly a "collection of information," and HRSA would be sponsoring it by conditioning access to 340B-priced drugs on this data submission.

HRSA has also taken the position that the Collection of Information described in the Extension Notice is identical to the Collection of Information described in both its August 7, 2025 (corrected) announcement of the 340B Rebate Model Pilot Program and *340B Rebate Model Pilot Program Application, Implementation, and Evaluation* Information Collection Review record which OMB approved on an emergency basis.[7] However, neither the August 7 announcement nor the ICR record account for subsequent changes to the Collection of Information. As a result, HRSA's description of the Collection of Information is incomplete for at least three reasons. First, HRSA will require covered entities to submit not only the pharmacy claims information described in the August 7 notice, but also medical claims information, to manufacturers.[8] Second, the Extension Notice fails to account for other information that covered entities will be required to submit to Second Sight Solutions to participate in the Rebate Model Pilot Program. This includes "Know Your Business" information such as an EIN, an IRS Form CP575 with the entity's address, Articles of Incorporation, a Form W-9, and a "certified Bank Letter from a U.S. financial institution."[9] Users will also be required to provide contact information to facilitate multi-factor authentication.[10] Finally, Beacon Channel Management also requires users to accept unilateral, nonnegotiable terms and conditions as a prerequisite to registering for the platform.[11] Since a

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[4] 5 C.F.R. § 1320.8(d).
[5] 5 C.F.R. § 1320.8(d)(1).
[6] A product owned by Second Sight Solutions, LLC.
[7] OMB Control No. 0906-0111; *see also* Email from HRSA Paperwork Team to J. Junger, Nov. 12, 2025 (includes a hyperlink to https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202508-0906-002) (Attachment 1).
[8] HRSA, *340B Rebate Model Pilot Program* (https://www.hrsa.gov/opa/340b-model-pilot-program) (last accessed Nov. 12, 2025).
[9] Second Sight Solutions, *Beacon Support Center*, "Beacon Account Creation" Questions 5 & 8 (https://support.beaconchannelmanagement.com/en/articles/9589827-rebate-model-frequently-asked-questions) (last accessed Nov. 12, 2025).
[10] *Id.* at Question 5. [BEACON FAQS]
[11] *See* Email from Support from Beacon Channel Management to a Covered Entity Representative, Nov. 11, 2025 (redacted to preserve confidentiality; original on file with Hall Render at Doc. ID 4922-1432-8697) (Attachment 2).

Collection of Information "may be in any form or format" including "contracts" or "agreements,"[12] HRSA should have included the Beacon Channel Management Terms of Use in the Extension Notice.

HRSA's failure to include the medical claims data, Know Your Business and bank information, and Beacon Channel Management Terms of Use in the Extension Notice means that HRSA has not fully informed the public about the content of the Proposed CoI. In addition, it has led HRSA to underestimate the burden that covered entities will endure to obtain drugs at the 340B ceiling price. For example, the addition of medical claims data to the Proposed CoI will increase the burden on covered entities to identify, collect, filter, transmit, and retain data. This is compounded by the fact that the Medical Claims Data Fields includes a mandatory, non-standard field, "Claim Line Number." "Claim Line Number" presumably refers to the line on which the covered entity recorded the applicable data in Form Locators 42 through 49 of the UB-04/837I form. However, CMS's Claims Processing Manual[13] does not treat the "Claim Line Number" as a unique Form Locator, whereas other Form Locators (such as FL01, Billing Provider Name) are assigned a particular "Line" number. Not only is it unclear what information is being requested of covered entities, but also, it is unclear whether covered entities will be able to provide the required information without developing new tools, queries, or other techniques within their EMR software.

Regarding the "Know Your Business" information submission, our experience is that the personnel involved in operating the 340B Program for covered entities—principally pharmacists, pharmacy technicians, and data analysts—are unlikely to have direct access to the Know Your Business information such as Articles of Incorporation or a certified Bank Letter. Personnel from other business units, such as finance and legal, will need to be involved to comply with these requirements.

Finally, the Beacon Channel Management Terms of Use impose a unique burden on covered entities: the burden of unconstitutional conditions. HRSA has explicitly approved the use of the Beacon platform, and has deferred to Beacon and manufacturers on important aspects of program implementation, such as the definition of required data elements.[14] In addition, covered entities wishing to use the Beacon platform must agree to the platform's Terms of Use.[15] These terms include waivers of important constitutional rights and liberties. For example, Section 3a of the Terms require the covered entity to grant Second Sight Solutions a "worldwide, sublicensable, non-exclusive, royalty-free, perpetual, and irrevocable right to collect, process, disclose, create derivative works of, and otherwise use the Rebate Data[.]" Section 10 contains a forum selection, choice of law, and class action waiver. Section 7 requires the covered entity to indemnify Second

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[12] 5 C.F.R. § 1320.3(c)(1).
[13] CMS Claims Processing Manual, Ch. 25.
[14] For example, HRSA's FAQ webpage for the 340B Rebate Model Pilot Program includes the below question and response:
Question: What do each of the allowable data fields mean?
Answer: Please refer to the notices provided by each manufacturer and available resources on the IT vendors' website for data definitions and operational FAQs. HRSA, *340B Rebate Model Pilot Program* (https://www.hrsa.gov/opa/340b-model-pilot-program) (last accessed Nov. 12, 2025).
[15] Beacon Channel Management, *Beacon Rebate Model Terms of Use* (Oct. 1, 2025) (https://cm.beaconchannelmanagement.com/pages/terms) (last accessed Nov. 12, 2025).

Sight Solutions. And Section 6 limits Second Sight's liability for direct damages to $1,000. These conditions and others would raise serious issues under the First and Fifth Amendments if HRSA attempted to impose them directly on covered entities. As the Supreme Court has recognized, "the unconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them."[16] Said more simply, HRSA cannot endorse a rebate system in which manufacturers can withhold the 340B discount unless covered entities forfeit their constitutional rights. Since all covered entities must accept the Beacon Terms of Use to receive the 340B discount on the covered drugs, the Terms of Use constitute a "collection of information," and these concerns are squarely within the scope of this PRA review.

In addition to these constitutional concerns, the Beacon platform raises substantial privacy concerns, too. The ICR record for HRSA's emergency approval incorrectly states that the ICR does not request personally identifiable information. This is categorically untrue. The Beacon platform relies on the transmission of identifiers which, under the HIPAA "safe harbor" deidentification method, must be removed from a data set to render that data set "deidentified." These elements include at least the fields identified below:

Pharmacy Claims Data Fields	**Medical Claims Data Fields**
Date of Service	Date of Service
Date Prescribed	Claim Number
Rx number	

According to Beacon, most of these values[17] are obscured through a salting and hashing process before data is uploaded to Beacon's servers. However, the Beacon platform is specifically designed to permit manufacturers to reidentify the data, reversing Beacon's deidentification process. The data flow is fully described in Beacon's Expert Determinations, which we attach in full for your review.[18] We refer specifically to Section 4, "Data Recipients and Scope of De-identification Designation" in each of the two Expert Determinations. There, the expert asserts that a covered entity could permissibly disclose data directly to a manufacturer. Whether or not this assertion is correct (which is questionable), it is categorically untrue that the Proposed CoI does not involve the disclosure of personally identifiable information. Further, since manufacturers are not HIPAA covered entities, the Proposed CoI contemplates the disclosure of patients' protected health information to an entity that is effectively outside the scope of the HHS Office for Civil Rights' regulatory authority.

III. The Proposed CoI Is More Burdensome Than Necessary

[16] *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 606 (2013).
[17] Beacon's Expert Determination for medical claims data states that the claim number, but not the date of service, is salted and hashed. Privasense, LLC, *Expert's Assessment of Second Sight Beacon De-identification Procedures* (Aug. 28, 2024) (Attachment 3); Privasense, LLC, *Expert's Assessment of Second Sight Beacon De-identification Procedures for Medical Benefits Claims Data*, p. 21 (Sep. 26, 2025) (Attachment 4).
[18] .

HRSA is further to reduce burden on affected respondents and should ensure the greatest possible utility from the information collected under the PRA.[19] HRSA is specifically required both to certify to the OMB that the proposed collection "reduces to the extent practicable and appropriate the burden on persons who shall provide information." 44 U.S.C. §3506(c)(3)(C).

In this instance, HRSA has not demonstrated that it has selected the least burdensome means of collecting covered entities' information. As mentioned above, HRSA's IT contractor, Beacon, is collecting medical claims information for patients, even for those administrations that are unrelated the Medicare or Medicaid programs. HRSA not only fails to acknowledge this burden in its notice, but the submission of this data is also overly burdensome. Further, Proposed CoI contemplates the submission of medical claims information, even though medical claims are outside the scope of the Medicare Drug Price Negotiation Program for 2026. HRSA has not addressed why the submission of medical claims data is necessary or what utility it serves other than to benefit manufacturers.

I. Conclusion

We urge HRSA to revise the Proposed CoI to address the serious infirmities described above. We appreciate your consideration of these comments and remain available to discuss practical alternatives to reduce burden and improve clarity consistent with the Paperwork Reduction Act.

Respectfully submitted,

Hall, Render, Killian, Heath & Lyman, P.C.

T. James Junger

CC: Todd A. Nova, Esq.

Enclosures:
(1) Email Chain between Hall Render and HRSA re: A Copy of Data Collection Plans
(2) Email Chain between Hall Render and Beacon Channel Management
(3) Expert's Assessment of Second Sight Beacon De-identification Procedures
(4) Expert's Assessment of Second Sight Beacon De-identification Procedures for Medical Benefit Claims Data

[19] 44 U.S.C. §3501(1)-(3). §3506(c)(3)(C).

Attachment 1

Junger, James

From: HRSA Paperwork <paperwork@hrsa.gov>
Sent: Wednesday, November 12, 2025 1:58 PM
To: Junger, James; HRSA Paperwork
Cc: Derzay, Julia V.; Nova, Todd A.
Subject: RE: Request re 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-0001---Extension

Hi James,

You can find the package here: View Information Collection Request (ICR) Package.

All the best,

HRSA Paperwork Team

From: Junger, James <jjunger@hallrender.com>
Sent: Wednesday, November 12, 2025 10:55 AM
To: HRSA Paperwork <paperwork@hrsa.gov>
Cc: Derzay, Julia V. <JDerzay@hallrender.com>; Nova, Todd A. <tnova@hallrender.com>
Subject: [EXTERNAL] RE: Request re 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-0001---Extension

Thank you. The first hyperlink didn't work; it routed me directly to the OMB homepage at reginfo.gov. Could you please check the link?

T. James Junger | Attorney
jjunger@hallrender.com | **vCard**

Hall, Render, Killian, Heath & Lyman, P.C. | **hallrender.com**
MILWAUKEE D: (414) 721-0922 | **F:** (414) 721-0491

From: HRSA Paperwork <paperwork@hrsa.gov>
Sent: Wednesday, November 12, 2025 9:54 AM
To: Junger, James <jjunger@hallrender.com>; HRSA Paperwork <paperwork@hrsa.gov>
Cc: Derzay, Julia V. <JDerzay@hallrender.com>; Nova, Todd A. <tnova@hallrender.com>
Subject: RE: Request re 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-0001---Extension

Hi James,

For the instruments, please visit http://reginfo.gov/public/do/PRAViewIC?ref_nbr=202508-0906-002&icID=277116.

For additional information, please visit the 340B Rebate Model Pilot Program webpage.

Best,

HRSA Paperwork Team

From: Junger, James <jjunger@hallrender.com>
Sent: Wednesday, November 12, 2025 10:25 AM
To: HRSA Paperwork <paperwork@hrsa.gov>
Cc: Derzay, Julia V. <JDerzay@hallrender.com>; Nova, Todd A. <tnova@hallrender.com>
Subject: [EXTERNAL] RE: Request re 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-0001---Extension

Dear Ms. Miller:

We are following up on the request below. Please provide the requested information pursuant to 5 C.F.R. § 1320.8(d)(2).

Thank you,
James

T. James Junger | Attorney
jjunger@hallrender.com | **vCard**

Hall, Render, Killian, Heath & Lyman, P.C. | hallrender.com
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From: Junger, James
Sent: Tuesday, November 4, 2025 4:48 PM
To: 'paperwork@hrsa.gov' <paperwork@hrsa.gov>
Cc: Derzay, Julia V. <jderzay@hallrender.com>; Nova, Todd A. <tnova@hallrender.com>
Subject: Request re 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-0001---Extension

Dear Ms. Miller:

I am writing to request a copy of the data collection plans and draft instruments for the below Information Collection:

340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-0001---Extension

In addition, I am writing to ask for the estimated financial burden for this Information Collection.

Thank you,
James

T. James Junger
Attorney
jjunger@hallrender.com | **vCard**

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Attachment 2

Junger, James

From: Support from Beacon Channel Management <support@beaconchannelmanagement.com>
Sent: Tuesday, November 11, 2025 5:05 PM
To: [redacted]
Cc: Junger, James; Nova, Todd A.; [redacted]
Subject: Re: Terms and Conditions

Hi!

Thank you for reaching out. We do not accept redlines to our Terms of Use outside of revisions required by state law for state owned entities.

Kind regards,

Beacon Support
support@beaconchannelmanagement.com
beaconchannelmanagement.com

On Tue, Nov 11, 2025 at 16:22 PM, [redacted] wrote:

Dear Second Sight Solutions:

Attached is a version of the terms and conditions for your Beacon Rebate Model platform which you posted on October 1, 2025. [redacted] are unable to accept the terms as written as they are wholly unreasonable, and we have made changes to address some of our most important concerns. To be clear, [redacted] would not enter into a contract on these terms if it had a choice between vendors, but it does not.

To ensure [redacted] are able to continue providing critical access to care for its patients via the necessary rebate funds under the 340B Program, [redacted] are accessing the Beacon Rebate Model platform out of necessity and under protest resulting from a lack of alternative options. Our attorneys, copied here, are ready to negotiate a mutually acceptable agreement.

Thank you,

[redacted]

Attachment 3

Expert's Assessment of Second Sight Beacon™ De-identification Procedures

Prepared by Privasense, LLC
Evaluation as of August 28, 2024

To whom correspondence should be addressed:
Bradley Malin, Ph.D.*
Email: brad.malin@gmail.com

*This document reflects the work and viewpoint of the preparer of this work and is representative of neither his primary employer (Vanderbilt University Medical Center of Nashville, TN) nor of any granting agency through which his work at his primary employer is supported, including the National Institutes of Health, the National Science Foundation, or the Patient Centered Outcomes Research Institute.

Document History

Version #	Effective Date	Summary of Reasons for Changes
1.0	August 27, 2024	• Original

able of Contents

1. Introduction

Under the 340B drug pricing program, pharmaceutical companies must agree to charge certain purchasers (known as "340B covered entities") discounted prices on outpatient prescription drugs provided to their patients in order to obtain coverage of those drugs under the Medicaid drug rebate program and Medicare Part B. Drugs purchased at the discounted price may be used by 340B covered entities to fill prescriptions for their patients at their own pharmacy and/or at third-party contracted pharmacies. When the pharmacies fill the prescriptions, the pharmacies will typically seek payment from the patient or his/her third-party payor for drug and the dispensing of the drug.

Under contracts with Plans/PBMs, pharmaceutical companies may also agree to pay a rebate to a Plan/PBM on outpatient prescription drugs utilized by its members. To prevent cumulative or duplicative discounts, the rebate contract will typically include provisions intended to ensure that the rebate is exclusive and cannot be combined with other discounts. Such provisions may preclude a Plan/PBM from claiming a rebate on drugs purchased under the 340B drug pricing program. Similarly, pharmaceutical companies are statutorily prohibited from having to pay a Medicaid rebate for a drug purchased at a 340B price. Despite such statutory and contractual limitations on duplicate rebates, state Medicaid programs and Plans/PBMs frequently still seek rebates for drugs purchased under the 340B drug pricing program, typically because they may not be able to identify readily such utilization based on standard information obtained from the pharmacies.

Currently, the process to identify and resolve duplicate Medicaid and commercial rebates on 340B purchased outpatient drugs is inefficient and ineffective. It involves covered entities disclosing protected health information ("PHI") in the form of prescription or claims data to pharmaceutical manufacturers, and pharmaceutical manufacturers attempting to link this information to their rebate data. The disclosure of PHI in this context is permitted under the Health Insurance Portability and Accountability Act, as amended, and its implementing regulations ("HIPAA") as a disclosure for "payment" purposes.[1]

[1] *See* 45 CFR 164.502(a)(1)(ii) and the definition of "payment" at 45 CFR 164.501. *See also* HIPAA FAQ 455 and 456 available online at https://www.hhs.gov/hipaa/for-professionals/faq/455/does-hipaa-permit-

Establishing better processes to identify and resolve such duplicate Medicaid and commercial rebates on 340B purchased outpatient drugs is a priority for pharmaceutical manufacturers.

Second Sight Solutions, LLC ("Second Sight" or "SSS") is a technology company that has created certain technology and processes to facilitate the data exchanges and analyses necessary for pharmaceutical manufacturers to more efficiently and effectively identify and resolve duplicate Medicaid and commercial rebates on 340B purchased outpatient drugs, known as the Beacon™ offering. The Beacon™ offering includes, but is not limited to, the following technologies:

(1) A technology solution, implemented as the Beacon™ Web Application at www.beaconchannelmanagement.com, to support the collection of de-identified 340B Claims data from 340B covered entities.

(2) A technology solution, deployed on-premises as part of the Beacon™ Manufacturer Client, to:

   (a) Process and de-identify Rebate Data by applying Second Sight's proprietary salt key and hashing algorithm to de-identify Company's Rebate Data on an ongoing basis.

   (b) Link de-identified 340B Claims data with de-identified Rebate Data in a de-identified manner.

   (c) Determine duplicate rebates in the Rebate Data and generate reports thereof.

In its operation of the Beacon™ offering and corresponding technologies, Second Sight seeks to ensure that its collection and linking of the 340B Claims data and Rebate Data occurs in a de-identified manner such that it does not need to serve as a business associate to 340B covered entities and to ensure that the minimum necessary data is provided. Specifically, Second Sight plans to receive and process this information in a

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health-plans-to-disclose-information-to-pharmaceutical-manufacturers/index.html (last visited July 19, 2023) and https://www.hhs.gov/hipaa/for-professionals/faq/456/does-hipaa-permit-state-medicaid-agencies-to-disclose-information-to-pharmaceutical-manufacturers/index.html (last visited July 19, 2023).

manner that meets the de-identification standard under the HIPAA Privacy Rule, as overseen by the Office for Civil Rights at the U.S. Department of Health and Human Services. The HIPAA Privacy Rule provides an explicit definition of de-identified data, as well as two implementation options to meet the definition: i) Safe Harbor and ii) Expert Determination. Due to the fact that de-identified data is no longer subject to the Privacy Rule (or HIPAA more generally), it can be processed and/or commoditized without oversight by HHS.

Second Sight hired me to design a data de-identification plan that is compliant with generally agreed upon standards. Specifically, I worked with management at Second Sight, as well as its technology development partner Bridge, to develop a plan to ensure that the data provided to Second Sight and the linking methodology satisfies the Expert Determination model (which has colloquially been referred to as the "Statistical Standard" [Malin 2010]). The de-identification principles invoked by this plan are meant to be consistent with the HIPAA Privacy Rule as it is currently defined and may require reconsideration in the event subsequent rule amendments transpire.

As will be reviewed in greater depth below, I reviewed the risk associated with the data fields to be transferred to Second Sight. Based on this review, I categorized the data into fields that (i) could directly identify patients (i.e., direct identifiers), (ii) have sufficient potential to indirectly identify patients (i.e., quasi-identifiers), and (iii) those which do not have sufficient potential to identify the individuals (i.e., non-identifiers). Following this coarse-level categorization, I performed a statistical analysis, based on population statistics to show that the data transferred in the clear would have a low risk of re-identification in the hands of Second Sight. For certain fields that were deemed to be too risky to share, hashing processes were set in place to transform data into a format that was consistently represented, but would not provide information that would lead to a patient's identity.

The following sections of this document review relevant components of HIPAA, provide a high-level overview of the patient-derived data to be disseminated and describe how the protections instituted for the data relate to the regulatory requirements of de-identification.

2. Privacy Rules and Regulations

In the United States, there is no centralized legal statute for data protection. Rather, a patchwork of laws is tailored to oversee the handling and disclosure of specific types of personal data, such as the Graham-Leach-Bliley Act for financial data, the Federal Educational Rights and Privacy Act for student data, and HIPAA, which is the most pertinent to this report. Specifically, under HIPAA, the Privacy Rule protects all "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. The Privacy Rule calls this information "protected health information" (PHI). By definition, "individually identifiable health information" is information, including demographic data that relates to:

- the individual's past, present or future physical or mental health or condition,
- the provision of health care to the individual, or
- the past, present, or future payment for the provision of health care to the individual,
- and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual.

PHI includes many common identifiers (e.g., name, address, birth date, Social Security Number), but there are also potential "quasi-identifiers" which may permit a recipient of the data to determine the identity of the corresponding subject.

When health information does not identify an individual, and there is no reasonable basis to believe that it can be used to identify an individual, it is said to be "de-identified" and is not protected by the Privacy Rule.

More specifically, 45 C.F.R., section 164.514(a) of the Privacy Rule provides the standard for de-identification of individually identifiable health information:

> **§ 164.514 Other requirements relating to uses and disclosures of protected health information.**
> (a) *Standard: de-identification of protected health information.* Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information.

Section 164.514(b) of the HIPAA Privacy Rule contains the implementation specifications that a covered entity, or affiliated business associate, must follow to meet the de-identification standard. In particular, the HIPAA Privacy Rule outlines two routes by which health data can be designated as de-identified. The first route is the "Expert Determination" method.

> (b) *Implementation specifications: requirements for de-identification of protected health information.* A covered entity may determine that health information is not individually identifiable health information only if:
>
> (1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:
>
> (i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and
>
> (ii) Documents the methods and results of the analysis that justify such determination; or

This implementation specification is notable for this certification report for several reasons. First, this specification states that the de-identification assessment should be performed with respect to the ***anticipated recipient***. In the case of this certification, the anticipated recipient corresponds to Second Sight, which will receive the data pursuant to applicable terms of use and privacy policy. This ensures that there is clear circumscription around who has access to the data and the extent to which they are incentivized to maintain its privacy.

Second, the specification states that the assessment needs to consider the information that is reasonably available to the recipient. In this regard, it is evident that Second Sight is not aware of any of pharmacy interactions that patients have, which thus minimizes the likelihood that private knowledge could be leveraged for re-identification purposes.

Third, it states that the risk of identification for each record shared is not expected to be zero; rather, the risk must be "very small". Below, it will be shown how risk of identification can be quantified, and for the purposes of this certification, this risk will be compared to that which is inherent in the alternate de-identification implementation defined by the HIPAA Privacy Rule -- the "Safe Harbor" method.

(2)(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

(A) Names	
(B) All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000	
(C) All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older	
(D) Telephone numbers	(M) device identifiers and serial numbers
(E) Fax numbers	(N) Web Universal Resource Locators (URLs)
(F) Email addresses	(O) Internet Protocol (IP) addresses
(G) Social security numbers	(P) Biometric identifiers, including finger and voice prints
(H) Medical record numbers	
(I) Health plan beneficiary numbers	(Q) Full-face photographs and any comparable images
(J) Account numbers	(R) Any other unique, identifying number, characteristic, or code
(K) Certificate / license numbers	
(L) vehicle identifiers and serial numbers, including license plate numbers	

(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information

Satisfying either Expert Determination or Safe Harbor method will demonstrate that a covered entity, or an affiliated business associate, has met the standard in §164.514(a) above.

The HIPAA Privacy Rule goes on to provide direction with respect to a "re-identification" code (though, in this sense, this term is meant to mean the permissible tracking of a patient record) by the covered entity in §164.514(c). In practice, this is often referred to as pseudonymization, a convention that we use here to prevent ambiguity in the term re-identification.

> (c) Implementation specifications: re-identification. A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:
>
> (1) Derivation. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and
>
> (2) Security. The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

It is important to recognize that while the pseudonymization provision does not permit assignment of a code or other means of record identification that is derived from identifying individual information, a covered entity may disclose such derived information if an expert determines that the data meets the de-identification requirements at §164.514(b)(1). This is particularly the case if the resulting information cannot be translated to identify the individual. This is important to note because the data Second Sight de-identifies will be submitted over time, such that a record corresponding to a specific pseudonym may be recognized in disparate submissions. This is accomplished through the use of a consistent pseudonym for the patient.

3. Framework for Re-identification Risk Analysis

For the reader, it is critical to clearly articulate why a risk assessment is prudent and how it should be performed.

3.1. Principles of Identifiability

There are a number of detective-like investigations that have been published that demonstrate how health information devoid of explicit identifiers could be re-identified to the corresponding patient (e.g., [Sweeney 1997; El Emam 2006; Loukides 2010; Brown 2011; Solomon 2012; Cimino 2012; Atreya 2013, Sweeney 2013; Teague 2017, Yoo 2018; Rocher 2019; Branson 2020]). However, there is a significant difference between the description of a path by which health-related information could be re-identified and the likelihood that such a path would be leveraged by an adversary in the real world. [Malin 2010] The HIPAA Privacy Rule does not preclude the dissemination of data that could be re-identified. Rather, as noted in the previous section, health information can be designated as de-identified if one accounts for the *anticipated recipients* who use *reasonable* means to attempt to re-identify the information.

In this context, we must consider the broader environment in terms of how a reasonable recipient would attempt to pursue such a route. Table 1 summarizes the principles that are utilized to determine if health data is sufficiently de-identified and is based on [Malin 2010, Malin 2011]. These principles build on those defined by the Federal Committee on Statistical Methodology (referenced in the original publication of the Privacy Rule) [FCSM 2005]).

In general, it helps to separate the health information attributes, or types of data, into three classes of relatively risks: high, moderate and low. High risks correspond to those that put the patient in imminent danger of re-identification, such as the disclosure of their name or Social Security Number. These are risks that must be addressed through some form of data editing (e.g., via suppression or transformation of the data) in order to resolve them. Moderate risks are those that may lead to the indirect re-identification of the patient.

These are risks that need to be accounted for in a statistical analysis and may lead to data editing, but do not necessarily require it. Low risks are those that are negligible in nature due to the data's inability to communicate an apparent risk. This risks do not lead to statistical analysis are retained without any editing. Although risk actually is more of a continuum, this rough partition illustrates how context impacts risk.

Table 1. Principles to assist experts in the determination of the identifiability of health information.

Principle	Description	Examples
Replicability	Prioritize health information features into levels of risk according to the chance it will consistently occur in relation to the individual.	*Low:* The specific drug prescribed to a patient may change depending on their care provider.
		Moderate: The Rx number for a prescription is used to trace patient's pharmacy records over time and space.
Availability	Determine which external resources contain the patients' identifiers and the replicable features in the health information, as well as who is permitted access to the resource.	*Low:* The name of the prescriber for a patient is not readily available to Second Sight.
		Moderate: Patient identity and demographics (which may be inferred from geography and the prescriber) are often in public resources, such as voter records.
Distinguish-ability	Determine the extent to which the subject's data can be distinguished in the health information.	*Low:* It has been estimated that the combination of *Year of Birth, Gender,* and *3-Digit ZIP Code* is unique for approximately 0.04% of residents in the United States [Sweeney 2007]. This means that very few US residents could be identified through this combination of data alone.
		Moderate: It has been estimated that the combination of a patient's *Date of Birth, Gender,* and *5-Digit ZIP Code* is unique for over 50% of residents in the United States [Sweeney 2002, Golle 2006, Benitez 2010]. This means that over half of US residents could be uniquely described just with these three data elements.
Assess Risk	The greater the replicability, availability, and distinguishability of the health information, the greater the risk for identification.	*Low:* The drug dispensed by a pharmacy for a certain prescriber may be unique, but the data that could be leveraged to match to a named patient may not be independently replicable and are rarely disclosed in multiple resources to which many people have access.
		Moderate: Demographics are highly distinguishing, highly replicable, and are available in public resources.

These principles will be applied with respect to the intended recipients to determine the extent to which they could accomplish unapproved re-identification[2].

3.2. Principles of Risk

The framework provides insight into the types of information that should be considered in a risk assessment. However, risk itself requires some clarification. There are, in fact, several ways by which re-identification risk can be defined, which depend on the knowledge and goals of the attacker. In the literature, these risk metrics are often referred to as 1) *prosecutor*, 2) *journalist*, and 3) *marketer* risks. [Dankar 2010] These risk models distinguish between the population (e.g., all individuals dispensed drugs for a certain clinical indication) used by the attacker to commit a re-identification and the sample of individuals who are in the published data set (e.g., all individuals who reside in the geographic area where the dispense took place). It is assumed that the population, at the very least, includes all members of the sample, as well as additional individuals who could have become members of the sample. Thus, in a worst-case adversarial scenario, the sample is the same as the population.

The first two types of risks correspond to scenarios for the most easily attackable record in the data set. Specifically, the prosecutor and journalist risks correspond to the most re-identifiable person in the published data set (i.e., the sample) and population, respectively. However, this attack assumes that the riskiest individual is the one of interest for targeting by the adversary, which is likely to only be the case when the adversary is intending to demonstrate the vulnerabilities in a dataset without actually exploiting the individuals to whom such records correspond. By contrast, the marketer risk is an amortization of the risk over all individuals in the data set. In this scenario, the adversary aims to re-identify as many individuals as possible, but may not worry about committing a specific targeted identification. Thus, in such a scenario, the risk of the data

[2] As alluded to earlier, it should be noted that the term "re-identification" is overloaded in its definition. In the HIPAA Privacy Rule, it is meant to indicate the renaming of a de-identified record through some coded mechanism known to the covered entity that shared the data, thus the use of the term "re-identification code". However, the term is also used to indicate when a record has had its underlying patient identity established without the assistance of such a code. Throughout the remainder of this document the term is used with respect to the latter definition.

set is proportional to the average identifiability of a record in the data set. As such, the marketer risk is defined as the proportion of records that can be correctly re-identified in a data set sampled from a population (which again, could be the same groups).

In the Second Sight setting associated with this certification, the data will come forth in batches and it is not possible to determine which record might be of interest to a Second Sight employee. Moreover, it is not entirely possible to ascertain what specific information an analyst may utilize in an exploit. As such, to assess the risk of re-identification in this setting, we adopt the marketer risk model when data is shared to de-identified data users within Second Sight and its pharmaceutical manufacturer customers and rebate processors. In addition, we utilize a conservative ceiling on what is deemed to be acceptable risk by ensuring that the average (or expected) risk of re-identification in the system is no worse than what the HIPAA Safe Harbor policy would deem to be acceptable. As has been noted, the level of risk associated with Safe Harbor is often significantly smaller (by orders of magnitude) than what would be deemed to be an acceptable level of risk when assessing every record. For instance, as will be shown below, the Safe Harbor risk is on the order of 0.5%. However, this level of conservatism is prudent given that a guarantee of protection is not being afforded to every specific record shared.

Risk itself is actually a composite of the probability that an attack will be mounted (X) and the probability of success given that the attack is mounted (Y). In other words, the risk can be defined as $P(X)P(Y|X)$. The prior probability of attack is mitigated by legal, technical, and economic controls, which, in essence, serve as disincentives to malfeasance in the system. In this respect, the Second Sight de-identification strategy employs a combination of legal-, economic-, technical-, and statistical-based controls to mitigate the risk or re-identification. The following provides more specific details on these controls.

1. **Economic.** From an economic perspective, Second Sight's pharmaceutical manufacturer customers will pay a non-trivial monetary sum for Second Sight's

Beacon™ offering to collect the de-identified data and enable the identification and resolution of Medicaid and commercial rebates on 340B purchased outpatient drugs. Research has shown that such upfront payments of this order can serve as deterrents to potential would-be adversaries and mitigate the chance that re-identification attacks will be perpetrated. [Khokar 2014; Wan 2021]

2. **Legal.** When receiving and using data within Second Sight, employees are required to take due care to protect confidential information from unauthorized use, access, disclosure, destruction, loss or alteration. All applicable employees will sign a non-disclosure agreement indicating that they will maintain the privacy and confidentiality of the data collected from 340B covered entities, comply with the applicable terms of use and privacy policy, and not attempt to re-identify the data. Such non-disclosure agreement will also specify that violation of such confidentiality obligations could result in termination. Specifying that a violation of restricted uses may result in termination provides both monetary and reputational disincentive. While such policies do not guarantee a user will refrain from performing such acts, it does provide Second Sight with the ability to hold the employee accountable for their actions and open to civil suits in a court of law. Moreover, it provides grounds for termination.

   Employees who violate applicable confidentiality obligations and policies at their workplace could be subject to civil penalties associated with the violation of corporate computer policies. There is precedent in case law that employers can successfully sue ex-employees for stealing and misappropriating company data based on the Computer Fraud and Abuse Act (CFAA) and related laws. Examples of such cases include i) EF Cultural Travel B.V. v. Zefer Corp., 318 F.3d 58, 63 (1st Cir. 2003), which states "CFAA…is primarily a statute imposing limits on access and enhancing control by information providers.", and ii) U.S. v. John, 597 F.3d 263, 269, 272 (5th Cir. 2010), which states "official policy, which was reiterated in training programs that John attended, [that] prohibited misuse of the

company's internal computer systems and confidential customer information." Further details on such matters can be found in [Weller 2008].

Again, non-disclosure agreements do not guarantee that a user at Second Sight will refrain from misuse of Second Sight data, but it does provide customers to hold Second Sight, or for Second Sight to hold its employees, accountable for their actions and bring about civil suits in a court of law. Such protections are critical because, since de-identified data falls outside the scope of HIPAA, without such a contract, there would be no accountability for a re-identification performed by a recipient of the data.

3. **Technical Controls.** Beyond the de-identification principles described in this document, there are several types of technical controls that are in place to ensure that data is not inadvertently disclosed to unanticipated recipients. First, all connections made between a client[3] and the cloud computing environment to which data will be transferred will be secured using standard Transport Layer Security. Second, all de-identified data transferred to Second Sight will be maintained in a secured cloud computing environment, such that only authorized individuals will be able to access the data, using a unique user ID and password. Third, all data transferred to any binary application for purposes of the linking process is neither accessible by a manufacturer nor a manufacturer's rebate processor and utilizes ephemeral storage. More to the point, when the binary is run, the binary is making an API call to Second Sight to bring in data for the purposes of the linking process but that data is not written to a database. As a result, when the instance completes its run or it is stopped or terminated, all data is wiped from the application.

[3] A client is a computer or a program that, as part of its operations relies on sending a request to another program or computer hardware or software that accesses a service made available by a server. For example, web browsers are clients that connect to web servers.

4. **Attenuated Data.** From a statistical perspective, the data provided to Second Sight is attenuated to ensure that it does not include sufficient information to facilitate re-identification beyond a certain degree (discussed below).

While these controls cannot be guaranteed, evidence in information security indicates that they certainly lower the rate at which attacks against such systems are realized [Khokhar 2014; Xia 2015; Wan 2015; Xia 2021]. This probability of attack will be addressed in the following section, while the probability of success given the attack is a statistical question and will be addressed in further depth below.

4. Data Recipients and Scope of De-identification Designation

My assessment is performed in a manner that considers the context of the anticipated recipient of data, which in this case is Second Sight. For reference, a high-level schematic of the process and the scope of the de-identification designation are depicted in Figures 1 and 2. A stepwise walkthrough of the data transferred in each step of the process is shown in Figure 3.

The linkage process may take place at either Second Sight or at a manufacturer or manufacturer's rebate processor, through the use of technology that is provided by Second Sight. The following subsections address each of these scenarios. In both scenarios, based on historical experience, it was determined that the rate of exposure and/or attempted attack on de-identified data transferred to Second Sight, a manufacturer or the manufacturer's rebate processor is expected to be no greater than 0.1. [El Emam 2014]

4.1. Linking at Second Sight

In the first scenario, as shown in Figure 1, it can be seen that Second Sight is serving as an intermediary and facilitating data exchange between covered entities and pharmaceutical manufacturers that is already deemed to be permissible under HIPAA as disclosures for "payment" purposes. Second Sight is ensuring that the data it receives is fully de-identified when in Second Sight's control, not when in the hands of the covered entities or pharmaceutical manufacturers.

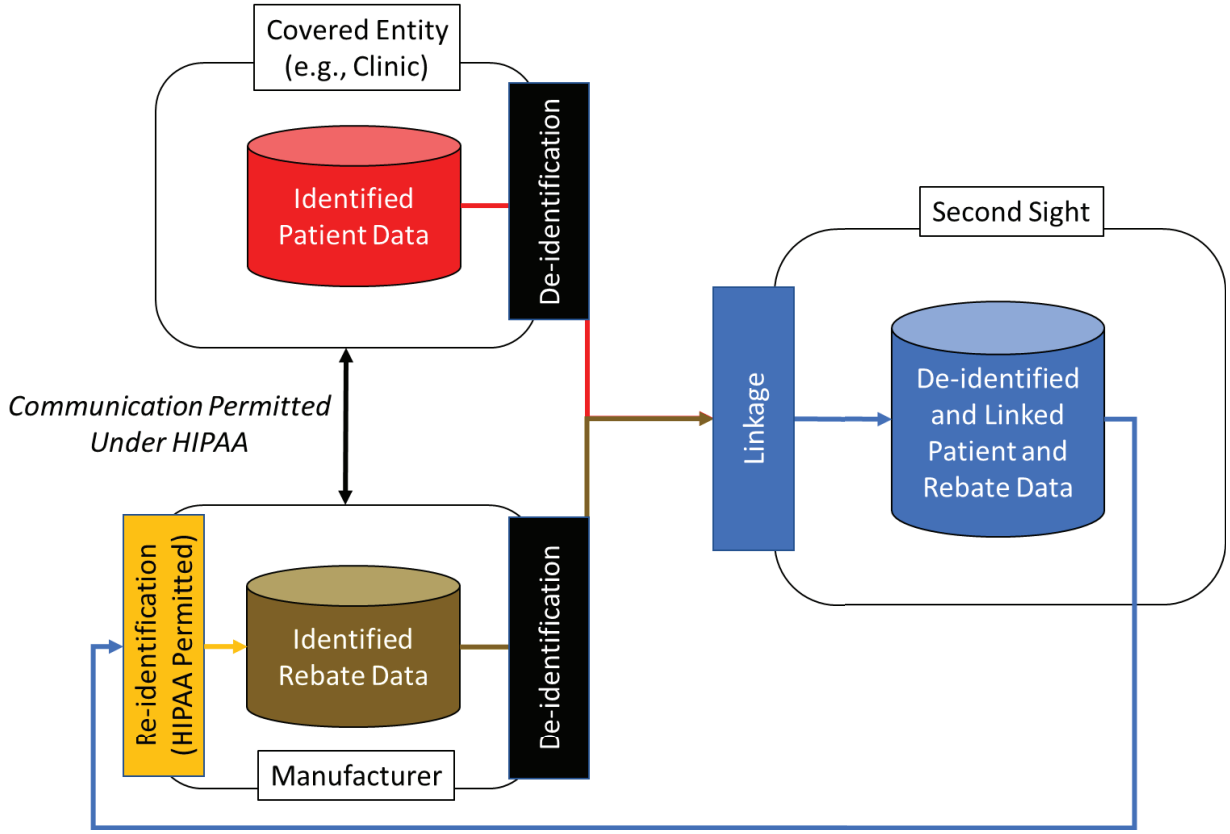


Figure 1. An illustration of where data processing is covered under HIPAA and where de-identification is required.

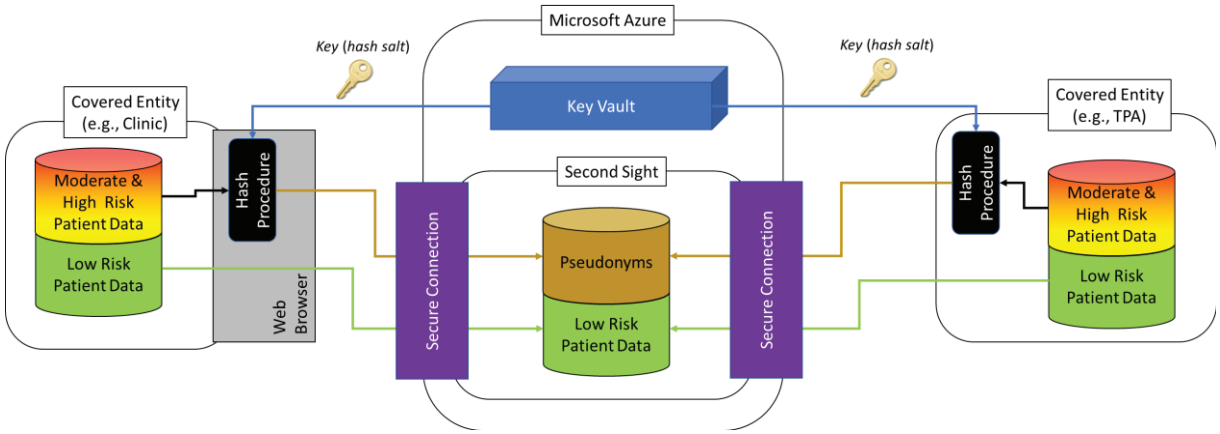


Figure 2. Health information transformation and flow between covered entities and Second Sight.

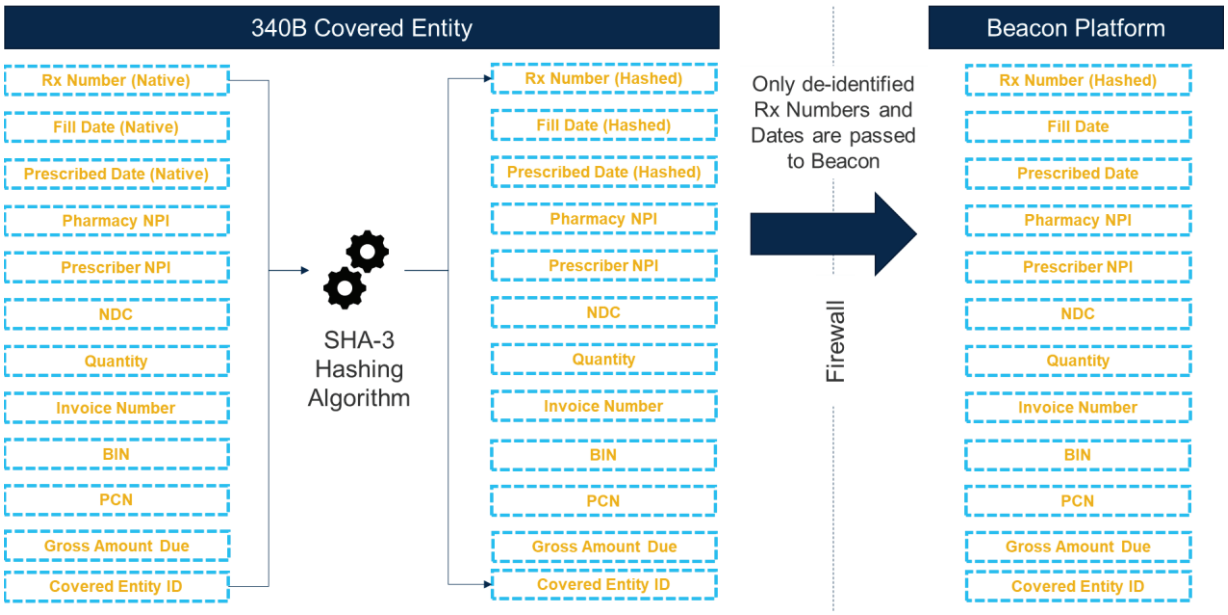
The specific details of the de-identification process are articulated in Figure 2. As can be seen, first, in preparation for data transformation, a Key Vault on Microsoft Azure is

instantiated to generate and store in escrow (for reuse) a random value that will be concatenated with PHI prior to its hashing.

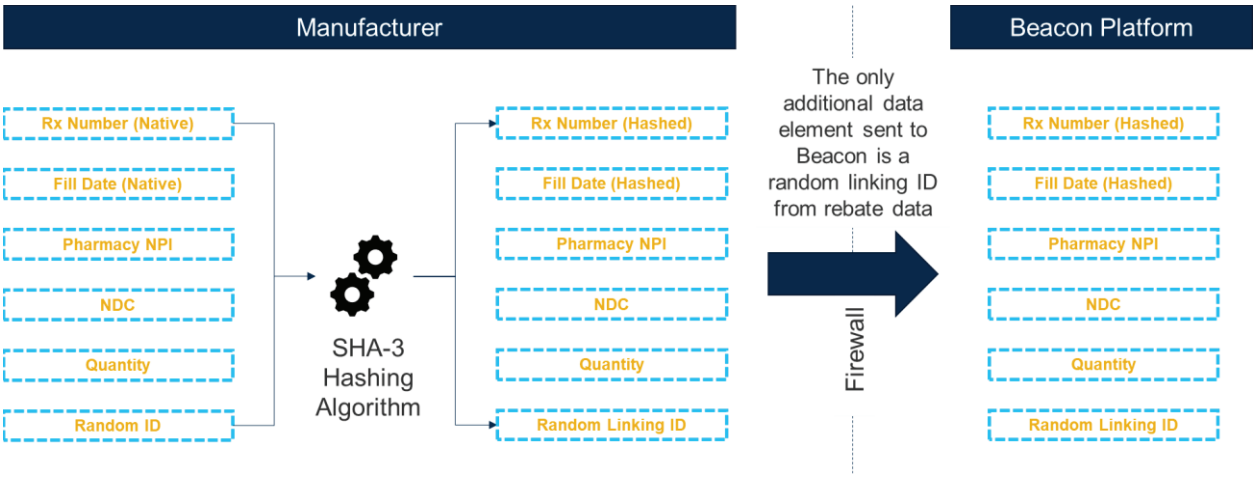
Second, when a covered entity is ready to transfer data, it will be provided with this random value in one of two ways. For covered entities who are connecting to Second Sight via a web browser, the random value will be transferred to the browser and invoked during the hashing process, which will take place within the browser. For covered entities who designate a third-party (e.g., a TPA) to submit these data on their behalf, Second Sight will provide software consisting of a compiled binary to the third-party. The random value is securely embedded into the binary to perform the hashing process offline.

Third, the hashed data (in the form of pseudonyms) and low risk data will be provided to Second Sight. For online covered entities, this transfer will take place over an HTTPS established between the local browser and Second Sight. For offline third parties, this transfer will take place over HTTPS established between the provided compiled binary and Second Sight.

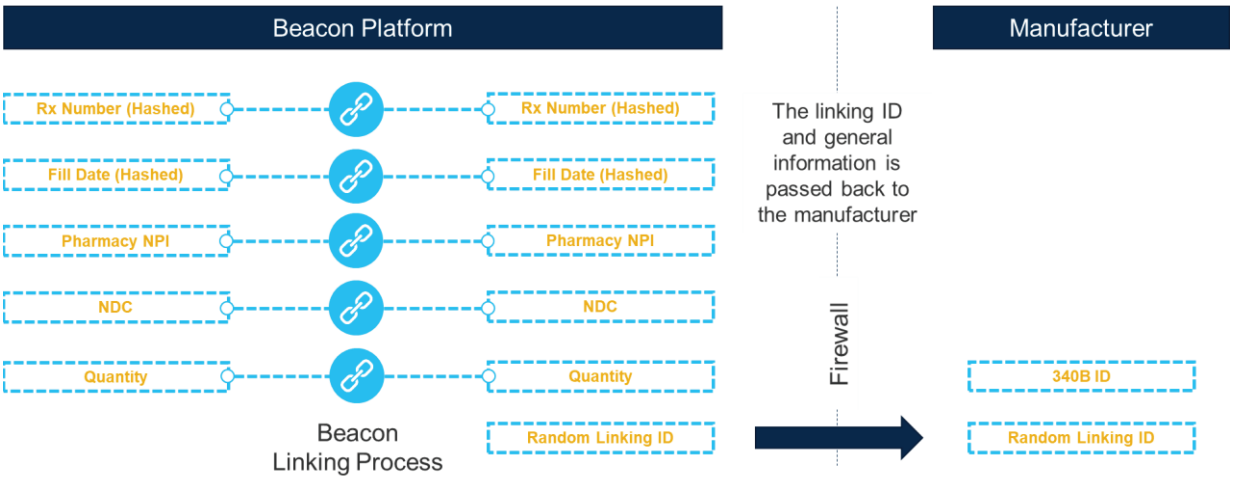
Figure 3 provides a stepwise walkthrough of the data transferred in each step of the process.



(a) Step 1: Covered entity 340B claims upload



(b) Step 2: Manufacturer rebate utilization upload



(c) Step 3: The Random Linking ID, corresponding to instances of linked claim and rebate data, along with the 340B ID, are sent to manufacturer

Figure 3. An illustration of the data transferred (a) from 340B covered entity to Beacon ESP platform in a de-identified manner, (b) from manufacturer to Beacon platform in a de-identified manner, and (c) from the Beacon platform back to the manufacturer in a linked and de-identified manner, which consists of the Random Linking ID, corresponding to instances of linked claim and rebate data, as well as the 340B ID, which indicates where the transaction occurred. (Note: These figures are intended to be illustrative and may not include every field that is not subject to hashing or linking.)

4.2. Linking at Manufacturer

Rather than perform linking at Second Sight, a manufacturer or its rebate processor may perform linkage locally. This is accomplished through software provided by Second Sight to the manufacturer or rebate processor, as well as a process between the user of Second Sight's software and Second Sight themselves, as described in this subsection.

The Beacon™ Manufacturer Client consists of a compiled binary application running on the manufacturer's or rebate processor's premises, along with a binary server running inside Second Sight, as shown in Figure 4.

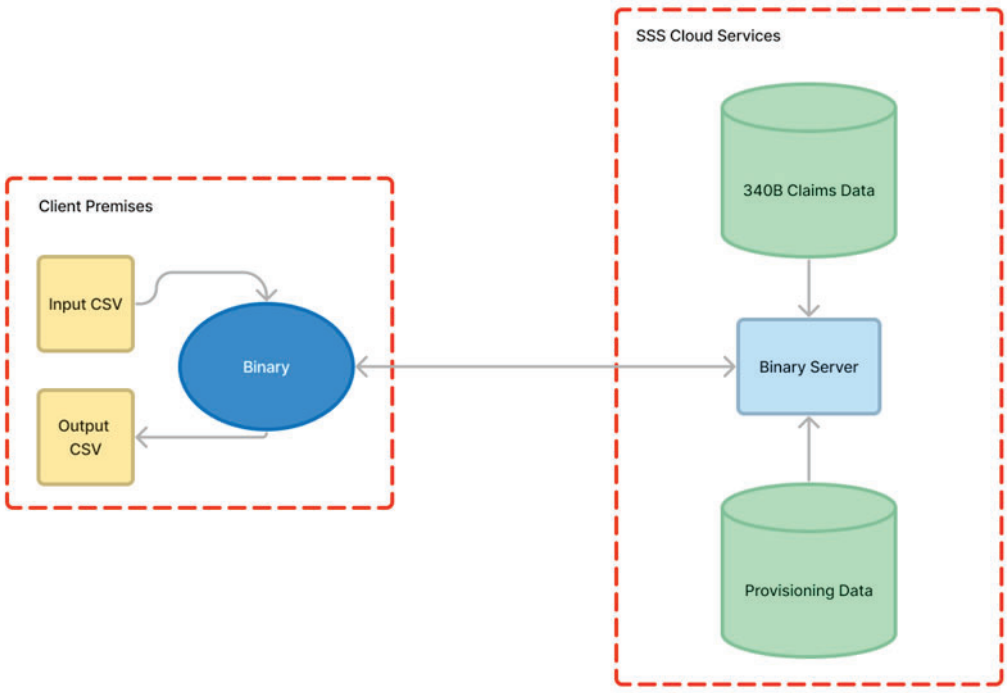


Figure 4. An illustration of the binary application running on-premises at a manufacturer or rebate processor and the coordination with Second Sight (referenced in Figure 4 as SSS).

The purpose of this software is to link rebate claims to corresponding 340B claims submitted via Beacon (the "Binary"). The Binary application is designed and configured with authentication and access controls that prohibit the manufacturer or rebate processor from accessing transferred 340B claims and de-identified data. The binary de-identifies

provided rebate data in order to perform this linking process. All linking occurs at the manufacturer or rebate processor such that no rebate data are ever sent to Second Sight.

To perform this process, the manufacturer or rebate processor provides a CSV rebate claims file to the binary application installed on premise (the "on-premises binary application"). The on-premises binary application makes an API call to the binary server operated by Second Sight to retrieve relevant 340B claims data. The on-premises binary application then de-identifies the rebate claims file and links the de-identified rebate data and de-identified 340B claims data. There is an output row for each rebate claim that was linked to a 340B claim. In addition, if there was an error in the rebate claim row then an output row for that rebate claim row will be generated, indicating the reason for the error. An output file comprised of the linking ID, 340B ID and set of status and error values is created by the on-premises binary application and made accessible to the manufacturer or rebate processor as depicted in Figure 5. Note that unlinked rebate claim rows are not present in the output file and the manufacturer or rebate processor receives no 340B claims data in the output file.

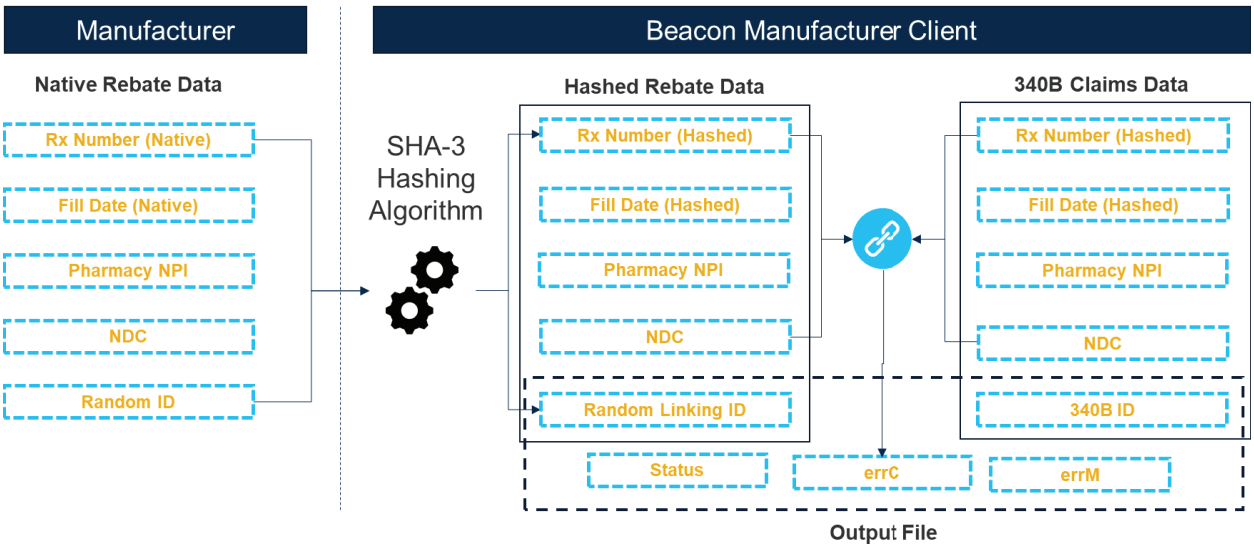


Figure 5. An illustration of the input of native rebate claims data, de-identification of rebate claims data, linking of rebate and 340B claims data and creation of an output record through the on-premises binary application. (Note: This figure is intended to be illustrative and may not include every field that is not subject to hashing or linking.)

In addition to generating an output file for use by the pharmaceutical manufacturer in their rebate payment processing, the binary also generates data that are sent to the binary server and maintained in the Second Sight environment. Similarly, the on-premises binary application receives data from the Second Sight environment via the binary server that are utilized as part of the rebate and claims data linking process. These data are not accessible by the manufacturer or rebate processor and is processed utilizing ephemeral storage that is not persisted, all data will be lost if the instance is completed, stopped, or terminated. Figure 6 provides detail on the data transferred between the binary application on premises at the manufacturer or rebate processor and the binary server operating in the Second Sight environment. All data traveling between the on-premise binary application and the binary server are fully encrypted using mutual TLS with 4096-bit encryption keys.

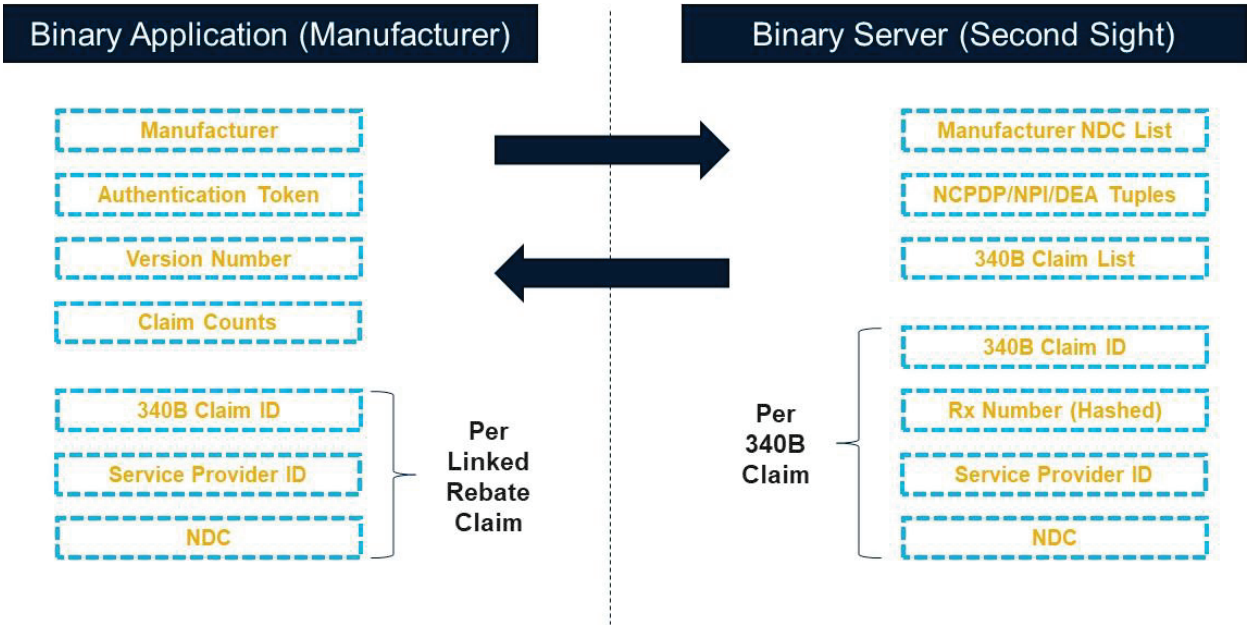


Figure 6. An illustration of the data elements transferred between the binary server residing within Second Sight's cloud computing environment and the binary application installed on premises with the manufacturer or rebate processor. (Note: This figure is intended to be illustrative and may not include every field that is not subject to hashing or linking.)

Every on-premise binary application is built specifically for a manufacturer or rebate processor. In particular, an X.509 client certificate[4] is generated using a Second Sight Certificate Authority where that client certificate contains the common name and organizational unit elements. This client certificate is presented to the server to authenticate each binary application. This ensures client non-repudiation, as well as the ability to reliably enforce access control.

An authentication token is provided by Second Sight for each manufacturer or rebate processor, this authentication token must be used with every request to the binary server and invocation of the on-premises binary. In addition to this authentication feature, there is also authorization. Second Sight explicitly grants the on-premise binary application the permission to receive the relevant 340B claims data that correspond to an authenticated token.

Binary activity and generated data sent to the Second Sight binary server are recorded and monitored with real time notification and alerting services. Second Sight can disable binary functionality and modify or immediately revoke authentication token access at any time.

[4] An X. 509 certificate binds an identity to a public key utilizing a digital certificate that uses the widely accepted international X. 509 public key infrastructure (PKI) standard to verify that a public key belongs to the user, computer or service identity contained within the certificate, X.509 certificates are used in many Internet protocols, including TLS/SSL.

5. Protection Model

The data protection model adopted by Second Sight is straightforward. The data fields that were considered are shown in Table 2, along with their gross risk designations. These designations are composed of three concepts. First, the fields were labeled with the type of information that they communicate that could be leveraged for re-identification purposes (i.e., Risk Type). Second, the fields were characterized with respect to the degree to which the information could be readily leveraged for re-identification purposes. Fields designated with a "low" status failed on one of the principles articulated in Table 1 and thus were not considered further in the re-identification assessment.

Fields designated as moderate were considered to be quasi-identifiers that were reviewed in the statistical risk assessment.

There were two fields designated as high. The first corresponds to the Rx ID, which is a unique value and used in conjunction with patient identifiers (e.g., personal name) during TPO. The second corresponds to the product serialization number, which has the potential to be unique for a patient. Based on their uniqueness, these were not considered in the statistical analysis and instead were designated as requiring transformation into pseudonyms before they could be transferred.

Table 2. Gross risk characterization of the data fields to be transferred to Second Sight. (APC = Adjudicated Pharmacy Claim; PR = Purchase Record)

Source	Field	Description	Risk Type	Risk Status	Transformation
APC	Date Of Service	Date the prescription was filled at the pharmacy. Sometimes referred to as the Fill Date.	*Date*	Moderate	No change
APC	Date Prescribed	Date the physician wrote the prescription. Always comes on or before the Date of Service.	*Date*	Moderate	No change
APC	Rx Number	Identifier applied to the prescription by the pharmacy.	*Unique ID used in TPO*	High	Hashed
APC	Fill Number	Indicates the number of times the prescription has been filled as of the current fill. For example, a value of 2 indicates that the prescription has been filled twice and the current fill is the second one.	-	Low	No change
APC	Ndc	National Drug Code which is a unique identifier of the drug dispensed to the patient.	*Gender*	Moderate	No change
APC	Quantity	Number of units dispensed to the patient.	-	Low	No change
APC	Wholesaler Invoice Number	Invoice number of the replenishment order made by the 340B covered entity. Always placed after the prescription is dispensed to the patient.	*Date*	Moderate	No change
APC	Prescriber Id	National provider identifier (NPI) of the physician that wrote the prescription.	*Geography*	Moderate	No change
APC	Prescriber ID Qualifier	A code that indicates the type of identifier included in the Prescriber ID field	-	Low	No change
APC	Service Provider ID	NPI of the pharmacy that filled the prescription	*Geography*	Moderate	No change
APC	Service Provider ID Qualifier (sometimes called Pharmacy NABP)	National Association of Boards of Pharmacy number of the pharmacy that filled the prescription	*Geography*	Moderate	No change
APC	Contracted Entity ID	HRSA assigned identifier of the 340B covered entity that designated the prescription as 340B and has a contract pharmacy arrangement with the dispensing pharmacy	*Geography*	Moderate	No change
APC	BIN	Bank identification number of the primary payer on the claim	*Geography*	Moderate	No change
APC	PCN	Processor control number assigned by the entity processing payment	*Geography*	Moderate	No change
APC	Gross Amount Due	Gross amount due to the pharmacy across all payers	-	Low	No change
PR	Ship To Location	NPI or DEA of the pharmacy where the drug was physically shipped	*Geography*	Moderate	No change
PR	Ship To Date	Date when the drug was shipped to the Ship To location	*Date*	Moderate	No change
PR	340B Account Number	Wholesaler account number utilized to purchase the dispensed drug	*Geography*	Moderate	No change
PR	Product Serialization Number	Unique ID assigned to the package shipped from the manufacturer to the wholesaler	*Unique ID used in TPO*	High	Hashed

With respect to the moderate risk fields, it was observed that these fields could communicate certain aspects about a patient.

First, while Safe Harbor prohibits the disclosure of dates that are shorter than one year in ambiguity, the Second Sight model retains dates of events. It was noted that none of these dates were associated with any life altering event that would be readily knowable in the public domain, such as dates of birth, death, or motor vehicle accidents. These factors have been exploited in highly publicized attacks mounted against the hospital discharge databases from Washington [Sweeney 2013], Maine and Vermont [Yoo 2018]. Thus, dates were retained, but considered in the quantitative risk assessment below.

Second, it was determined that the prescriber, the pharmacy, and the 340B ID could communicate certain geographic information about the patient. Based on my experience, I assumed that geographic area of residence could be inferred from such information with no greater certainty than the first three digits of the ZIP code. It was further observed that, in certain instances, the sex of the patient might be disclosed for a patient based on their prescription (e.g., birth control pill → female; treatment for erectile dysfunction → male).

6. A Risk Threshold

To perform a statistical analysis of re-identification potential, it is a common practice to assume a limited capability adversary who has access to certain pieces of knowledge about the targeted patient. In this regard, to determine an acceptable re-identification risk threshold for the data addressed in this report, the consultant first analyzed the factors that were the most likely to be exploited in a HIPAA Safe Harbor dataset, namely patient-related demographic and geographic information. As such, the consultant used public data from the U.S. Decennial Census [Census 2024] to determine the extent to which the following combination of features would allow for unique identification of individuals:

Age-90+,
Year of Death,
Gender,
Race,
Ethnicity,
3-*digit ZIP**

In this scenario, the age of the patient was top-recoded to 90+ and all ZIP codes with regions less than 20,000 people were grouped together into one aggregated region.

It was assumed that Race would correspond to traditional self-reported information akin to that which the U.S. Census Bureau or voter registration lists capture. In doing so, the race information was characterized as a value domain of {White, Black, Asian, Native American, Pacific Islander, Other}. Similarly, ethnicity corresponds to {Hispanic or Latino, Not Hispanic or Latino}.

I performed this analysis based on the attack described in [Sweeney 1997; Sweeney 2002; Golle 2006]. In particular, I utilized publicly accessible demographic tables from U.S. Census Bureau in the form of PCT12A through PCT12H, which report population

counts by age group, gender, and race combination.[5] This information was further subdivided by splitting the population along the 3-digit ZCTA (which was used as a proxy for the ZIP code), while grouping the ZCTAs with less than 20,000 people into a single group. For reference, the set of ZCTAs that were aggregated are shown in Table 4. For each ⟨gender, race, age, ZCTA⟩ population combination, the consultant aggregated the counts for all age groups over 89 years old.

Table 4. 3-digit ZCTA with populations expected to be less than 20,000 people in size.

ZIP-3	2020 Census Population
036	13,153
059	3,352
102	15,082
203	772
205	44
369	17,596
556	16,415
692	8,626
821	392
823	14,702
878	17,364
879	16,082
884	16,740
893	10,701

After constructing the dataset, I then estimated the number of unique individuals that reside in the population. The estimation process was based on the strategy proposed in [Golle 2006]. This is because the statistics published by the U.S. Census are in an aggregated form. For instance, the bureau reports how many males with age 50-54 reside in a certain 3-digit ZCTA and are Caucasian. For reference, let us call this number *n.* For our analysis, we need to disaggregate the five-year bin into one-year bins and calculate the expected number of bins with one individual. This disaggregation is a traditional balls-to-bins problem. In a generalized form, if we assume we want the number of bins with exactly *i* people, the problem reduces to a binomial function of the form:

[5] It has been noted that there exists a certain amount of error in the public version of the U.S. Census data that may influence analyses with age 65 and older. [Alexander 2010] Yet, the expert noted that such inaccuracy is at the cell level, while the analysis conducted for this assessment is about aggregated results. Thus, it was not expected that such errors would influence the general findings of this investigation.

$$f_i(n) = \binom{n}{i} b^{1-n}(b-1)^{n-i}$$

For this analysis, we set *i* equal to one, reducing the computation to:

$$f_i(n) = n\left(\frac{b-1}{b}\right)^{n-1}$$

The value for *b* varies for different age groups in the Census data. For instance, age group 0-4 has 5 bins, while age group 60-61 has 2 bins.

After computing this value for each bin, the results are summed and normalized by the total U.S. population in the Census tables. Based on this analysis, it was found that 0.681% of the U.S. population was estimated to be unique, which translates into a re-identification risk of 0.00681.

7. Final Risk Analysis

7.1. Unique IDs

The unique identifiers managed by Second Sight are translated into salted one-way hashed values. One-way hashes have been applied by various covered entities, such as in Indiana [Grannis 2002, 2007], Palo Alto, [Weber 2012], Chicago [Kho 2015], Florida [Bian 2019], and Tennessee [Roden 2008], to obscure patient identifiers and facilitate longitudinal studies or data integration across healthcare systems.

In essence the one-way hash is a function *H* that takes a *message* as input and returns a *hash* value as output:

$$H(message) = hash$$

It is assumed that the hash function is public knowledge (or at least known to all of the entities participating in the system). Various functions that have been applied include MD5 and the class of SHA algorithms. Given an input, the function generates the same output with extremely high probability (i.e., there is a very low probability of a collision). And, given an output, it is computationally difficult, and for all intents and purposes impractical, to discern the corresponding input.

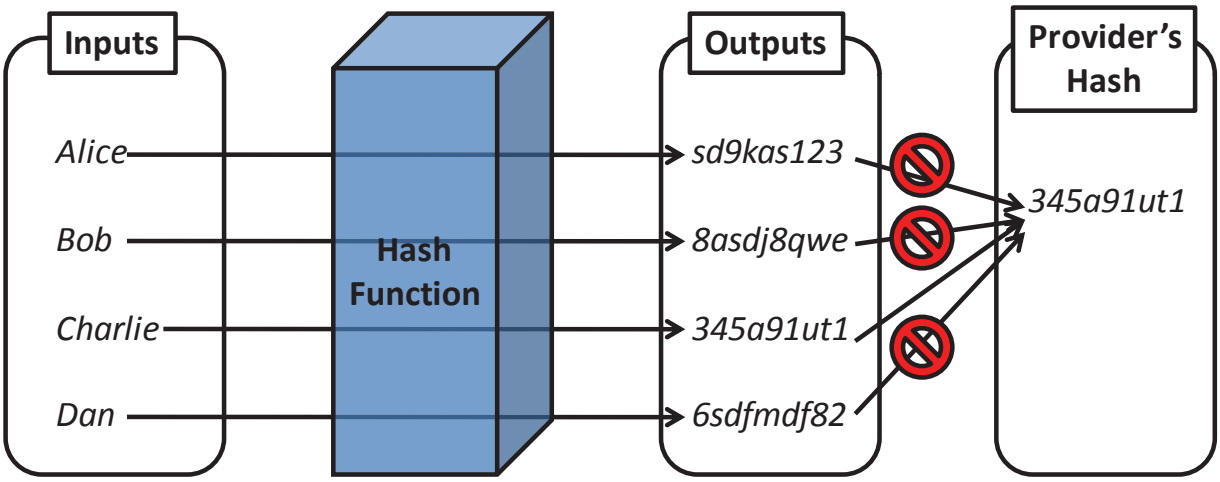


Figure 7. Example of a dictionary attack on hashed identifiers. In this case, the broker would learn that all information received about patient *345a91ut1* corresponds to *Charlie*.

It is important to recognize; however, that if the hash is simply applied to the message only, that the recipient of the message (i.e., Second Sight) could run a *dictionary* attack to discover the corresponding message for any hash. In this attack, the recipient would generate a list of all possible inputs to the function and test if the output corresponds to the received *hash*. This attack is exemplified in Figure 7.

To thwart this attack, it is important to "salt" the hash. Basically, the salt is a random number that is combined with the message.

$$H(message,salt) = saltedHash$$

The salt can be made arbitrarily large and, in doing so, the ability for the recipient of the *saltedHash* value can be made arbitrary small.

Second Sight has specifically adopted the SHA3-256 hash function. This is a standard hash function, deemed by NIST to be sufficiently secure. As such, the function itself does not violate the de-identification model under the HIPAA Privacy Rule. It should be noted that Second Sight may replace this hash function with another provided that NIST has

vetted and confirmed the function to have a level of security that is no weaker than the weakest function in the SHA3 hash family.

As noted earlier, the salt key will be generated by the Microsoft Azure Key Vault system, which Second Sight will not have access to. The salt itself will consist of 16-byte hexadecimal value, which indicates that the complexity of the salt (and thus the security of the system) corresponds to 128-bits.

On a commodity server, this would require years, if not decades, to run. Alternatively, if such an attack was pushed over to a cloud computing infrastructure with parallel compute notes, the cost to run the attack would be hundreds of thousands of dollars, and more likely to be over a million dollars to execute efficiently. Given that recent research suggests personal medical records hold value no greater than $400 per record on average, this threat is deemed to be sufficiently undesirable for an adversary to even attempt such attack. [Wan 2021] Moreover, this implies that the adversary would also recognize when they have been successful. Given the time and cost associated with cycling through so many possible variations, the risk of a brute force dictionary attack against the hash codes received by Second Sight was deemed to be sufficiently small.

7.2. Quasi-IDs for Second Sight

Next, the I ran a statistical analysis based on the fields that Second Sight will receive in the clear (i.e., without transformation). In so doing, a harmonized single quasi-identifying model was considered. Specifically, this model was:

{
Date of Service (inferred from wholesaler invoice number)
3-digit ZIP* (inferred from prescriber, the pharmacy, or 340B ID),
Sex
}

As done earlier, the expert performed this analysis based on the attack described in [Sweeney 1997; 2002].

Based on this analysis, it was estimated that no greater than 0.2281% of the U.S. population was expected to be unique, or a risk of 0.00281. Additionally, based on historical experience, the rate of exposure and/or attempted attack on the data by the recipients of this data is expected to be no greater than 0.1. [El Emam 2014]. Thus, the overall risk is expected to be no greater than 0.1 * 0.00281 = 0.000281, which is lower than the Safe Harbor threshold set in Section 6.

8. Determination

It is my opinion that the de-identification model, as described in this document, for the Second Sight Beacon™ offering meets the de-identification requirements set forth in the HIPAA Privacy Rule. As such, there is a very low risk of re-identification of a patient. This opinion is based upon the design of the Second Sight data sharing practices as defined on August 28, 2024.

This determination will be void if there are changes made to the system that are not in accordance with the recommended embellishments described above. Given the fact that threats to identifiability evolve over time, this certification is subject to a time limitation, such that this determination will expire forty-eight months from July 9, 2024.

DocuSigned by:
Bradley Malin
3451567A92564D6...

8/28/2024

Bradley A. Malin, Ph.D. Date

Consultant

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10. Information About the Expert

Bradley Malin, Ph.D. is the founder and principal consultant at Privasense, LLC. He is currently a Professor of Biomedical Informatics, Biostatistics, and Computer Science at Vanderbilt University, where he founded and currently directs the Vanderbilt Health Information Privacy Laboratory. He is an internationally recognized expert on data privacy and has served on national advisory committees for the National Academy of Medicine at the National Academy of Sciences regarding the management of data from electronic medical record systems and biorepositories, as well as the Technical Anonymisation Group of the European Medicines Agency. He has consulted on de-identification solutions for numerous industrial, not-for-profit, and government agencies. His research has been published through over two hundred peer-reviewed articles, portions of which have been cited in the Federal Register, Congressional briefings, and popular media outlets such as Nature News, Scientific American, and MIT Technology Review. Among various honors, he received the prestigious Presidential Early Career Award for Scientists and Engineers (PECASE) is an elected fellow of the American College of Medical Informatics (ACMI), International Academy of Health Sciences Informatics (IAHSI), American Institute for Medical and Biological Engineering (AIMBE), the Institute for Electrical and Electronics Engineering (IEEE), and the National Academy of Medicine (NAM). He received a bachelor's in biological sciences, master's in public policy and management, and doctorate in computer science, all from Carnegie Mellon University. Additional information can be found at http://www.hiplab.org/people/malin.

Attachment 4

Expert's Assessment of Second Sight Beacon™ De-identification Procedures for Medical Benefits Claims Data

Prepared by Privasense, LLC
Evaluation as of September 26, 2025

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*This document reflects the work and viewpoint of the preparer of this work and is representative of neither his primary employer (Vanderbilt University Medical Center of Nashville, TN) nor of any granting agency through which his work at his primary employer is supported, including the National Institutes of Health, the National Science Foundation, or the Patient Centered Outcomes Research Institute.

Document History

Version	Effective Date	Summary of Reasons for Changes
1	August 28, 2024	• Original
2	September 26, 2025	• Addition of claim line and wholesale invoice number to data dictionary

Table of Contents

1. Introduction

Under the 340B drug pricing program, pharmaceutical companies must agree to charge certain purchasers (known as "340B covered entities") discounted prices on outpatient prescription drugs provided to their patients in order to obtain coverage of those drugs under the Medicaid drug rebate program and Medicare Part B. Drugs purchased at the discounted price may be used by 340B covered entities to fill prescriptions for their patients at their own pharmacy and/or at third-party contracted pharmacies. When the pharmacies fill the prescriptions, the pharmacies will typically seek payment from the patient or his/her third-party payor for drug and the dispensing of the drug.

Under contracts with Plans/PBMs, pharmaceutical companies may also agree to pay a rebate to a Plan/PBM on outpatient prescription drugs utilized by its members. To prevent cumulative or duplicative discounts, the rebate contract will typically include provisions intended to ensure that the rebate is exclusive and cannot be combined with other discounts. Such provisions may preclude a Plan/PBM from claiming a rebate on drugs purchased under the 340B drug pricing program. Similarly, pharmaceutical companies are statutorily prohibited from having to pay a Medicaid rebate for a drug purchased at a 340B price. Despite such statutory and contractual limitations on duplicate rebates, state Medicaid programs and Plans/PBMs frequently still seek rebates for drugs purchased under the 340B drug pricing program, typically because they may not be able to identify readily such utilization based on standard information obtained from the pharmacies.

Currently, the process to identify and resolve duplicate Medicaid and commercial rebates on 340B purchased outpatient drugs is inefficient and ineffective. It involves covered entities disclosing protected health information ("PHI") in the form of prescription or claims data to pharmaceutical manufacturers, and pharmaceutical manufacturers attempting to link this information to their rebate data. The disclosure of PHI in this context is permitted under the Health Insurance Portability and Accountability Act, as amended, and its implementing regulations ("HIPAA") as a disclosure for "payment" purposes.[1]

[1] *See* 45 CFR 164.502(a)(1)(ii) and the definition of "payment" at 45 CFR 164.501. *See also* HIPAA FAQ 455 and 456 available online at https://www.hhs.gov/hipaa/for-professionals/faq/455/does-hipaa-permit-health-plans-to-

Establishing better processes to identify and resolve such duplicate Medicaid and commercial rebates on 340B purchased outpatient drugs is a priority for pharmaceutical manufacturers.

Second Sight Solutions, LLC ("Second Sight" or "SSS") is a technology company that has created certain technology and processes to facilitate the data exchanges and analyses necessary for pharmaceutical manufacturers to more efficiently and effectively identify and resolve duplicate Medicaid and commercial rebates on 340B purchased outpatient drugs, known as the Beacon™ offering. Beacon™ also enables pharmaceutical manufacturers to assess eligibility of an individual prescription for 340B pricing. The 340B ESP™ offering includes, but is not limited to, the following technologies:

(1) A technology solution, implemented as the Beacon™ Web Application at www.beaconchannelmanagement.com, to support the collection of de-identified 340B Claims data from 340B covered entities.

(2) A technology solution, deployed on-premise as part of the Beacon™ Manufacturer Client, to:

   (a) Process and de-identify Rebate Data by applying Second Sight's proprietary salt key and hashing algorithm to de-identify Company's Rebate Data on an ongoing basis.

   (b) Link de-identified 340B Claims data with de-identified Rebate Data in a de-identified manner.

   (c) Determine duplicate rebates in the Rebate Data and generate reports thereof.

   (d) Evaluate de-identified 340B Claims data for 340B eligibility.

In its operation of the Beacon™ offering and corresponding technologies, Second Sight seeks to ensure that its collection and linking of the 340B Claims data, in the form of data sourced from adjudicated Medical Benefits Claims data and Rebate data, occurs in a de-identified manner such that it does not need to serve as a business associate to 340B

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disclose-information-to-pharmaceutical-manufacturers/index.html (last visited January 15, 2024) and https://www.hhs.gov/hipaa/for-professionals/faq/456/does-hipaa-permit-state-medicaid-agencies-to-disclose-information-to-pharmaceutical-manufacturers/index.html (last visited January 15, 2024).

covered entities and to ensure that the minimum necessary data is provided. Specifically, Second Sight plans to receive and process this information in a manner that meets the de-identification standard under the HIPAA Privacy Rule, as overseen by the Office for Civil Rights at the U.S. Department of Health and Human Services. The HIPAA Privacy Rule provides an explicit definition of de-identified data, as well as two implementation options to meet the definition: i) Safe Harbor and ii) Expert Determination. Due to the fact that de-identified data is no longer subject to the Privacy Rule (or HIPAA more generally), it can be processed and/or commoditized without oversight by HHS.

Second Sight hired me to design a data de-identification plan that is compliant with generally agreed upon standards. Specifically, I worked with management at Second Sight, to develop a plan to ensure that the data provided to Second Sight and the linking methodology satisfies the Expert Determination model (which has colloquially been referred to as the "Statistical Standard" [Malin 2010]). The de-identification principles invoked by this plan are meant to be consistent with the HIPAA Privacy Rule as it is currently defined and may require reconsideration in the event subsequent rule amendments transpire.

As will be reviewed in greater depth below, I reviewed the risk associated with the data fields to be transferred to Second Sight. Based on this review, I categorized the data into fields that (i) have sufficient potential to indirectly identify patients (i.e., quasi-identifiers), and (ii) those which do not have sufficient potential to identify the individuals (i.e., non-identifiers). Following this coarse-level categorization, I performed a statistical analysis, based on population statistics to show that the data transferred in the clear would have a low risk of re-identification in the hands of Second Sight. For one field that was deemed to be too risky to share, a hashing process was set in place to transform data into a format that was consistently represented, but would not provide information that would lead to a patient's identity.

The following sections of this document review relevant components of HIPAA, provide a high-level overview of the patient-derived data to be disseminated and describe how the protections instituted for the data relate to the regulatory requirements of de-identification.

2. Privacy Rules and Regulations

In the United States, there is no centralized legal statute for data protection. Rather, a patchwork of laws is tailored to oversee the handling and disclosure of specific types of personal data, such as the Graham-Leach-Bliley Act for financial data, the Federal Educational Rights and Privacy Act for student data, and HIPAA, which is the most pertinent to this report. Specifically, under HIPAA, the Privacy Rule protects all "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. The Privacy Rule calls this information "protected health information" (PHI). By definition, "individually identifiable health information" is information, including demographic data that relates to:

- the individual's past, present or future physical or mental health or condition,
- the provision of health care to the individual, or
- the past, present, or future payment for the provision of health care to the individual,
- and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual.

PHI includes many common identifiers (e.g., name, address, birth date, Social Security Number), but there are also potential "quasi-identifiers" which may permit a recipient of the data to determine the identity of the corresponding subject.

When health information does not identify an individual, and there is no reasonable basis to believe that it can be used to identify an individual, it is said to be "de-identified" and is not protected by the Privacy Rule.

More specifically, 45 C.F.R., section 164.514(a) of the Privacy Rule provides the standard for de-identification of individually identifiable health information:

> **§ 164.514 Other requirements relating to uses and disclosures of protected health information.**
> (a) *Standard: de-identification of protected health information.* Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information.

Section 164.514(b) of the HIPAA Privacy Rule contains the implementation specifications that a covered entity, or affiliated business associate, must follow to meet the de-identification standard. In particular, the HIPAA Privacy Rule outlines two routes by which health data can be designated as de-identified. The first route is the "Expert Determination" method.

> (b) *Implementation specifications: requirements for de-identification of protected health information.* A covered entity may determine that health information is not individually identifiable health information only if:
>
> (1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:
>
> (i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and
>
> (ii) Documents the methods and results of the analysis that justify such determination; or

This implementation specification is notable for this certification report for several reasons. First, this specification states that the de-identification assessment should be performed with respect to the ***anticipated recipient***. In the case of this certification, the anticipated recipient corresponds to Second Sight, which will receive the Medical Benefits Claims Data pursuant to applicable terms of use and privacy policy. This ensures that there is clear circumscription around who has access to the data and the extent to which they are incentivized to maintain its privacy.

Second, the specification states that the assessment needs to consider the information that is reasonably available to the recipient. In this regard, it is evident that Second Sight is not aware of any of pharmacy interactions that patients have, which thus minimizes the likelihood that private knowledge could be leveraged for re-identification purposes.

Third, it states that the risk of identification for each record shared is not expected to be zero; rather, the risk must be "very small". Below, it will be shown how risk of identification can be quantified, and for the purposes of this certification, this risk will be compared to that which is inherent in the alternate de-identification implementation defined by the HIPAA Privacy Rule -- the "Safe Harbor" method.

(2)(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

(A) Names	
(B) All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000	
(C) All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older	
(D) Telephone numbers	(M) device identifiers and serial numbers
(E) Fax numbers	(N) Web Universal Resource Locators (URLs)
(F) Email addresses	(O) Internet Protocol (IP) addresses
(G) Social security numbers	(P) Biometric identifiers, including finger and voice prints
(H) Medical record numbers	
(I) Health plan beneficiary numbers	(Q) Full-face photographs and any comparable images
(J) Account numbers	(R) Any other unique, identifying number, characteristic, or code
(K) Certificate / license numbers	
(L) vehicle identifiers and serial numbers, including license plate numbers	

(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information

Satisfying either Expert Determination or Safe Harbor method will demonstrate that a covered entity, or an affiliated business associate, has met the standard in §164.514(a) above.

The HIPAA Privacy Rule goes on to provide direction with respect to a "re-identification" code (though, in this sense, this term is meant to mean the permissible tracking of a patient record) by the covered entity in §164.514(c). In practice, this is often referred to as pseudonymization, a convention that we use here to prevent ambiguity in the term re-identification.

> (c) Implementation specifications: re-identification. A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:
>
> (1) Derivation. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and
>
> (2) Security. The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

It is important to recognize that while the pseudonymization provision does not permit assignment of a code or other means of record identification that is derived from identifying individual information, a covered entity may disclose such derived information if an expert determines that the data meets the de-identification requirements at §164.514(b)(1). This is particularly the case if the resulting information cannot be translated to identify the individual. This is important to note because the data Second Sight de-identifies will be submitted over time, such that a record corresponding to a specific pseudonym may be recognized in disparate submissions. This is accomplished through the use of a consistent pseudonym for the patient.

3. Framework for Re-identification Risk Analysis

For the reader, it is critical to clearly articulate why a risk assessment is prudent and how it should be performed.

3.1. Principles of Identifiability

There are a number of detective-like investigations that have been published that demonstrate how health information devoid of explicit identifiers could be re-identified to the corresponding patient (e.g., [Sweeney 1997; El Emam 2006; Loukides 2010; Brown 2011; Solomon 2012; Cimino 2012; Atreya 2013, Sweeney 2013; Teague 2017, Yoo 2018; Rocher 2019; Bransson 2020]). However, there is a significant difference between the description of a path by which health-related information could be re-identified and the likelihood that such a path would be leveraged by an adversary in the real world. [Malin 2010] The HIPAA Privacy Rule does not preclude the dissemination of data that could be re-identified. Rather, as noted in the previous section, health information can be designated as de-identified if one accounts for the ***anticipated recipients*** who use *reasonable* means to attempt to re-identify the information.

In this context, we must consider the broader environment in terms of how a reasonable recipient would attempt to pursue such a route. Table 1 summarizes the principles that are utilized to determine if health data is sufficiently de-identified and is based on [Malin 2010, Malin 2011]. These principles build on those defined by the Federal Committee on Statistical Methodology (referenced in the original publication of the Privacy Rule) [FCSM 2005]).

In general, it helps to separate the health information attributes, or types of data, into three classes of relatively risks: high, moderate and low. High risks correspond to those that put the patient in imminent danger of re-identification, such as the disclosure of their name or Social Security Number. These are risks that must be addressed through some form of data editing (e.g., via suppression or transformation of the data) in order to resolve them. Moderate risks are those that may lead to the indirect re-identification of the patient.

These are risks that need to be accounted for in a statistical analysis and may lead to data editing, but do not necessarily require it. Low risks are those that are negligible in nature due to the data's inability to communicate an apparent risk. This type of risk does not lead to statistical analysis, such that the corresponding fields are retained without any editing. Although risk is more of a continuum, this rough partition illustrates how context impacts risk.

Table 1. Principles to assist experts in the determination of the identifiability of health information.

Principle	Description	Examples
Replicability	Prioritize health information features into levels of risk according to the chance it will consistently occur in relation to the individual.	*Low:* The specific drug prescribed to a patient may change depending on their care provider.
		Moderate: The claim number for a prescription is used to trace patient's pharmacy records over time and space.
Availability	Determine which external resources contain the patients' identifiers and the replicable features in the health information, as well as who is permitted access to the resource.	*Low:* The name of the prescriber for a patient is not readily available to Second Sight.
		Moderate: Patient demographics (which may be inferred from geography and the prescriber) are often in public resources, such as voter records.
Distinguish-ability	Determine the extent to which the subject's data can be distinguished in the health information.	*Low:* It has been estimated that the combination of *Year of Birth, Gender,* and *3-Digit ZIP Code* is unique for approximately 0.04% of residents in the United States [Sweeney 2007]. This means that very few US residents could be identified through this combination of data alone.
		Moderate: It has been estimated that the combination of a patient's *Date of Birth, Gender,* and *5-Digit ZIP Code* is unique for over 50% of residents in the United States [Sweeney 2002, Golle 2006, Benitez 2010]. This means that over half of US residents could be uniquely described just with these three data elements.
Assess Risk	The greater the replicability, availability, and distinguishability of the health information, the greater the risk for identification.	*Low:* The drug dispensed by a pharmacy for a certain prescriber may be unique, but the data that could be leveraged to match to a named patient may not be independently replicable and are rarely disclosed in multiple resources to which many people have access.
		Moderate: Demographics are highly distinguishing, highly replicable, and are available in public resources.

These principles will be applied with respect to the intended recipients to determine the extent to which they could accomplish unapproved re-identification[2].

3.2. Principles of Risk

The framework provides insight into the types of information that should be considered in a risk assessment. However, risk itself requires some clarification. There are, in fact, several ways by which re-identification risk can be defined, which depend on the knowledge and goals of the attacker. In the literature, these risk metrics are often referred to as 1) *prosecutor*, 2) *journalist*, and 3) *marketer* risks. [Dankar 2010] These risk models distinguish between the population (e.g., all individuals dispensed drugs for a certain clinical indication) used by the attacker to commit a re-identification and the sample of individuals who are in the published data set (e.g., all individuals who reside in the geographic area where the dispense took place). It is assumed that the population, at the very least, includes all members of the sample, as well as additional individuals who could have become members of the sample. Thus, in a worst-case adversarial scenario, the sample is the same as the population.

The first two types of risks correspond to scenarios for the most easily attackable record in the data set. Specifically, the prosecutor and journalist risks correspond to the most re-identifiable person in the published data set (i.e., the sample) and population, respectively. However, this attack assumes that the riskiest individual is the one of interest for targeting by the adversary, which is likely to only be the case when the adversary is intending to demonstrate the vulnerabilities in a dataset without actually exploiting the individuals to whom such records correspond. By contrast, the marketer risk is an amortization of the risk over all individuals in the data set. In this scenario, the adversary aims to re-identify as many individuals as possible, but may not worry about committing a specific targeted identification. Thus, in such a scenario, the risk of the data

[2] As alluded to earlier, it should be noted that the term "re-identification" is overloaded in its definition. In the HIPAA Privacy Rule, it is meant to indicate the renaming of a de-identified record through some coded mechanism known to the covered entity that shared the data, thus the use of the term "re-identification code". However, the term is also used to indicate when a record has had its underlying patient identity established without the assistance of such a code. Throughout the remainder of this document the term is used with respect to the latter definition.

set is proportional to the average identifiability of a record in the data set. As such, the marketer risk is defined as the proportion of records that can be correctly re-identified in a data set sampled from a population (which again, could be the same groups).

In the Second Sight setting associated with this certification, the Medical Benefits Claims Data will come forth in batches and it is not possible to determine which record might be of interest to a Second Sight employee. Moreover, it is not entirely possible to ascertain what specific information an analyst may utilize in an exploit. As such, to assess the risk of re-identification in this setting, we adopt the marketer risk model when data is shared to de-identified data users within Second Sight and its pharmaceutical manufacturer customers and rebate processors. In addition, we utilize a conservative ceiling on what is deemed to be acceptable risk by ensuring that the average (or expected) risk of re-identification in the system is no worse than what the HIPAA Safe Harbor policy would deem to be acceptable. As has been noted, the level of risk associated with Safe Harbor is often significantly smaller (by orders of magnitude) than what would be deemed to be an acceptable level of risk when assessing every record. For instance, as will be shown below, the Safe Harbor risk is on the order of 0.5%. However, this level of conservatism is prudent given that a guarantee of protection is not being afforded to every specific record shared.

Risk itself is actually a composite of the probability that an attack will be mounted (X) and the probability of success given that the attack is mounted (Y). In other words, the risk can be defined as $P(X)P(Y|X)$. The prior probability of attack is mitigated by legal, technical, and economic controls, which, in essence, serve as disincentives to malfeasance in the system. In this respect, the Second Sight de-identification strategy employs a combination of legal-, economic-, technical-, and statistical-based controls to mitigate the risk or re-identification. The following provides more specific details on these controls.

1. **Economic.** From an economic perspective, Second Sight's pharmaceutical manufacturer customers will pay a non-trivial monetary sum for Second Sight's

Beacon™ offering to collect the de-identified Medical Benefits Claims Data and enable the identification and resolution of Medicaid and commercial rebates on 340B purchased outpatient drugs. Research has shown that such upfront payments of this order can serve as deterrents to potential would-be adversaries and mitigate the chance that re-identification attacks will be perpetrated. [Khokar 2014, Wan 2015]

2. **Legal.** When receiving and using Medical Benefits Claims Data within Second Sight, employees are required to take due care to protect confidential information from unauthorized use, access, disclosure, destruction, loss or alteration. All applicable employees will sign a non-disclosure agreement indicating that they will maintain the privacy and confidentiality of the data collected from 340B covered entities, comply with the applicable terms of use and privacy policy, and not attempt to re-identify the data. Such non-disclosure agreement will also specify that violation of such confidentiality obligations could result in termination. Specifying that a violation of restricted uses may result in termination provides both monetary and reputational disincentive. While such policies do not guarantee a user will refrain from performing such acts, it does provide Second Sight with the ability to hold the employee accountable for their actions and open to civil suits in a court of law. Moreover, it provides grounds for termination.

   Employees who violate applicable confidentiality obligations and policies at their workplace could be subject to civil penalties associated with the violation of corporate computer policies. There is precedent in case law that employers can successfully sue ex-employees for stealing and misappropriating company data based on the Computer Fraud and Abuse Act (CFAA) and related laws. Examples of such cases include i) EF Cultural Travel B.V. v. Zefer Corp., 318 F.3d 58, 63 (1st Cir. 2003), which states "CFAA…is primarily a statute imposing limits on access and enhancing control by information providers.", and ii) U.S. v. John, 597 F.3d 263, 269, 272 (5th Cir. 2010), which states "official policy, which was reiterated in training programs that John attended, [that] prohibited misuse of the

company's internal computer systems and confidential customer information." Further details on such matters can be found in [Weller 2008].

Again, non-disclosure agreements do not guarantee that a user at Second Sight will refrain from misuse of Second Sight data, but it does provide customers to hold Second Sight, or for Second Sight to hold its employees, accountable for their actions and bring about civil suits in a court of law. Such protections are critical because, since de-identified data falls outside the scope of HIPAA, without such a contract, there would be no accountability for a re-identification performed by a recipient of the data.

3. **Technical Controls.** Beyond the de-identification principles described in this document, there are several types of technical controls that are in place to ensure that Medical Benefits Claims Data is not inadvertently disclosed to unanticipated recipients. First, all connections made between a client[3] and the cloud computing environment to which data will be transferred will be secured using standard Transport Layer Security. Second, all de-identified data transferred to Second Sight will be maintained in a secured cloud computing environment, such that only authorized individuals will be able to access the data, using a unique user ID and password. Third, all data transferred to any binary application for purposes of the linking process is neither accessible by a manufacturer nor a manufacturer's rebate processor and utilizes ephemeral storage. More to the point, when a the binary is run, the binary is making an API call to Second Sight to bring in data for the purposes of the linking process but that data is not written to a database. As a result, when the instance completes its run or it is stopped or terminated, all data is wiped from the application.

[3] A client is a computer or a program that, as part of its operations relies on sending a request to another program or computer hardware or software that accesses a service made available by a server. For example, web browsers are clients that connect to web servers.

4. **Attenuated Data.** From a statistical perspective, the Medical Benefits Claims Data provided to Second Sight is attenuated to ensure that it does not include sufficient information to facilitate re-identification beyond a certain degree (discussed below).

While these controls cannot be guaranteed, evidence in information security indicates that they certainly lower the rate at which attacks against such systems are realized [Khokhar 2014; Xia 2015; Wan 2015; Xia 2023]. This probability of attack will be addressed in the following section, while the probability of success given the attack is a statistical question and will be addressed in further depth below.

4. Data Recipients and Scope of De-identification Designation

My assessment is performed in a manner that considers the context of the anticipated recipient of data, which in this case is Second Sight. For reference, a high-level schematic of the process and the scope of the de-identification designation are depicted in Figures 1 and 2. A stepwise walkthrough of the data transferred in each step of the process is shown in Figure 3.

The linkage process may take place at either Second Sight or at a manufacturer or manufacturer's rebate processor, through the use of technology that is provided by Second Sight. The following subsections address each of these scenarios. In both scenarios, based on historical experience, it was determined that the rate of exposure and/or attempted attack on de-identified Medical Benefits Claims Data transferred to Second Sight, a manufacturer or the manufacturer's rebate processor is expected to be no greater than 0.1. [El Emam 2014]

4.1. Linking at Second Sight

In the first scenario, as shown in Figure 1, it can be seen that Second Sight is serving as an intermediary and facilitating data exchange between covered entities and pharmaceutical manufacturers that is already deemed to be permissible under HIPAA as disclosures for "payment" purposes. Second Sight is ensuring that the Medical Benefits Claims Data it receives is fully de-identified when in Second Sight's control, not when in the hands of the covered entities or pharmaceutical manufacturers.

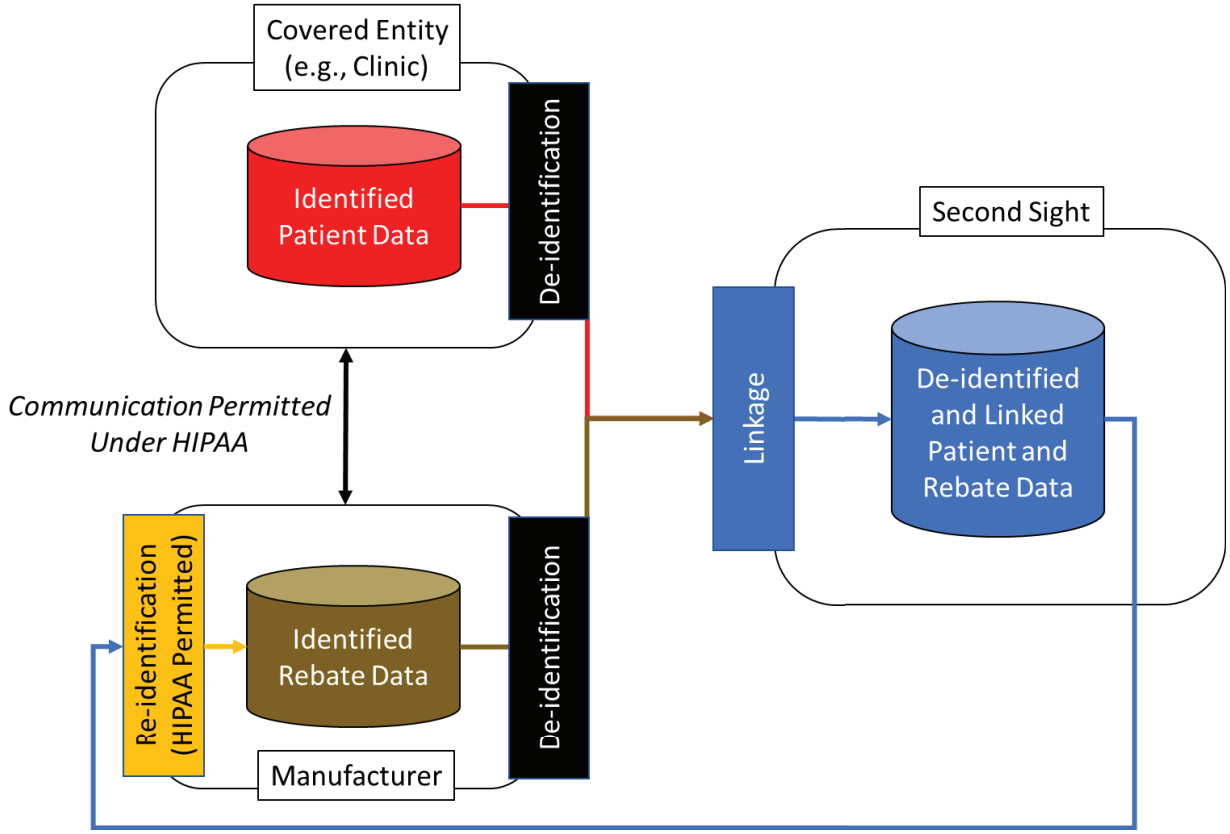


Figure 1. An illustration of where data processing is covered under HIPAA and where de-identification is required.

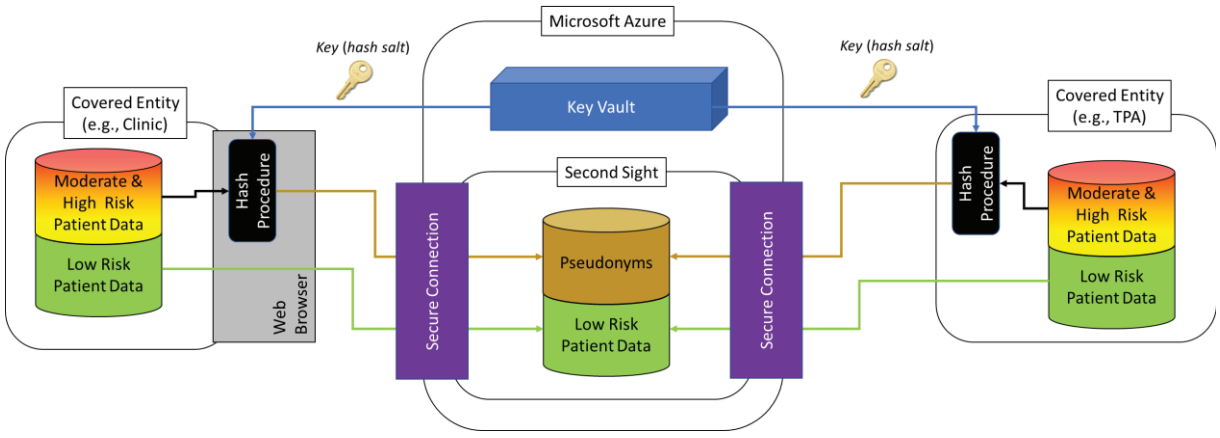


Figure 2. Health information transformation and flow between covered entities and Second Sight.

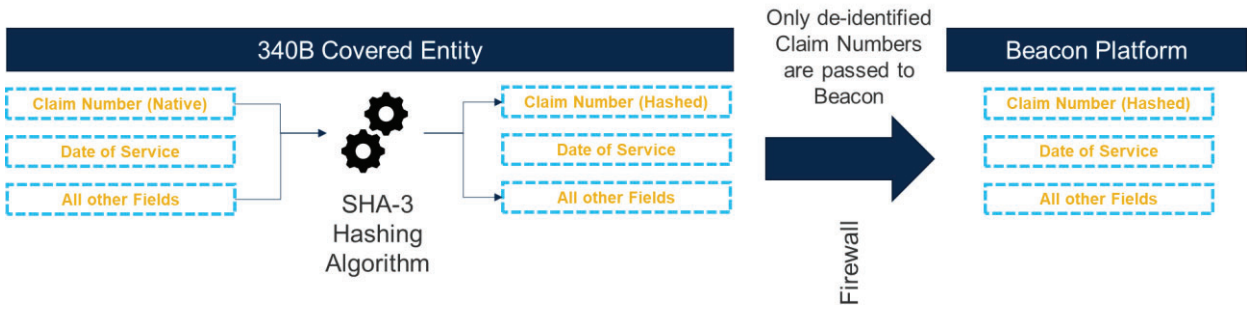
The specific details of the de-identification process are articulated in Figure 2. As can be seen, first, in preparation for data transformation, a Key Vault on Microsoft Azure is

instantiated to generate and store in escrow (for reuse) a random value that will be concatenated with PHI prior to its hashing.

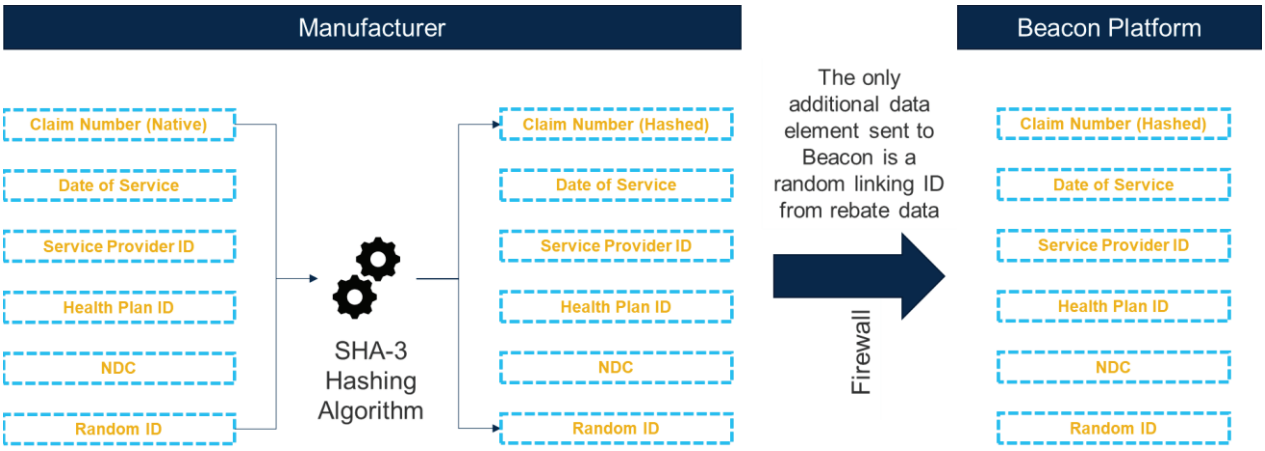
Second, when a covered entity is ready to transfer Medical Benefits Claims Data, it will be provided with this random value in one of two ways. For covered entities who are connecting to Second Sight via a web browser, the random value will be transferred to the browser and invoked during the hashing process, which will take place within the browser. For covered entities who designate a third-party (e.g., a TPA) to submit these data on their behalf, Second Sight will provide software consisting of a compiled binary to the third-party. The random value is securely embedded into the binary to perform the hashing process offline.

Third, the hashed data (in the form of pseudonyms) and low and moderate risk data will be provided to Second Sight. For online covered entities, this transfer will take place over an HTTPS established between the local browser and Second Sight. For offline third parties, this transfer will take place over HTTPS established between the provided compiled binary and Second Sight.

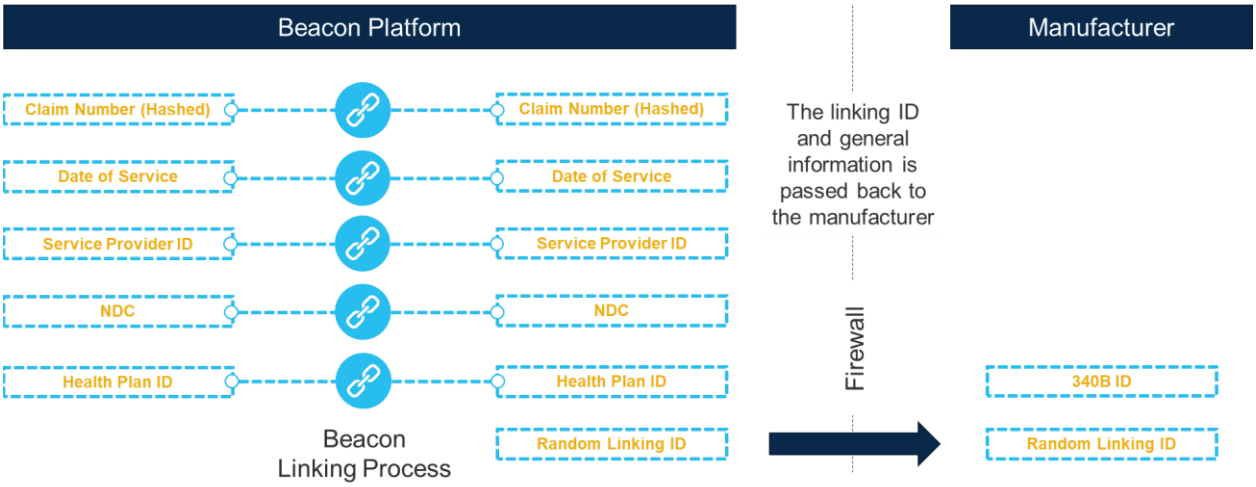
Figure 3 below provides a stepwise walkthrough of the data transferred in each step of the process.



(a) Step 1: Covered entity 340B claims upload



(b) Step 2: Manufacturer rebate utilization upload



(c) Step 3: The Random Linking ID, corresponding to instances of linked pharmacy claim and rebate data, along with the 340B ID, are sent to manufacturer

Figure 3. An illustration of the data transferred (a) from 340B covered entity to Beacon platform in a de-identified manner, (b) from manufacturer to Beacon platform in a de-identified manner, and (c) from the Beacon platform back to the manufacturer in a linked and de-identified manner, which consists of the Random Linking ID, corresponding to instances of linked claim and rebate data, as well as the 340B ID, which indicates where the transaction occurred.

4.2. Linking at Manufacturer

Rather than perform linking at Second Sight, a manufacturer or its rebate processor may perform linkage locally. This is accomplished through software provided by Second Sight to the manufacturer or rebate processor, as well as a process between the user of Second Sight's software and Second Sight themselves, as described in this subsection.

The Beacon™ Manufacturer Client consists of a compiled binary application running on the manufacturer's or rebate processor's premises, along with a binary server running inside Second Sight, as shown in Figure 4.

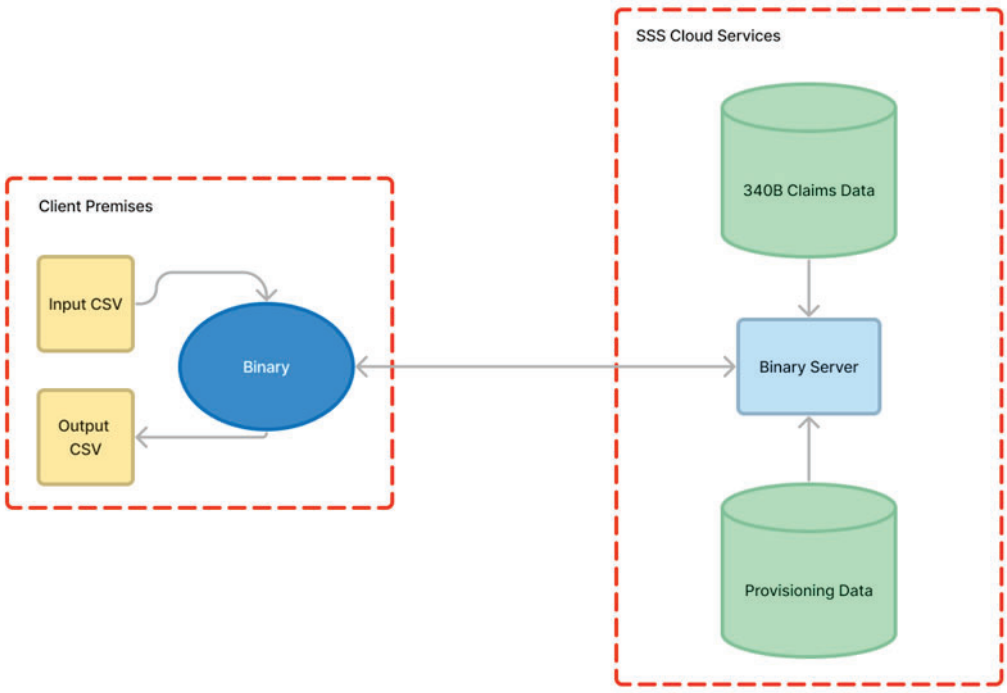


Figure 4. An illustration of the binary application running on-premise at a manufacturer or rebate processor and the coordination with Second Sight (referenced in Figure 4 as SSS).

The purpose of this software is to link rebate claims to corresponding 340B claims submitted via Beacon (the "Binary"). The Binary application is designed and configured with authentication and access controls that prohibit the manufacturer or rebate processor

from accessing transferred 340B claims and de-identified data. The binary de-identifies provided rebate data in order to perform this linking process. All linking occurs at the manufacturer or rebate processor such that no rebate data are ever sent to Second Sight .

To perform this process, the manufacturer or rebate processor provides a CSV rebate claims file to the binary application installed on premise (the "on-premise binary application"). The on-premise binary application makes an API call to the binary server operated by Second Sight to retrieve relevant 340B claims data. The on-premise binary application then de-identifies the rebate claims file and links the de-identified rebate data and de-identified 340B claims data. There is an output row for each rebate claim that was linked to a 340B claim. In addition, if there was an error in the rebate claim row then an output row for that rebate claim row will be generated, indicating the reason for the error. An output file comprised of the linking ID, 340B ID and set of status and error values is created by the on-premise binary application and made accessible to the manufacturer or rebate processor as depicted in Figure 5. Note that unlinked rebate claim rows are not present in the output file and the manufacturer or rebate processor receives no 340B claims data in the output file.

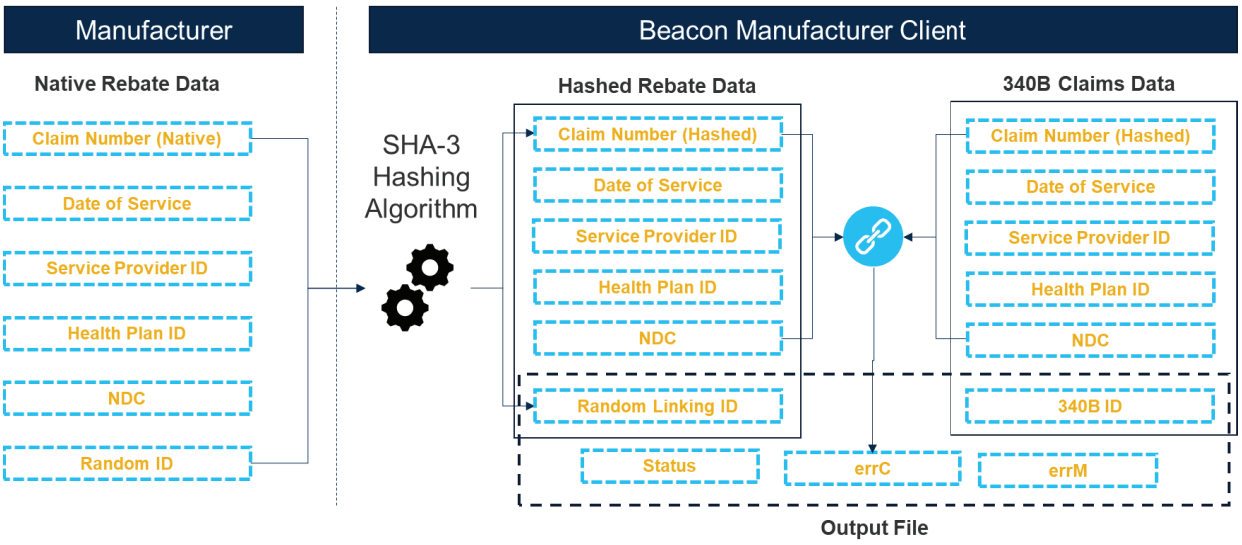


Figure 5. An illustration of the input of native rebate claims data, de-identification of rebate claims data, linking of rebate and 340B claims data and creation of an output record through the on-premise binary application.

In addition to generating an output file for use by the pharmaceutical manufacturer in their rebate payment processing, the binary also generates data that are sent to the binary server and maintained in the Second Sight environment. Similarly, the on-premise binary application receives data from the Second Sight environment via the binary server that are utilized as part of the rebate and claims data linking process. These data are not accessible by the manufacturer or rebate processor and is processed utilizing ephemeral storage which is not persisted, all data will be lost if the instance is completed, stopped, or terminated. Figure 6 provides detail on the data transferred between the binary application on premises at the manufacturer or rebate processor and the binary server operating in the Second Sight environment. All data traveling between the on-premise binary application and the binary server are fully encrypted using mutual TLS with 4096-bit encryption keys.

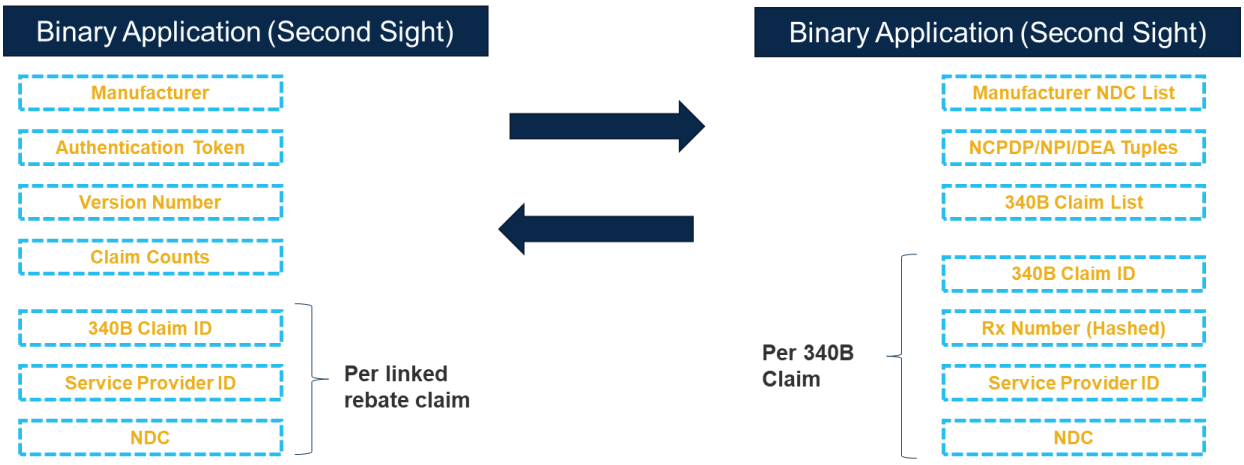


Figure 6. An illustration of the data elements transferred between the binary server residing within Second Sight's cloud computing environment and the binary application installed on premises with the manufacturer or rebate processor.

Every on-premise binary application is built specifically for a manufacturer or rebate processor. In particular, an X.509 client certificate[4] is generated using a Second Sight Certificate Authority where that client certificate contains the common name and organizational unit elements. This client certificate is presented to the server to authenticate each binary application. This ensures client non-repudiation, as well as the ability to reliably enforce access control.

An authentication token is provided by Second Sight for each manufacturer or rebate processor, this authentication token must be used with every request to the binary server and invocation of the on-premises binary. In addition to this authentication feature, there is also authorization. Second Sight explicitly grants the on-premise binary application the permission to receive the relevant 340B claims data that correspond to an authenticated token.

Binary activity and generated data sent to the Second Sight binary server are recorded and monitored with real time notification and alerting services. Second Sight can disable binary functionality and modify or immediately revoke authentication token access at any time.

[4] An X. 509 certificate binds an identity to a public key utilizing a digital certificate that uses the widely accepted international X. 509 public key infrastructure (PKI) standard to verify that a public key belongs to the user, computer or service identity contained within the certificate, X.509 certificates are used in many Internet protocols, including TLS/SSL.

5. De-identification Model

The Medical Benefits Claims Data protection model adopted by Second Sight is straightforward. The data fields that were considered are shown in Table 2, along with their gross risk designations. These designations are composed of three concepts. First, the fields were labeled with the type of information that they communicate that could be leveraged for re-identification purposes (i.e., Risk Type). Second, the fields were characterized with respect to the degree to which the information could be readily leveraged for re-identification purposes. Fields designated with a "low" status failed on one of the principles articulated in Table 1 and thus were not considered further in the re-identification assessment.

Fields designated as "moderate" were considered quasi-identifiers that were reviewed in the statistical risk assessment, some of which may have been subject to some degree of transformation.

It should be noted that manufacturers may adopt policies that require eligible 340B contract pharmacy purchases to occur on or after a threshold date. To support the implementation of this type of policy, claims data submitted through the 340B ESP platform will include a flag indicating whether the claim conforms with the specific policy. Prior to uploading data to the Beacon platform, the date of service on the claim will be compared with the pharmaceutical manufacturer's policy and the flag will be populated with a Boolean indication of whether the date of service is in compliance with the manufacturer's policy. This value will be included in the claims data submission. It was confirmed that the time between the current date and the threshold date will never be less than one week in length.

Table 2. Gross risk characterization of the data fields to be transferred to Second Sight.

NCPDP Field Name	Field Description	Risk Type	Risk Status	Transformation
Plan ID Qualifier	Identifies the type of data being submitted in the Plan ID Code (600-94) field.	-	Low	No change
Plan ID Code	ID assigned to identify the plan.	-	Low	No change
Plan name	The name of the plan.	Geography	Moderate	No change
Service Provider ID Qualifier	Code qualifying the Service Provider ID (201-B1).	-	Low	No change

Service Provider ID	ID assigned to a pharmacy or provider.	Geography	Moderate	No change
Product Service ID Qualifier	Code qualifying the value in Product/Service ID (407-D7).	-	Low	No change
Product Service ID	ID of the product dispensed or service provided.	Geography	Moderate	No change
Billed HCPCS quantity	Total quantity being submitted.	-	Low	No change
Billed HCPCS Unit of Measure	NCPDP standard product billing codes.	-	Low	No change
Prescription Type		-	Low	No change
Date of Service	Identifies date the prescription was filled or professional service rendered or subsequent payer began coverage following Part A expiration in a long-term care setting only.	Date	Moderate	No change
Prescriber ID Qualifier	Code qualifying the Prescriber ID (411-DB).	-	Low	No change
Prescriber ID	ID assigned to the prescriber.	Geography	Moderate	No change
Claim Number	A unique identifier for a prescription and claim processor	Unique ID	Moderate	Hashed
Claim Line Number	The line number with the claim	-	Low	No change
HCPCS Code	A subset of the HCPCS Level II code set with a high-order value of J that has been used to identify certain drugs and other items.	Death	Low	No change
HCPCS Code Modifier 1	Code specifying drug and other items.	-	Low	No change
HCPCS Code Modifier 2	Code specifying drug and other items.	-	Low	No change
Wholesaler Invoice Number		Date	Moderate	No change

With respect to the moderate risk fields, it was observed that these fields could communicate certain aspects about a patient. First, while Safe Harbor prohibits dates of events, it was determined, and confirmed via statistical analysis (see below) that the date of the service could be retained in the Medical Benefits Claims Data.

Second, it was determined that the prescriber, the pharmacy, and the 340B ID could communicate certain geographic information about the patient. Based on my experience, I assumed that geographic area of residence could be inferred from such information with no greater certainty than the first three digits of the ZIP code. It was further observed that, in certain instances, the sex of the patient might be disclosed for a patient based on their prescription (e.g., birth control pill → female; treatment for erectile dysfunction → male).

Finally, it should be noted that HCPCS codes are included in the Medical Benefits Claims Data, which have a history of contributing re-identification risk due to death indicators. However, it was confirmed that the HCPCS codes in the Medical Benefits Claims do not communicate death indicators. Specifically, it was represented that none of the following values would be in the data:

- *G9256*: Documentation of patient death following cas
- *G9260*: Documentation of patient death following cea
- *G9262*: Documentation of patient death in the hospital following endovascular aaa repair
- *G9433*: Death - permanent nursing home resident or receiving hospice or palliative care any time during the measurement period
- *G9812*: Patient died including all deaths occurring during the hospitalization in which the operation was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure
- *G9814*: Death occurring during the index acute care hospitalization
- *G9816*: Death occurring after discharge from the hospital but within 30 days post procedure

6. A Risk Threshold

To perform a statistical analysis of re-identification potential, it is a common practice to assume a limited capability adversary who has access to certain pieces of knowledge about the targeted patient. In this regard, to assess re-identification risk for the data, the consultant first analyzed the factors that were the most likely to be exploited given this resource, namely patient-related demographic and geographic information. As such, the consultant used public data from the U.S. Decennial Census [Census 2024] to determine the extent to which the following combination of features would allow for unique identification of individuals: {*Age-90+*, *Year of Death*, *Gender*, *Race*, *Ethnicity*, 3-*digit ZIP**}. In this scenario, the age of the patient was top-recoded to 90+ and all ZIP codes with regions less than 20,000 people were grouped together into one aggregated region.

It was assumed that Race would correspond to traditional self-reported information akin to that which the U.S. Census Bureau or voter registration lists capture. In doing so, the race information was characterized as a value domain of {White, Black, Asian, Native American, Pacific Islander, Other}. Similarly, ethnicity corresponds to {Hispanic or Latino, Not Hispanic or Latino}

I performed this analysis based on the attack described in [Sweeney 1997; Sweeney 2002; Golle 2006]. In particular, I utilized publicly accessible demographic tables from U.S. Census Bureau in the form of PCT12A through PCT12H, which report population counts by age group, gender, and race combination.[5] This information was further subdivided by splitting the population along the 3-digit ZCTA (which was used as a proxy for the ZIP code), while grouping the ZCTAs with less than 20,000 people into a single group. For reference, the set of ZCTAs that were aggregated are shown in Table 4. For each ⟨gender, race, age, ZCTA⟩ population combination, the consultant aggregated the counts for all age groups over 89 years old.

[5] It has been noted that there exists a certain amount of error in the public version of the U.S. Census data that may influence analyses with age 65 and older. [Alexander 2010] Yet, the expert noted that such inaccuracy is at the cell level, while the analysis conducted for this assessment is about aggregated results. Thus, it was not expected that such errors would influence the general findings of this investigation.

Table 4. 3-digit ZCTA with populations expected to be less than 20,000 people in size.

036	059	063	102	203	556	692	790
821	823	830	831	878	879	884	890
893							

After constructing the dataset, I then estimated the number of unique individuals that reside in the population. The estimation process was based on the strategy proposed in [Golle 2006]. This is because the statistics published by the U.S. Census are in an aggregated form. For instance, the bureau reports how many males with age 50-54 reside in a certain 3-digit ZCTA and are Caucasian. For reference, let us call this number *n.* For our analysis, we need to disaggregate the five-year bin into one-year bins and calculate the expected number of bins with one individual. This disaggregation is a traditional balls-to-bins problem. In a generalized form, if we assume we want the number of bins with exactly *i* people, the problem reduces to a binomial function of the form:

$$f_i(n) = \binom{n}{i} b^{1-n}(b-1)^{n-i}$$

For this analysis, we set *i* equal to one, reducing the computation to:

$$f_i(n) = n\left(\frac{b-1}{b}\right)^{n-1}$$

The value for *b* varies for different age groups in the Census data. For instance, age group 0-4 has 5 bins, while age group 60-61 has 2 bins.

After computing this value for each bin, the results are summed and normalized by the total U.S. population in the Census tables. Based on this analysis, it was found that 0.89% of the U.S. population was estimated to be unique, or a risk of 0.0089.

7. Final Risk Analysis

7.1. Unique IDs

The unique identifiers managed by Second Sight are translated into salted one-way hashed values. One-way hashes have been applied in Florida [Bian 2019], Illinois [Kho 2015], Indiana [Grannis 2002, 2007], Palo Alto [Weber 2012], and Tennessee [Roden 2008] to obscure patient identifiers. In essence the one-way hash is a function *H* that takes a *message* as input and returns a *hash* value as output:

$$H(message) = hash$$

It is assumed that the hash function is public knowledge (or at least known to all of the entities participating in the system). Various functions that have been applied include MD5 and the class of SHA algorithms. Given an input, the function generates the same output with extremely high probability (i.e., there is a very low probability of a collision). And, given an output, it is computationally difficult, and for all intents and purposes impractical, to discern the corresponding input.

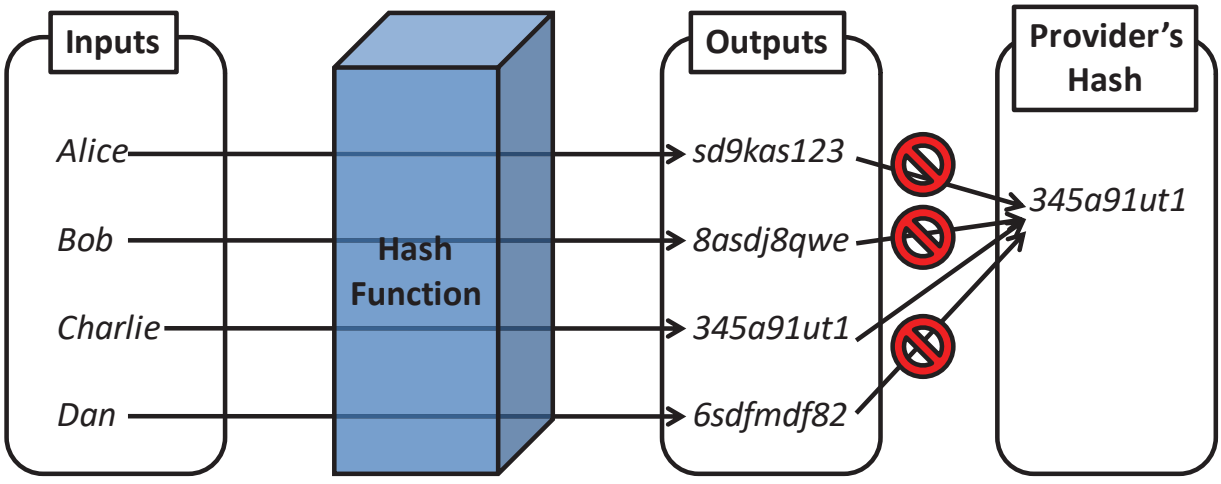


Figure 4. Example of a dictionary attack on hashed identifiers. In this case, the broker would learn that all information received about patient *345a91ut1* corresponds to *Charlie*.

It is important to recognize; however, that if the hash is simply applied to the message only, that the recipient of the message (i.e., Second Sight) could run a *dictionary* attack

to discover the corresponding message for any hash. In this attack, the recipient would generate a list of all possible inputs to the function and test if the output corresponds to the received *hash*. This attack is exemplified in Figure 4.

To thwart this attack, it is important to "salt" the hash. Basically, the salt is a random number that is combined with the message.

$$H(message,salt) = saltedHash$$

The salt can be made arbitrarily large and, in doing so, the ability for the recipient of the *saltedHash* value can be made arbitrary small.

Second Sight has specifically adopted the SHA3-256 hash function. This is a standard hash function, deemed by NIST to be sufficiently secure. As such, the function itself does not violate the de-identification model under the HIPAA Privacy Rule. It should be noted that Second Sight may replace this hash function with another provided that NIST has vetted and confirmed the function to have a level of security that is no weaker than the weakest function in the SHA3 hash family.

As noted earlier, the salt key will be generated by the Microsoft Azure Key Vault system, which Second Sight will not have access to. The salt itself will consist of 16-byte hexadecimal value, which indicates that the complexity of the salt (and thus the security of the system) corresponds to 128-bits.

On a commodity server, this would require years, if not decades, to run. Alternatively, if such an attack was pushed over to a cloud computing infrastructure with parallel compute notes, the cost to run the attack would be hundreds of thousands of dollars, and more likely to be over a million dollars to execute efficiently. Given that recent research suggests personal medical records hold value no greater than $400 per record on average, this threat is deemed to be sufficiently undesirable for an adversary to even attempt such attack. [Wan 2015] Moreover, this implies that the adversary would also

recognize when they have been successful. Given the time and cost associated with cycling through so many possible variations, the risk of a brute force dictionary attack against the hash codes received by Second Sight was deemed to be sufficiently small.

7.2. Quasi-IDs for Second Sight

Next, the I ran a statistical analysis based on the Medical Benefits Claims Data fields that Second Sight will receive in the clear (i.e., without transformation). In so doing, a harmonized single quasi-identifying model was considered. Specifically, this model was:

{
Date of Service,
3-digit ZIP* (inferred from prescriber, the pharmacy, or 340B ID),
Sex
}

As done earlier, the expert performed this analysis based on the attack described in [Sweeney 1997; 2002].

Based on this analysis, it was estimated that no greater than 0.228% of the U.S. population was expected to be unique or a risk of 0.00228. Given that the prior probability of an attack is no greater than 0.1, the overall risk is expected to be no greater than 0.1*0.00228 = 0.000228, which is no greater than the Safe Harbor threshold.

8. Determination

It is my opinion that the de-identification model, as described in this document, for the Enhanced Pharmacy Claims data shared through the Second Sight Beacon™ offering meets the de-identification requirements set forth in the HIPAA Privacy Rule. As such, there is a very low risk of re-identification of a patient. This opinion is based upon the design of the Second Sight data sharing practices as defined on September 26, 2025.

This determination will be void if there are changes made to the system that are not in accordance with the recommended embellishments described above. Given the fact that threats to identifiability evolve over time, this certification is subject to a time limitation, such that this determination will expire forty-eight months from February 8, 2024.

DocuSigned by:
Bradley Malin
3451567A92564D6...

9/26/2025

Bradley A. Malin, Ph.D. Date

Consultant

9. References

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10. Information About the Expert

Bradley Malin, Ph.D. is the founder and principal consultant at Privasense, LLC. He is currently a Professor of Biomedical Informatics, Biostatistics, and Computer Science at Vanderbilt University, where he founded and currently directs the Vanderbilt Health Information Privacy Laboratory. He is an internationally recognized expert on data privacy and has served on national advisory committees for the National Academy of Medicine at the National Academy of Sciences regarding the management of data from electronic medical record systems and biorepositories, as well as the Technical Anonymisation Group of the European Medicines Agency. He has consulted on de-identification solutions for numerous industrial, not-for-profit, and government agencies. His research has been published through over 250 peer-reviewed articles, portions of which have been cited in the Federal Register, Congressional briefings, and popular media outlets such as Nature News, Scientific American, and MIT Technology Review. Among various honors, he received the prestigious Presidential Early Career Award for Scientists and Engineers (PECASE) is an elected fellow of the American College of Medical Informatics (ACMI), International Academy of Health Sciences Informatics (IAHSI), American Institute for Medical and Biological Engineering (AIMBE), the Institute of Electrical and Electronics Engineering (IEEE), and the National Academy of Medicine (NAM). He received a bachelor's in biological sciences, master's in public policy and management, and doctorate in computer science, all from Carnegie Mellon University. Additional information can be found at http://www.hiplab.org/people/malin.

CORNERSTONE CARE
COMMUNITY HEALTH CENTERS

April 27th, 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 **Cornerstone Care, 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 (CHCs), Cornerstone Care again requests that CHCs be exempted from the pilot program.**

Cornerstone Care is a nonprofit community health center committed to providing high-quality, integrated, and affordable healthcare services to all. We began in 1978 with a simple but powerful belief that everyone deserves access to healthcare. What started in a Victorian house in Greensboro, Pennsylvania, has grown into a trusted network of care serving more than 23,000 patients in 2025 in fourteen sites and three mobile units across Greene, Washington, Fayette, and Allegheny counties.

As the communities we serve have grown and changed, so has Cornerstone Care. We've expanded beyond primary care to offer a full range of services including medical, pediatrics, behavioral health, dental, vision, pharmacy and other specialty care. Ensuring patients and families can find the support they need close to home. Through every stage of growth, our focus has remained the same: meeting people where they are with compassionate, patient-centered care. Today, Cornerstone Care continues to build on foundation, strengthening communities, improving health outcomes, and removing barriers to care—so that every individual has the opportunity to live a healthy life. *The 340B program has been critical to fueling Cornerstone Care's ability to respond to changing needs in our community.* Our analysis indicates that shifting to a rebate model would undermine our ability to continue that responsiveness into the future and would likely force us to curtail existing programs and locations targeting the most underserved patients and communities in our service area.

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 **23,000** 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**: **Cornerstone Care** anticipates needing to add 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, **Cornerstone Care** will face an increased administrative burden to monitor rebate claims and payments. We estimate 2000 hours annually will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **Cornerstone Care** anticipates an additional $255,000.00 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

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

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. **$30,000 – $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 **$30,000** to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves **23,000** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at $1,375,000.00 annually.

The In-House Pharmacy: The Burden of IT Integration

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

- **System Interoperability:** Unlike contract pharmacies that use TPAs, in-house pharmacies must directly integrate their Electronic Health Record (EHR) and Pharmacy Management System (PMS) with a complex new rebate infrastructure.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools.
- **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 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 **52** 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. 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

Cornerstone Care 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.

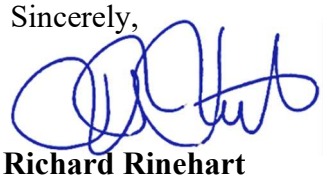
- **Sliding Fee Scale:** A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of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

Conclusion

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

Cornerstone Care 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 Nicole Coneybeer, Pharmacy Program Administrator at nconeybeer@cornerstonecare.com**.**

Sincerely,



Richard Rinehart
Chief Executive Officer

[6] HRSA FAQ

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

MOUNTAIN PARK HEALTH CENTER

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 **Mountain Park Health Center ("Mountain Park"),** 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, Mountain Park Health Center again requests that CHCs be exempted from the pilot program.**

Each year, more than 100,000 members of the community receive high-quality primary health care at one of Mountain Park's 11 clinics located in underserved areas across metropolitan Phoenix. Mountain Park serves patients from all walks of life through all stages of life. Mountain Park was the first Joint Commission accredited Federally Qualified Health Center in Arizona, achieving ambulatory health accreditation in 1999 and Primary Care Medical Home accreditation in 2014. Primary care services provided directly at Mountain Park include medical care for adults; pediatric care for infants, children, and adolescents; obstetrical and gynecological care for women; and integrated behavioral health care for all patients. Mountain Park also provides dental services at three clinics, and full-service pharmacies at two clinics. Other professional services provided on-site include nutrition and dietitian services, and a wide array of enabling services that support primary care, including eligibility assistance as well as language and translation programs. The organization is committed to meeting each patient's physical and mental health care needs, including prevention, wellness, acute care, and chronic care services. Sliding fees discounts cover all services provided at Mountain Park. As a Patient Centered Medical Home, Mountain Park actively supports the patient's ability and desire to learn to manage their own care. Each patient has a designated care team which includes the patient at the center, a primary care provider (PCP), non-provider personnel (e.g., medical assistants and case managers), and same day access to integrated behavioral health providers and registered dietitians. Same day access to a clinical pharmacist is also part of the patients' care teams. These teams provide health care services and self-management support, arrange for needed resources, and provide care coordination or other services.

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

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

By requiring CHCs to purchase medications at full price and wait for rebates, this model would cause significant financial turmoil and directly affect our ability to serve the **103,000** 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**: Mountain Park Health Center anticipates needing at least 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 for 2026 MFP drugs, Mountain Park will face an increased administrative burden to monitor rebate claims and payments. Approximately 40 hours per week will be required to report 340B rebate claims to a third-party platform. In addition, if the fifteen (15) additional MFP drugs proposed for 2027 are added, Mountain Park anticipates an additional 10 hours per week, for a total of 50 hours per week, exceeding 1.0 FTE.
- **External Vendor Costs**: Mountain Park Health Center anticipates an additional **$500,000** for external vendors, including consultants, legal counsel, program coordination, third-party administrators (TPAs), electronic medical records (EMRs), pharmacy software, and reconciliation services.

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

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.

The In-House Pharmacy: The Burden of IT Integration

Mountain Park Health Center operates two 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. Mountain Park's current EHR does not include an embedded pharmacy module to support clinic administered drugs, and we do not anticipate that capability for several years. In addition, Mountain Park's current PMS does not support uploading price files that differ from those provided by our drug wholesaler. To bill correctly under Arizona's Medicaid program, we would be required to bill at end acquisition cost, even though acquisition pricing would differ materially before and after rebate reconciliation. This hinders the process of being able to use the same drug file for all billing in our pharmacy and will place great burden on our staff.
- **One-Time Integration Costs:** We anticipate high upfront costs to pay software vendors for custom API builds and "Price File" reconciliation tools.
- **Ongoing Resource Diversion:** Staff who currently manage pharmacy services will be forced to spend an additional 20 hours per week manually pulling "Purchase Files" and "Price Files" to verify that every rebate check matches the statutory 340B price.

The Contract Pharmacy: The Burden of Network Coordination

The rebate model introduces a new complexity that threatens the existence of contractual arrangements. My CHC currently partners with seven (7) pharmacy companies 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 **many** different pharmacy locations to ensure rebates are paid correctly.

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] Mountain Park Health Center currently spends **approximately 20 hours per week**

[2] Internal NACHC survey data

managing CAD record-keeping under its existing processes. Implementation of a rebate model would require an **additional 40 hours per week**, for a total of approximately **60 hours per week**, to comply with CAD reporting and reconciliation requirements. If Mountain Park were to implement a new CAD module within its current EHR system – an option that is **not yet available** - the **implementation and ongoing annual costs would exceed $70,000**. The inventory module that is currently available cannot support required record-keeping and is not expected to be viable for several years, further increasing reliance on manual processes and significantly increasing administrative burden at the expense of patient-facing services.

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

Mountain Park 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.[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 strain, with nearly half operating with fewer than 90 days of cash on hand, and one in

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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)

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. **Mountain Park is committed to ensuring that no patient goes without life-saving care. Through our pharmacy, we provide affordable access to critical medications, such as treatments for blood clots, that many patients would otherwise be unable to obtain. The 340B program empowers us to remove financial barriers for low-income patients, making essential services accessible even when families must prioritize basic needs like rent and food. By easing the burden of medication costs, we help patients choose their health without having to choose between survival necessities, ultimately saving lives and strengthening our community.**

Conclusion

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

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[5] HRSA FAQ

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

Mountain Park 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 **Maegan Burris, PharmD – Associate Director of Pharmacy at mburris@mphc-az.org.**

Sincerely,

John Swagert, MD
Chief Executive Officer
Mountain Park Heath Center

CORNERSTONE CARE
COMMUNITY HEALTH CENTERS

April 27th, 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 **Cornerstone Care, 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 (CHCs), Cornerstone Care again requests that CHCs be exempted from the pilot program.**

Cornerstone Care is a nonprofit community health center committed to providing high-quality, integrated, and affordable healthcare services to all. We began in 1978 with a simple but powerful belief that everyone deserves access to healthcare. What started in a Victorian house in Greensboro, Pennsylvania, has grown into a trusted network of care serving more than 23,000 patients in 2025 in fourteen sites and three mobile units across Greene, Washington, Fayette, and Allegheny counties.

As the communities we serve have grown and changed, so has Cornerstone Care. We've expanded beyond primary care to offer a full range of services including medical, pediatrics, behavioral health, dental, vision, pharmacy and other specialty care. Ensuring patients and families can find the support they need close to home. Through every stage of growth, our focus has remained the same: meeting people where they are with compassionate, patient-centered care. Today, Cornerstone Care continues to build on foundation, strengthening communities, improving health outcomes, and removing barriers to care—so that every individual has the opportunity to live a healthy life. *The 340B program has been critical to fueling Cornerstone Care's ability to respond to changing needs in our community.* Our analysis indicates that shifting to a rebate model would undermine our ability to continue that responsiveness into the future and would likely force us to curtail existing programs and locations targeting the most underserved patients and communities in our service area.

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 **23,000** 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**: **Cornerstone Care** anticipates needing to add 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, **Cornerstone Care** will face an increased administrative burden to monitor rebate claims and payments. We estimate 2000 hours annually will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **Cornerstone Care** anticipates an additional $255,000.00 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

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

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. **$30,000 – $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 **$30,000** to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves **23,000** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at $1,375,000.00 annually.

The In-House Pharmacy: The Burden of IT Integration

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

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

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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

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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

Cornerstone Care 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

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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.

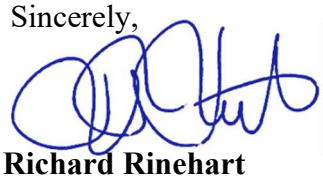
- **Sliding Fee Scale:** A rebate model creates substantial uncertainty about CHCs' ability to apply sliding-fee discounts at the point of sale. By statute and regulation, CHCs are required to offer sliding fee discounts for all required and additional health services within the HRSA-approved scope of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

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

Cornerstone Care 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 Nicole Coneybeer, Pharmacy Program Administrator at nconeybeer@cornerstonecare.com**.**

Sincerely,



Richard Rinehart
Chief Executive Officer

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CORNERSTONE CARE
COMMUNITY HEALTH CENTERS

April 27th, 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 **Cornerstone Care, 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 (CHCs), Cornerstone Care again requests that CHCs be exempted from the pilot program.**

Cornerstone Care is a nonprofit community health center committed to providing high-quality, integrated, and affordable healthcare services to all. We began in 1978 with a simple but powerful belief that everyone deserves access to healthcare. What started in a Victorian house in Greensboro, Pennsylvania, has grown into a trusted network of care serving more than 23,000 patients in 2025 in fourteen sites and three mobile units across Greene, Washington, Fayette, and Allegheny counties.

As the communities we serve have grown and changed, so has Cornerstone Care. We've expanded beyond primary care to offer a full range of services including medical, pediatrics, behavioral health, dental, vision, pharmacy and other specialty care. Ensuring patients and families can find the support they need close to home. Through every stage of growth, our focus has remained the same: meeting people where they are with compassionate, patient-centered care. Today, Cornerstone Care continues to build on foundation, strengthening communities, improving health outcomes, and removing barriers to care—so that every individual has the opportunity to live a healthy life. *The 340B program has been critical to fueling Cornerstone Care's ability to respond to changing needs in our community.* Our analysis indicates that shifting to a rebate model would undermine our ability to continue that responsiveness into the future and would likely force us to curtail existing programs and locations targeting the most underserved patients and communities in our service area.

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 **23,000** 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**: **Cornerstone Care** anticipates needing to add 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, **Cornerstone Care** will face an increased administrative burden to monitor rebate claims and payments. We estimate 2000 hours annually will be required to report 340B rebate claims to a third-party platform.
- **External Vendor Costs**: **Cornerstone Care** anticipates an additional $255,000.00 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

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

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. **$30,000 – $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 **$30,000** to maintain these rebate-tracking features. These permanent, recurring costs diminish our 340B savings.
- **Total Cost:** For our CHC, which serves **23,000** patients, the total projected increase in expenses, including labor, IT, and carrying costs, is estimated at $1,375,000.00 annually.

The In-House Pharmacy: The Burden of IT Integration

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

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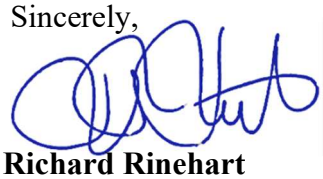

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