Howard Brown Health

July 15, 2026

Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, Maryland 20857
Submitted electronically via www.reginfo.gov

RE: Agency Information Collection Activities: Proposed Collection: Public Comment Request (30-Day Notice); Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW (FR Doc. 2026-11989, 91 Fed. Reg. 35989, June 15, 2026)

Dear Director Britton:

Howard Brown Health is one of the largest health centers in the Midwest, serving more than 40,000 patients across seven clinic locations in Chicago. Howard Brown serves adults and youth in its diverse health and social service delivery system focused around seven major programmatic divisions: primary medical care, behavioral health, research, HIV/STI prevention, youth services, elder services, and community initiatives. As a federally qualified health center (FQHC), Howard Brown provides services regardless of a patient's ability to pay or insurance status. Around 20% of Howard Brown's patients are uninsured and we serve vulnerable patients from all over Illinois including rural and low-income areas.

The 340B program is foundational to our 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 community health center (CHC) pharmacy operations nationwide. Based on information from other CHCs as well as our internal 340B team, the hours and dollars spent complying with a rebate program would be significant. Our focus in this letter is on the practical utility of a rebate program, accuracy of the burden estimate, and minimization of burden of the proposed collection, consistent with 44 U.S.C. 3506(c)(2)(A). Howard Brown appreciates the opportunity to comment on this Information Collection Request (ICR).

I. Summary of Howard Brown's Recommendations

1. Howard Brown strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program since the additional compliance burden would be overwhelming for safety-net providers operating on an average margin

of negative two percent, with one quarter of CHCs operating below negative five percent.
2. Howard Brown calculates the annual burden of complying with the Pilot Program to be between 397 and 847 hours per year, costing between $68,182 and $145, 351 annually.
3. Howard Brown recommends HRSA requires a single uniform set of data fields, formats, and submission timelines across all manufacturers, and prohibits manufacturers from requesting additional data fields from covered entities, unless first approved by HRSA.
4. Howard Brown recommends that covered entities be permitted to submit data through a single neutral-party platform, ensuring consistent processes and eliminating duplicative system interactions.
5. Howard Brown requests that HRSA make all approved manufacturer plans and manufacturer-reported data publicly available in their entirety on OPA's website.
6. Howard Brown recommends HRSA's burden analysis account for covered entities already reporting duplicative data necessary in a 340B rebate pilot program to the existing CMS Medicare Part D 340B Data Repository.

II. HRSA Has Materially Underestimated the Burden on Community Health Centers to Submit Claims Data to Manufacturers

The ICR estimates an average of **5 hours per response** for covered entities reporting claims data to a third-party platform, applied across 15,249 covered entities, filing 52 responses each (792,948 total responses; 3,964,740 total burden hours, costing $523,345,680 annually).[1] HRSA's burden logic[2] assumes that each CHC will complete a 5 hour data reporting cycle weekly for the entire covered entity. This is an underestimate of the true burden estimate from our 340B team (see below), and likely an underestimate for most CHCs across the nation, many of whom do not have dedicated 340B teams.

Howard Brown requests that HRSA address the inconsistencies in the methods used to estimate the burden of the proposed rebate pilot on CHCs. HRSA has asked covered entities to comment on the "the time expended by persons to generate, maintain, retain, disclose, or provide the information requested." This comment request does not appear to include time spent reconciling submissions and tracking rebate status, and addressing errors, denials, or follow-up requests, which CHCs expect to be the most burdensome steps. Additionally, the methodology does not consider the burden of new financial tasks the rebate model would impose on CHCS, such as applying for new lines of credit or changing payment management with wholesalers.

According to the ICR, HRSA developed its burden estimate by applying a "task-based methodology that considers the discrete activities required to complete a reporting cycle, including:

1. Identifying and extracting eligible claims data;

2. Formatting and validating data to meet manufacturer specifications;
3. Submitting the data;
4. Reconciling submissions and tracking rebate status; and
5. Addressing errors, denials, or follow-up requests." [4]

Working within HRSA's five-element methodology, the cumulative per-response time for a CHC greatly exceeds five hours. HRSA's covered entity-level assumption does not accurately reflect how CHCs participate in the 340B Program. In contrast to hospital covered entities whose child sites obtain their 340B-eligibility from the hospital itself, each CHC location is individually 340B eligible and operates as a "parent" site for purposes of purchasing and data reporting. Accordingly, CHCs must separately register contract pharmacies under grantee sites on OPAIS by obtaining separate HINs for each 340B ID (reflecting individual pharmacy relationships), aligning wholesaler accounts to the associated site 340B IDs to ensure the purchases are properly aligned to a specific site, making the necessary designations in the manufacturer chosen platform, submitting utilization data for each designated site (which entails manipulating TPA reports, since most systems do not accommodate this nuance of CHC reporting), reconciling submission data, and troubleshooting any discrepancies. This is all at the individual site or 340B ID level.

II. Howard Brown Burden Estimate

To assist HRSA in developing a more accurate, evidence-based, per-response estimate, Howard Brown's burden for providing requested data is provided below. The burden estimate components reflect HRSA's five task-based activities and capture the entity-specific drivers, including number of impacted claims, number of TPAs, and claim types reported without a TPA, that materially affect burden.

Entity Profile and Burden Drivers

Burden Driver	Entity's Value
Covered entity type (e.g., CHC, CHC-LAL, CHC-638)	CHC
Number of registered 340B IDs	11
Number of unique patients served annually	40,067
Estimated Selected Drug Claims per Reporting Cycle	58
Estimated number of impacted claims per year (selected drugs)	2998
Number of participating manufacturer IT platforms reported to	2
Number of distinct manufacturer data specifications / file formats	13
Number of third-party administrators (TPAs) used	4
Number of contract pharmacy locations	208
Number of entity-owned (in-house) pharmacies	0

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Time per Task-Based Activity (per Reporting Cycle)

Task-Based Activity (per HRSA methodology)	Est. Hours / Cycle (Low End)	Est. Hours / Cycle (High End)
1. Identifying and extracting eligible claims data	0.33 hour	0.33 hour
2. Formatting and validating data to meet manufacturer specifications	1.00 hour	1.00 hour
3. Submitting the data	0.50 hour	0.50 hour
4. Reconciling submissions and tracking rebate status	3.00 hour	3.00 hour
5. Addressing errors, denials, or follow-up requests	2.9 hour	11.53 hour
Subtotal: Estimated hours per response/cycle	7.64 hour	16.29 hour

Annualized Burden Calculation (cycle = week)

Calculation	Entity's Value (Low End)	Entity's Value (High End)
Estimated hours per response/cycle (per week)	7.64 hours	16.29 hours
Number of responses (Task Cycles) per year (HRSA used 52, assuming 1 per week)	312.00 hours	312.00 hours
Estimated ongoing annual burden hours (hours/cycle × responses/year)	397.33 hours	847.00 hours
Responsible staff roles (OPA assigned hourly rate of $132/hour for a pharmacist)	$68,182	$145, 351

CHC Specific Burden Factors

A. Manufacturer Restriction Platform Burden

Based on our experience with the two manufacturer restriction platforms that we are currently using, there are several additional burden factors to consider:

- We have a scheduled meeting every two weeks to review any new notices and related issues from ESP. Email notices are not explicit and require investigation from the platform. Reports provided are not helpful while the user platform is not intuitive, and finally, the manufacturer restrictions are not standardized. Altogether, this requires additional labor to properly utilize the platforms and identify issues.
- In the past, we have experienced loss and interruption of 340B pricing without notice or explanation, as well as significant delay in response on how to resolve

issues. As a result, we now audit manufacturer access using different methods so that we can proactively keep our providers and patients informed about potential interruptions to 340B pricing, and work proactively to regain it.
- The platform support services are limited and generally just direct us to the manufacturer, which is not helpful.
    - The new platform, Truzo, requires users to review all sites and contract pharmacy information to ensure it belongs to CE which is additional work for the CE and with the onus following on the CE to ensure the information is correct.

B. Rebate Model Burden

In order to be properly prepared to implement a rebate model, Howard Brown has hired one additional FTE. Furthermore, we anticipate burden from lack of interoperability between platforms and datasets, repeated data-mapping, and duplicate submission of identical claim data across manufacturer platforms. Additional time-based tasks include:

- Distribution of tasks among covered entity staff (i.e. pharmacist and 340B program pulling records from different areas of the 340B program) and needs creating new workflows/processes, and for initial and ongoing training;
- Challenges anticipated for staff recruitment, training, and retention costs attributable to the new reporting workflow;
- Time to download quarterly price files;
- Time per prescription to manually update 340B price assuming sliding scale or Medicaid;
- Time and resources for IT support for multiple platform and dataset management.
- Time related to reconciling rebates with claims and purchases, and working through denials
- Time to write up and implement new related policy and procedures

III. Burden Associated with the Manufacturer Collections Should Address Downstream Effects on Covered Entities

A. Manufacturer Plan Submissions (Estimated 8 Hours; 11 Respondents)

The ICR estimates 8 hours per manufacturer plan submission across 11 manufacturers, totaling 88 total burden hours.[14] Howard Brown does not opine on the time a manufacturer needs to draft a plan but emphasizes that the content of these plans directly determines covered-entity burden. **Howard Brown requests all approved manufacturer plans be publicly published in their entirety on OPA's website.**

Published manufacturer plans should include complete descriptions of "dispense to rebate" calculation logics to be used by manufacturers' IT platform vendors, including any conditions such as reasonable use timeframes (e.g., rebate requests must be made

within X days of a WAC purchase), to alleviate participation burden. This would also align with the 340B rebate pilot's stated intent to improve program transparency.

B. Manufacturer Monthly Purchase Reports (Estimated 2 Hours; 132 Responses)

The ICR estimates 2 hours per monthly purchase report, 12 reports per manufacturer across 11 manufacturers, totaling 264 total burden hours.[15] **Howard Brown supports robust manufacturer reporting to OPA and the 340B Prime Vendor as a program-integrity measure. We also recommend HRSA make manufacturer-reported performance data publicly available on OPA's website.**

For transparency purposes, we strongly suggest the following metrics be made publicly available, both by drug and by manufacturer:

- Average days from claim submission to rebate payment
- Percentage of rebates paid after 10 days
- Percentage of rebates denied by denial reason
- Aggregate volume of rebates requested and rebates approved.

IV. The Pilot Duplicates Reporting Already Being Requested Under the CMS Medicare Part D 340B Data Repository

HRSA's covered entity burden estimate fails to account for the substantial duplication of effort between the anticipated Rebate Model Pilot and the new Medicare Part D Claims Data 340B Repository (the "340B repository"). The Centers for Medicare and Medicaid Services (CMS) finalized the 340B repository in the Calendar Year 2026 Physician Fee Schedule final rule (90 Fed. Reg. 49266) as part of its implementation of the Medicare Part D Drug Inflation Rebate Program under the Inflation Reduction Act. CMS plans to make the repository available for submissions beginning October 1, 2026, which matches the general timeframe in which this Pilot is expected to operate. Both collections require covered entities to identify, extract, format, and transmit claims-level data on the very same 340B dispenses, yet they are being built as separate, parallel systems with different operators, specifications, and workflows. This is precisely the type of information collection burden that the Paperwork Reduction Act directs agencies to identify and avoid under 44 U.S.C. 3506(c)(3)(A) and 3506(c)(3)(B).

The standardized data elements required for the 340B repository, including date of service, prescription number, fill number, dispensing pharmacy NPI and NDC-11, and the covered entity's 340B ID are all data elements that covered entities would also submit under the Pilot. Although repository participation is currently voluntary, CMS has actively encouraged broad participation, suggesting mandatory participation is likely in the near future. As a result, covered entities will likely be required to maintain two distinct claims data pipelines for the same underlying claims, each with distinct validation rules, submission processes, reconciliation activities, and record-

retention requirements. **HRSA's burden analysis should expressly account for the fact that covered entities are simultaneously standing up the processes and systems needed for the 340B repository, and that the Pilot adds a second, non-interoperable reporting obligation on top of it.**

To mitigate these concerns, Howard Brown recommends that HRSA:

1. Exempt CHCs from the rebate model.
2. Expressly account for the duplicative burden of the 340B repository in its per response and annual burden estimates rather than treating the Pilot reporting as a standalone, first-time data exercise;
3. Coordinate with CMS so that the data elements, formats, and submission timelines for the Pilot align with the 340B repository to the greatest extent possible, ideally allowing a single, standardized covered entity submission to serve both purposes; and
4. Leverage the 340B repository as the source of truth for deduplication wherever feasible, rather than requiring covered entities to construct an additional, parallel reporting channel to each manufacturer's chosen platform.

V. Recommendations to Reduce 340B Rebate Model Burden

The burden of a 340B rebate model is driven primarily by fragmentation in data standards, submission pathways, and platform requirements by drug manufacturers, forcing covered entities to duplicate data mapping, submission, and reconciliation efforts across systems. **To address this burden at its source, Howard Brown recommends HRSA require a single uniform set of data fields, formats, and submission timelines across all manufacturers, and prohibit unapproved additional data requests.** In the absence of standardization, these parallel workflows significantly expand the administrative workload beyond HRSA's assumptions.[5] **Howard Brown further recommends covered entities be permitted to submit data through a single neutral-party platform, ensuring consistent processes and eliminating duplicative system interactions.**

We have outlined several of these burdens in more detail below:

- **Rebate processes mirror existing data submissions to manufacturers.** HRSA is correct that many CHCs are already submitting the majority of the requested data elements (except for BIN & PCN) regularly through the 340B ESP platform. At present, Teva is the only manufacturer included in the proposed rebate pilot that does not request data from CHCs for contract pharmacies. Furthermore, six of the manufacturers also require entity-level claims as a condition of sale to covered entity sites and pharmacies listed as 340B-eligible on OPAIS. We respectfully disagree that program transparency will improve since identical data is already being submitted through 340B ESP. The proposed rebate pilot would replicate existing processes, while

significantly increasing the burden on covered entities through an exponential increase in the volume, complexity, and financial risk, with little evidence it will improve 340B Program operations.

- **Lack of standardization across manufacturer platforms.** Today, covered entities already submit manufacturer-restriction claims data through Second Sight Solutions' 340B ESP and Truzo (Kalderos/Model N) platforms. Under the anticipated rebate model, there is potential for manufacturer participants to use multiple, non-interoperable platforms with different data specifications. As a result, covered entities may need to identify, format, validate, submit, reconcile, and pursue denials for the selected-drug claims across multiple manufacturer platforms, each with its own registration, data specifications, file layouts, and workflows. Variation across manufacturer platforms will require multiple logins, repeated mapping, and duplicate submission of the same underlying claim data. Presently, Truzo's platform is highly manual, requiring individual, customized submissions tailored to each participating manufacturer rather than a single standardized file. Potentially maintaining claims data in parallel across multiple manufacturer IT platforms and tracking rebate status and denials separately in each, multiplies the CHCs burden.
- **TPA automation is not a consistently viable solution.** A significant volume of CHC 340B activity, including clinic-administered drugs and entity-owned pharmacies, occurs outside the TPA workflow that HRSA has assumed is standard. For many CHCs, there is no existing automated TPA "extract-and-submit" pipeline for these claims. Therefore, identification, formatting, and submission for these areas will be predominantly manual. Many existing TPAs' automated data upload processes are designed for hospitals, uploading all data through the parent-site 340B ID. For CHCs utilizing TPAs for entity-owned or contract pharmacies, this means their TPAs' automated data submission processes are not designed for the CHCs grantee site specific data upload needs. If the CHC did use the TPA's hospital-centric automated data upload process, it would create submission errors. On average, CHCs, even with TPAs, must upload data manually to the manufacturer IT platforms. The few TPAs with CHC-specific data upload processes charge CHCs extra for this, reducing 340B savings that could otherwise be used to expand services, increase access to affordable medications, and improve patient care. Many CHCs operate across contract pharmacies, entity-owned pharmacies, and Clinic Administered Drugs (CADs) workflows, and those activities do not reside in a single data stream that can be exported once and sent to manufacturer IT platforms.[6]
- **Clinic-administered drugs (CAD) and paper records.** The majority of CADs are bundled into the CHCs' Prospective Payment System and are not separately billed. For many CHCs, administration logs are maintained on paper or in visit notes rather than in discrete reportable fields within electronic medication administration records (eMAR). Converting these records into the claims-level electronic data elements required for rebate submission is a manual process that imposes additional burden not captured by HRSA's "automated-extract" assumptions.

- **Reconciliation and denial management.** Tasks (4) and (5) of HRSA's methodology[7] are recurring and resource intensive. A time study of current CHC submission processes, conducted by NACHC's 340B Technical Advisors, FQHC 340B Compliance, found that, even at maximum efficiency, an experienced individual requires at least 20 minutes to investigate and resolve a denial or erroneous claim.[8] Because no empirical study currently exists for the proposed 340B rebate model, NACHC estimated reasonable range of claim classification error and claim denial rates using available proxy measures. Improper payment rates reported across CMS programs provide a reasonable lower-bound benchmark for claims requiring staff investigation, appeals, or reconciliation, while reported implementation experience from the Beacon Maximum Fair Price (MFP) rebate program provides an upper-bound benchmark during the launch of a new national rebate infrastructure.
    - Together, these data suggest claim classification rates provide a reasonable range from approximately 10% to 40% while claim denial rates could range from approximately 5% to 20%.[9] Additional evidence from Medicare Advantage further demonstrates the administrative burden associated with claim denials.[10] The study found approximately 17% of prior authorization denials meeting Medicare coverage rules were ultimately overturned upon appeal, illustrating that claim denials frequently require extensive provider review, documentation, and follow-up before payment is received. Even assuming a minimum claim classification error rate of 10% and a claim denial rate of 5%, both of which require CHC staff investigation, the estimated burden for claim error and denial is associated with claim investigation ranges from 4 hours for smaller CHCs to more than 50 hours weekly for larger CHCs. Although Beacon MFP's performance is expected to improve as the program matures, the timeframe for resolving technical, operational, and system integration challenges remains uncertain. Accordingly, the estimates range provide a reasonable basis for estimating the administrative burden CHCs can expect during implementation of the 340B rebate model.
- **Medical-claims data elements differ from pharmacy fields.** Proposed medical claims data elements, including claim line number, claim number, health plan name, health plan ID, and health plan ID qualifier, are not standardized across health care systems and may not be available at the time of claim submission. Assembling and validating these distinct data field sets adds burden beyond a routine pharmacy extract.

In summary, HRSA estimates appear to envision one data upload per week. Operational realities dictate that CHCs will have numerous disparate data sets to address each week. While TPAs do offer the potential to improve efficiency, they also drive added cost.

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VI. Conclusion

Howard Brown strongly urges HRSA to exempt CHCs from any 340B Rebate Model Pilot Program. As discussed in previous comment letters, a rebate model represents a substantial departure from the original intent of the 340B program; to allow safety-net providers to "stretch scarce Federal resources" and provide more comprehensive care. This pilot 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, many 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 upfront 340B discount, making it operationally impossible to provide the sliding fee scale and steeply discounted medications required by law. **We believe that a 340B rebate pilot would cause disproportionate harm to the 52 million patients served by CHCs.**

We appreciate the opportunity to respond to this ICR on the 340B Rebate Model Pilot Program and look forward to continuing to engage with HRSA on this prominent issue. If you have any questions, please contact Tim Wang, Director of Policy and Advocacy, at timothyw@howardbrown.org.

Sincerely,

Travis Gayles, MD, PhD
President and CEO

Howard Brown Health

Supplemental Supporting Data

HRSA Estimated Data Burden & Cost (All CEs)

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Covered Entities reporting claims data to third party platform	15,249	52	792,948	5	3964740
Total	15,260		793,091		3,965,092

Type of Respondent	Instrument	Total Estimated Burden Hours	Hourly Wage Rate	Total Respondent Costs
Pharmacist	Covered Entities reporting claims data to third party platform	3,964,740	$132.00	$523,345,680

HRSA Estimated CHC Data Burden & Cost

Health Center By CE reporting claims data to third party platform	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
CHC	1302	52	67,704	5	338,520
FQHC-LAL	150	52	7,800	5	39,000
Total	1,452		75,504	10	**377,520**

Type of Respondent	Instrument	Total Estimated Burden Hours	Hourly Rate	Total Respondent Costs
Pharmacist	Covered Entities reporting claims data to third party platform	377,520	$132.00	$49,832,640
Estimated Total		3,965,356		$49,832,640

Proposed Pilot Manufacturers Current Data Conditions for Sale at 340B Pricing

Manufacturer	Drug	CHC Contract Pharmacy Data Requirements	CHC Entity Claims Data	Platform

			Requirements (Effective)	
AbbVie	Imbruvica, Linzess, Vraylar	Yes		340B ESP
Amgen	Enbrel, Otezla; Otezla XR	Yes	Yes (6/1/2026)	340B ESP
Astellas	Xtandi	Yes		340B ESP
AstraZeneca	Calquence, Farxiga	Yes	Yes (5/1/2026)	340B ESP
BI	Jardiance, Ofev, Tradjenta	Yes	Yes (7/6/2026)	340B ESP
BMS	Eliquis, Pomalyst	Yes	Yes (5/1/2026)	340B ESP
GSK	Breo Ellipta, Trelegy Ellipta	Yes	Yes (7/1/2026)	340B ESP
Merck	Janumet, Januvia	Yes		340B ESP
Novo Nordisk	Ozempic, Rybelsus, Wegovy	Yes	Yes (4/1/2026)	340B ESP
Pfizer	Ibrance	Yes		340B ESP
Teva	Austedo; Austedo Xr	Hospitals Only		340B ESP