SUPPORTING STATEMENT

340B Rebate Model Pilot Program Application, Implementation, and Evaluation Notice

OMB Control No. 0906-NEW

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Health Resources and Services Administration (HRSA) is submitting this information collection request to the Office of Management and Budget (OMB) for review and approval of the 340B Rebate Model Pilot Program Application, Implementation, and Evaluation Notice. Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, created the 340B Drug Pricing Discount Program in section 340B of the Public Health Service Act (PHSA), which enables 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). Eligible covered entity types are defined in section 340B(a)(4) of the PHS Act, as amended and codified at 42 U.S.C. 256b(a)(4)). Under sections 1927(a)(1) and (a)(5)(A) of the Social Security Act, a manufacturer must enter into an agreement with the Secretary that complies with section 340B of the PHS Act ''[i]n order for payment to be available under section 1903(a) or under part B of title XVIII of the Social Security Act for covered outpatient drugs of a manufacturer." When a manufacturer signs a Pharmaceutical Pricing Agreement (PPA)[1] it agrees that the prices charged for covered outpatient drugs to covered entities will not exceed statutorily defined 340B ceiling prices. 340B ceiling prices are based on quarterly pricing reports that manufacturers must provide to the Secretary through the Centers for Medicare & Medicaid Services (CMS) and are calculated and verified by HRSA.

HRSA's Office of Pharmacy Affairs (OPA), which administers the 340B Program, has received numerous requests from manufacturers related to implementation of proposed rebate models for the 340B Program. The manufacturer proposals varied in scope and how they would be operationalized. Whereas the 340B Program has traditionally operated as a point of sale or up-front discount program (i.e., a covered entity receives the 340B price reduction at the time of purchase), under a rebate model, a covered entity would initially purchase drugs at commercial prices and then, after dispensing the drugs to 340B patients, would submit claims to manufacturers for a cash rebate reflecting the difference between the acquisition cost and the 340B ceiling price. Section 340B(a)(1) of the PHSA states, "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs … purchased by a covered entity … does not exceed [designated ceiling prices.]" This provision in the 340B statute expressly gives the Secretary the authority to choose between rebates or discounts to effectuate the ceiling price. Implementing a rebate model proposal without Secretarial approval would violate section 340B(a)(1) of the PHSA.

OPA intends to issue a Notice Regarding 340B Rebate Model Pilot Program (2026 Notice) to provide a mechanism through which qualifying drug manufacturers may effectuate the 340B ceiling price for certain drugs sold to covered entities. The goal of the 340B Rebate Model Pilot Program (Pilot) will be to address Maximum Fair Price deduplication, and to increase transparency and improve oversight of the 340B Program. HRSA will use data collected through the Pilot to more effectively prevent

[1] See OMB Control No. 0915-0327.

duplicate discounts relative to existing mechanisms and to inform future policy considerations related to program integrity and compliance.

The scope of the anticipated Pilot will be limited to the NDC-11s included on the IRA Drug Price Negotiation Program's Selected Drug List for 2026 and 2027[2] regardless of payer. After assessment of the Pilot, which will include feedback from various stakeholders and data and reports that manufacturers send to HRSA to determine the effectiveness of the Pilot, HRSA may consider expanding the rebate model to other drugs or adopting the model on a more permanent basis.

HRSA developed the information collection request (ICR) to collect Pilot plans from manufacturers. The ICR also addresses the post-implementation collection of monthly sales and other data from manufacturers for HRSA's evaluation of the Pilot and for overall 340B program integrity surveillance and compliance monitoring, as well as the collection of data submitted by covered entities to manufacturers to request a rebate.

2. Purpose and Use of Information Collection

HRSA expects that there will be three types of information collection under the Pilot.

i. HRSA will evaluate and approve plans for participation in a Pilot based on the elements required in the anticipated 2026 Notice. At a minimum, those plans will include information that demonstrates compliance with the following criteria:

- Plan must identify the IT platform to be used for covered entity data submission and include assurances that all costs for IT platform used for data submission, be borne by the manufacturer.
- Plan must allow for 90 calendar days' notice to covered entities and other impacted stakeholders before implementing an approved rebate pilot plan, with instructions for registering for any IT platforms. Changes to approved plans must be submitted to OPA for review and approval prior to implementation, including the mechanism by which covered entities are to acquire drugs included in the rebate model pilot. OPA will determine if the changes can take effect immediately or if they require a notification period to covered entities. Manufacturers will be expected to provide HRSA with a copy of their final approved plan for public posting on HRSA's website to ensure consistency with what HRSA approved.
- Plan must allow for covered entities to order the selected drugs under existing distribution mechanisms (e.g., 340B wholesaler accounts with WAC prices loaded) to ensure purchases flow through existing infrastructure.
- Plan must provide technical assistance/customer service component and ensure that opportunities to engage directly with the manufacturer in good faith regarding questions or concerns are made available to covered entities through both the IT platform and provide a point of contact at the manufacturer.
- Plan must ensure that the IT platform has assurances in place to ensure that the data is secure and protected and collection of the data is limited to the elements listed below that are necessary for providing 340B rebates pursuant to section 340B(a)(1) of the PHSA.
- Plan must ensure that the IT platform has mechanisms in place to protect the privacy and security of PHI or other PII, which is required to be safeguarded in a manner consistent with any applicable federal and state privacy and data security laws, including the Health Insurance Portability and Accountability Act (HIPAA). Plan must describe how any

[2] Medicare Drug Price Negotiation Selected Drug List, available at https://www.cms.gov/files/zip/medicare-drug-price-negotiation-selected-drug-list.zip.

instances an expectation would not apply broadly to all covered entities, and if any, will be communicated to both HRSA and affected covered entities (e.g., covered entities without access to a third-party administrator or rural hospitals or health centers).

- Plan must ensure that covered entities are allowed to submit and report data (as detailed below), at a minimum, up to 45 calendar days from date of dispense, with allowances for extenuating circumstances and other exceptions, including adjustments when a 340B status change occurs on a claim.
- Plan must ensure that the IT platform will have the capacity to receive data from all applicable covered entities and to filter and use only the data required to effectuate the rebate (e.g., if drugs other than a selected drug for initial price applicability year 2026 or 2027 during its price applicability period under the IRA Drug Price Negotiation Program are submitted, the platform will be able to identify and discard unneeded data).
- Plan must ensure that the IT platform will have the capability to provide real-time reconciliation reports for covered entities to be informed of the rebate status of submitted claims.
- Plan must ensure that a quarterly 340B price file for each of the manufacturer's 11-digit NDCs is made available to covered entities, so that covered entities may use the price file in conjunction with pharmacy billing systems to appropriately account for actual acquisition cost (i.e., post rebate price) for Medicaid billing and also to assist with sliding fee scales or cost sharing with patients.
- Plan must require the manufacturer to provide HRSA/OPA with periodic reports consistent with the information outlined in this Notice, in a format and manner specified by HRSA/OPA (instructions forthcoming). Such data should detail data on purchases provided through rebates, information related to claim denials, and other information that may evaluate the effectiveness of the rebate model.
- Plan must include the rebate calculation equal to the wholesale acquisition cost (WAC) less the 340B ceiling price on the day of dispense.
- Plan must specify that rebates are paid at the unit level.
- Plan must include details to accommodate up to 2 unreplenished accumulated packages during the implementation phase. Covered entities shall have a 15-calendar day grace period, in which they may submit rebate requests for up to 2 unreplenished accumulated packages, prior to the Pilot's respective effective dates depending on covered entity type. For example, a covered entity may request a rebate for up to 2 packages of a product dispensed from its neutral inventory on December 16, even though the effective date for the product's participation in the pilot is January 1. The request for such rebates should still be made within 45 days of dispense.
- Plan must ensure that all rebates are paid to the covered entity (or denied, with documentation to support) within 10 calendar days of completed data submission. If the submission is returned for incomplete data, the 10-day clock for rebate payment will restart when all necessary data is submitted.
- Plan must ensure that 340B rebates are not denied based on eligibility or compliance concerns with diversion or Medicaid duplicate discounts, pursuant to sections 340B(a)(5)(A) and (B) of the Public Health Service Act and should provide for rationale and specific documentation for reasons claims are denied (e.g., nonduplication of discounts for a selected drug for which the MFP is required under the IRA Drug Price Negotiation Program or 340B rebate provided to another covered entity on the same claim). Rebates may not be denied for perceived lack of WAC purchases. If a manufacturer has concerns regarding Medicaid duplicate discounts, diversion, eligibility, or insufficient WAC purchases to support rebate requests, the manufacturer must raise those concerns directly with HRSA/OPA or utilize the 340B statutory mechanisms, such as audits and administrative dispute resolution, for addressing such issues. Covered entities are also afforded opportunities to raise concerns with

HRSA/OPA if there are issues with rebate denials through reporting tools sent to 340Bpricing@hrsa.gov.

- Plan must ensure that its implementation of the Pilot is limited to using the 340B rebates model only on sales of selected drugs for the initial price applicability years 2026 or 2027, as included on the IRA Drug Price Negotiation Program's Selected Drug List ("List"), regardless of payer and only during the selected drug's effective dates of negotiated prices. The NDC-11s of the selected drug are included in the Pilot only to the extent they are on the List and the selected drug is in its price applicability period in the IRA Drug Price Negotiation Program.

ii. In addition to the initial manufacturer plan submissions, the Pilot will require submission of monthly reports from participating drug manufacturers, detailing purchase data, information related to claim denials, and other information that may evaluate the effectiveness of the rebate model. This information will be provided to HRSA from manufacturers for all rebate claims submitted by covered entities and submitted through the 340B Prime Vendor. The specific information included in the data instrument, at a minimum, will include:

- Unique Claim Identifier
- Claim submission date
- 340B ID
- 11-digit NDC purchased
- Date of Service (dispense date)
- Quantity
- Unit Wholesale Acquisition Cost (WAC) price
- Unit 340B ceiling price
- Unit Maximum Fair Price (MFP)
- Rebate amount
- Rebate Date Paid
- Rejection Reason (if applicable)

In addition, HRSA will ask manufacturers for:

- Aggregated sales by covered entity type
- Average days from claim submission to rebate payment
- Number of rebates paid after 10 days
- Number of rebates denied with denial reasons
- Number of MFP claims deduplicated as a result of the Pilot

iii. While HRSA will not be collecting data directly from covered entities as part of a Pilot, manufacturers' plans will require that covered entities submit readily available pharmacy and medical claims data on eligible 340B drug purchases to a third-party platform, in order to issue rebates on those dispenses to achieve the 340B ceiling price. The data fields are limited to:

Pharmacy Claims Data Fields	Medical Claims Data Fields
Date of Service	Date of Service
Date Prescribed	Claim Line Number
Rx number	Claim Number
Fill number	Unit of Measure
11 Digit National Drug Code (NDC)	11 Digit National Drug Code (NDC)
Quantity Dispensed	Quantity
Prescriber ID	Rendering Physician ID
Service Provider ID	Service Provider ID
340B ID	340B ID
Rx Bank Identification Number (BIN)	Health Plan Name
Rx Processor Control Number (PCN)	Health Plan ID
	Health Plan ID Qualifier (if available)

3. Use of Improved Information Technology and Burden Reduction

Information technology has been used to reduce burden. All data to be collected is currently readily available information for covered entities and reports may be easily accessed through covered entities' 340B third-party administrators. Manufacturers in the Pilot will establish Information Technology (IT) platforms to accept the data from covered entities and facilitate the electronic transfer of funds for payment of rebates.

4. Efforts to Identify Duplication and Use of Similar Information

The information HRSA expects to collect from manufacturers will not be duplicative of any other information collection. The information that covered entities will provide to manufacturers is similar to information many covered entities currently provide to similar IT platforms to access 340B pricing for drugs dispensed at contract pharmacies. However, some payer information fields (ex. BIN/PCN) are fields not routinely requested for these 340B transactions. Additionally, medical claims data is generated from different sources than from retail pharmacy claims. While certain fields for medical claims use analogous data elements in place of pharmacy-specific fields, these substitutions reflect the structural differences between claim types and do not require covered entities to collect or maintain any new or additional information beyond what is already captured in the ordinary course of billing and claims processing for Medicare, Medicaid and commercial payers.

5. Impact on Small Businesses or Other Small Entities

The collection of information will impact small businesses, including rural health clinics, community health centers and other small safety-net providers that may be eligible for the 340B Program and identify as such. The information to be collected will be limited to the minimum required for the intended purposes of the Pilot, and reflect data that covered entities are already required to maintain

and furnish to other parties. The limited scope will be proportional to the number of dispenses relative to the size of the covered entity. For example, a small health clinic will purchase and dispense a smaller volume of Initial Price Applicability Year (IPAY) 2026 and 2027 and therefore are not expected to generate a sizable number of reportable claims for the Pilot, limiting the burden on these entities.

6. Consequences if Information Collected Less Frequently

Manufacturers will submit plans for approval to participate in the Pilot. Once approved for the Pilot, participating manufacturers will be required to submit monthly purchase data reports to HRSA. If the monthly information is collected less frequently, the evaluation of the Pilot would be ineffective. Monthly reporting allows HRSA to monitor key performance indicators, including rebate payment timeliness, denial rates, claims submission volumes, and potential operational issues, on a more contemporaneous basis. More frequent reporting also enables HRSA to identify emerging trends, assess manufacturer compliance with Pilot requirements, and address potential concerns before they become systemic. If reporting were collected only on a quarterly basis, HRSA's ability to evaluate Pilot performance, conduct timely oversight, and assess program integrity would be significantly delayed. Monthly reporting therefore provides the level of timeliness necessary to support effective Pilot administration while minimizing reporting burden by limiting submissions to standardized data elements already maintained by manufacturers. Covered entities will be expected to collect and submit data routinely to obtain rebates quickly. Manufacturers are required to pay rebates within ten calendar days of receiving a complete claim submission from a covered entity.

7. Circumstances Relating to the Guidelines in 5 CFR 1320. 5

The data will be collected in a manner fully consistent with the guidelines in 5 C.F.R. 1320.5(d)(2).

8. Comments in Response to the Federal Register Notice/Outside Consultation

Section 8A

A 60-day notice was published in the *Federal Register* for this ICR on February 26, 2026 (91 Fed. Reg. 9632).

A 30-day notice was published in the *Federal Register* for this ICR on June 15, 2026 (91 Fed. Reg. 35989).

There were one hundred and eighty (180) timely, non-duplicative public comments on the 60-day *Federal Register* notice. Commenters included hospitals, health systems, community health centers, pharmacies, manufacturers, vendors, and national associations. Comments addressed burden estimates, reporting requirements, operational complexity, and data submission processes.

Below is a summary of key themes raised in the comments that were in-scope of the 60-Day Federal Register Notice and HRSA's response:

I. Burden on Drug Manufacturers to Submit 340B Rebate Pilot Plans

Comment: Multiple commenters reported that HRSA will bear the operational burden of reviewing and reconciling multiple manufacturer rebate plan submissions under the Paperwork Reduction Act (PRA). These commenters noted that HRSA's collection of multiple, distinct manufacturer rebate plans will

create a duplicative and fragmented administrative burden. One commenter stressed that HRSA's approach allows each manufacturer to propose unique rebate processes and data requirements, resulting in disparate systems that HRSA must evaluate, and entities must navigate. Several commenters stated HRSA underestimated the agency's burden analysis for evaluating manufacturer proposals and collecting associated plan documentation and such fragmentation can impair HRSA's capacity to ensure equitable participation and may magnify regulatory and data integrity risks. Another commenter suggested that HRSA will need expanded staff to review manufacturer-submitted plans to ensure accuracy across all rebate plans.

Response: HRSA thanks these commenters for their concerns and suggestions. HRSA previously reviewed the eligible drug manufacturer plans under the 2025 Notice and posted summaries of the plans on the 340B Program's main website in October 2025. The OPA Director is aware of the workload of each OPA staff member and will be able to appropriately ensure the review and reconciliation of manufacturer rebate plan submissions while taking into consideration existing workload demands and priorities. Each approved manufacturer plan will include HRSA-approved standardized data fields for pharmacy and medical claims that covered entities will be required to submit in order to receive rebate payments. This action will result in uniform data elements across all participating manufacturers, which should minimize burden on covered entities.

Comment: A few commenters recommended that HRSA mandate uniform data fields, formats and submission timelines among participating manufacturers to minimize the administrative and financial burden of plan collection associated with covered entities receiving timely and appropriate 340B rebates and ensure fairness across participating manufacturers.

Response: HRSA thanks these commenters for their comment and intends to approve a limited set of uniform data fields across all approved manufacturer plans. HRSA will standardize the submission timelines within the plans by requiring covered entities to submit rebate claims data to manufacturers within 45 calendar days from the date the drug is dispensed, with allowances for extenuating circumstances. Manufacturers will be required to pay rebates (or issue denials with clear rationale and supporting documentation) within 10 calendar days after receiving the covered entity's complete rebate claim submission.

Comment: Multiple commenters urged HRSA to standardize pre-approved data exchange format to minimize variation or to establish a federal clearinghouse for all approved manufacturer plans. They contended that a neutral transaction facilitator would eliminate duplicate discounts, ensure uniform data fields, timelines, and claim reconciliation processes while maintaining upfront 340B pricing.

One commenter requested that HRSA centralize manufacturer plan submissions through a single OPA-administered system. Another commenter recommended that HRSA publicly disclose data templates from manufacturers' plans to minimize PRA burden and to enhance transparency.

Response: HRSA thanks the commenters for sharing these suggestions. To address commenters' concerns related to centralizing manufacturer plan submissions through an OPA administered system, all summaries of the selected manufacturers' plans will be publicly posted on both the OPA's website and the manufacturers' IT platform vendor website. HRSA does not plan to establish a federal clearinghouse for the Pilot. Proposals to establish clearinghouses or similar intermediaries are not specifically authorized

under the 340B statute, and such clearinghouses would not allow for pre-payment adjudication of 340B claims transactions.

II. Burden on Drug Manufacturers to Submit Reports to the Office of Pharmacy Affairs (OPA) for Evaluation

Comment: HRSA did not receive any comments specifically addressing or challenging the burden estimates associated with drug manufacturers submitting regular purchase data reports to OPA. While some commenters provided input on reporting structure and data processes, these comments did not address the estimated burden hours for manufacturer reporting. HRSA will maintain the total estimated annual burden hours for manufacturers for monthly purchase reports.

III. Burden on Covered Entities Submitting Data to Drug Manufacturers to Request a Rebate

Comment: HRSA received several comments regarding the estimated burden on covered entities to comply with the rebate model's data submission requirements. These commenters indicated that the Pilot will have severe administrative, financial, and operational burden on 340B covered entities. According to multiple commenters, HRSA underestimated the time burdens that this Pilot will impose on 340B covered entities. Numerous commentators reported that they will require more internal staff than HRSA estimated to manage claim submissions, mapping, and reconciliations. Several commenters reported that the Pilot will not only require staff expansion but will also require significant data analytics infrastructure updates and a third-party interface to help with automation and validation of claims. These commenters reported HRSA's estimate of five hours per week submission does not reflect the operational realities faced by certain providers that are under-resourced with slim to negative margins.

Commenters provided a wide range of burden estimates. Some commenters indicated that reporting could require significant staff time, including estimates exceeding 15–20 hours per submission or requiring ongoing weekly effort substantially greater than HRSA's estimate. Other commenters, including hospital associations, stated that compliance could require dedicated staff resources, including one or more full-time equivalent (FTE) employees to manage reporting, reconciliation, and compliance activities.

At the same time, other commenters explained that the required data elements reflect information the covered entities already are required to collect and maintain. They reported that some covered entities, especially hospitals, routinely extract and transmit similar claims data to their third-party administrators (TPAs). They reported there will be an increase in hours for initial system configuration and training, but the actual burden for ongoing weekly submissions will be reduced to minutes for most covered entities.

Response: HRSA thanks the commenters for their feedback related to the time, operational, and financial burden for covered entities to submit data to the drug manufacturers to implement the Pilot. HRSA acknowledges that commenters identified potential administrative, operational, and financial impacts associated with data submission. While HRSA recognizes these concerns, HRSA's notes that the Pilot will be designed to minimize reporting burdens. HRSA agrees with commenters that any actual burdens will vary across covered entities depending on size, infrastructure, and the volume of claims being reported. HRSA agrees that adopting the rebate mechanism for the select number of drugs in the Pilot will be a change for covered entities, and notes, however, that covered entities derive substantial financial benefits from the 340B Program, including revenue which is acquired when a covered entity is

reimbursed by a third-party payer for insured patients (e.g., insurance companies reimburse covered entities at full price for drugs that they bought at the 340B discount). Furthermore, participation in the 340B Program is voluntary and has always entailed certain compliance, operational, and other costs. HRSA will design the Pilot with the aim of minimizing administrative costs and burdens attributable to the Pilot. On balance, HRSA believes that the potential significant added benefits of the Pilot—gathering information on the feasibility of statutorily-authorized rebates, addressing 340B-MFP deduplication, improving transparency in 340B transactions, facilitating the prevention of 340B Medicaid duplicate discounts and diversion, and helping to collect data to support decision-making around future rebate models consistent with the 340B statute and Administration priorities, , —outweighed these costs. The potential Pilot design would limit the scope to approximately 5 percent of total 340B sales with the remaining 95 percent of drugs continuing under the upfront 340B discount model, require drug manufacturers to pay rebates within 10 calendar days of claims data submission, and limit data collection to only certain permitted fields.

While the Pilot may introduce incremental or transitional administrative and operational changes, HRSA believes the associated implementation costs are likely to remain low. HRSA agrees with commenters that the data that would be submitted to drug manufacturers reflects information that covered entities already routinely generate, maintain, and transmit to third parties for billing and reimbursement purposes. Since at least 2021, in connection with manufacturer contract pharmacy policies, many covered entities have been submitting claims data to an IT platform owned by the company Second Sight Solutions. Under the Pilot, covered entities are not required to submit any new pharmacy elements beyond what most covered entities are already submitting either as part of the manufacturer contract pharmacy claims submission process or what most covered entities already have readily available through TPAs.

To estimate burden, HRSA applied a task-based methodology that considers the discrete activities described by commenters, including data identification, extraction, validation, submission, reconciliation, and follow-up activities such as denial management. HRSA evaluated the range of estimates provided and normalized these inputs into a per-response burden estimate.

HRSA considered higher estimates provided by some commenters, including those based on full-time equivalent staffing. However, HRSA determined that these estimates reflect total operational workload rather than the incremental time required to complete individual reporting responses.

HRSA recognizes that covered entities vary in size, patient volume, staffing capacity, and technical infrastructure. As a result, actual burden may be lower for some entities and higher for others. The estimate of 5 hours per response reflects a reasonable median burden across this range and is consistent with guidance to estimate typical respondent effort.

Taken together, the comments demonstrate that the reporting process involves multiple steps beyond a simple transmission of data. However, based on the task-based methodology, the limited scope of the Pilot, and the ability of many covered entities to leverage existing systems and processes, HRSA has determined that maintaining the estimated burden of 5 hours per response provides a reasonable and appropriate estimate of the time required for covered entities to comply with the data submission requirements.

Comment: A few commenters noted that the lack of interoperability across manufacturer platforms would require multiple system logins, data-mapping exercises, and repeated submissions of identical claim data. This will result in a substantial increase in time, operational and administrative burden for covered entities.

Response: HRSA appreciates these commenters' concerns. HRSA acknowledges that variation across manufacturer platforms may increase administrative burden for some entities and has incorporated these considerations into the revised burden estimate. HRSA will continue to monitor interoperability during implementation. HRSA expects manufacturers and their designated platform vendors will be responsible for the development, operation, and maintenance of rebate processing platforms, including associated system costs for the rebate processing platform, and HRSA encourages platform designs that promote interoperability, minimize disruption to existing workflows, and reduce administrative burden on covered entities.

Comment: Multiple commenters expressed concerns about manufacturer rebate denials that can lead to further administrative and operational burdens. One commenter urged HRSA to require all denial reasons to receive a review for approval from HRSA. Manufacturers should be required to submit detailed explanations describing how and why a denial would occur, as well as the specific information they would provide to covered entities in support of the denial. Another commenter requested for HRSA to implement a "no-denial" policy. Some commenters requested for HRSA to make clear that manufacturers may not deny rebate claims for drugs dispensed by contract pharmacies on the basis that the arrangements are not approved under the manufacturers' contract pharmacy restrictions.

Response: HRSA thanks these commenters for this input. Covered entities should have access to the real-time rebate status of a claim, so they can easily reconcile claims submitted with rebates paid. If a claim takes longer than 10 days for a rebate to be paid, covered entities and manufacturers should work to resolve the issue. HRSA will not pre-approve manufacturers' denials, but it will monitor denial reasons and trends as part of its routine 340B Program oversight and ongoing Pilot evaluation. Covered entities may report denial issues to 340Bpricing@hrsa.gov. If HRSA observes trends toward a manufacturer not paying rebates within 10 days of data submissions, HRSA reserves the right to revoke the rebate model approval for that manufacturer.

Comment: One commenter urged HRSA to pre-approve any additional data fields that manufacturers may request from covered entities to avoid imposing unauthorized data collection and administrative burden on covered entities.

Response: We appreciate the commenter's concern and agree that no new data fields will be required by a manufacturer unless first approved by HRSA.

Comment: Some commenters raised privacy and data-sharing concerns regarding the transmission of claims-level information to manufacturers and third-party vendors. Commenters questioned whether the requested data could contain protected health information or otherwise create risks of patient re-identification, and they sought additional assurances regarding HIPAA compliance, data security, data retention practices, and limitations on the use of submitted information. Several commenters also recommended that HRSA limit data collection to the minimum information necessary to effectuate rebates and require agency approval before manufacturers request additional data elements.

Response: HRSA considered these concerns in evaluating the complexity of the reporting process and incorporated safeguards in the Pilot, including limiting data collection to specified standardized data fields and requiring manufacturer plans to include protections for patient privacy and data security.

Section 8B

HRSA expects to receive comments from 340B stakeholders throughout the duration of the Pilot, which will assist with evaluating the effectiveness of a rebate approach for a limited set of drugs.

9. Explanation of any Payment/Gift to Respondents

Respondents will not receive any payments or gifts.

10. Assurance of Confidentiality Provided to Respondents

The information collected by HRSA will be kept secure and protected. HRSA and its contractors will comply with the HHS Standard for Encryption of Computing Devices and Information to prevent unauthorized access to government information. Manufacturers will be required to address data security and confidentiality in the plans they initially submit to HRSA for approval to participate in the Pilot.

11. Justification for Sensitive Questions

Sensitive questions (such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private), will not be asked.

12. Estimates of Annualized Hour Burden

Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. In order to estimate the burden to submit plans for participation in the Pilot and produce and submit monthly purchase reports, OPA estimated the number of viable participants in the Pilot based on current eligibility criteria.

The total annual burden hours estimated for this ICR are summarized in the table below, to reflect the number of respondents once the Pilot is fully implemented. This includes 11 manufacturers of IPAY 2026 and IPAY 2027 drugs.

Estimated Burden Hours of Responses

Table 1

Form Name	Number of Respondents*	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
340B Program Rebate Model Pilot Program Plan Submission	11	1	11	8	88
Monthly purchase reports	11	12	132	2	264
Covered Entities reporting claims data to third party platform	15,249**	52	792,948	5	3,964,740
Total	15,260		793,091		3,965,092

* The 11 manufacturers will submit Plans and Monthly Purchase Reports (first two rows, above), while the 15,249 Covered Entities will submit Claims Data (third row, above). Therefore, the total number of respondents is 15,260.
** As of April 1, 2026.

13. Estimated Annualized Burden Costs to Respondents

The following is the burden cost estimate for this information collection request. The annualized burden costs for recipients reflects current Bureau of Labor Statistics data (May 2024), which have doubled to account for overhead costs and benefits.

Type of Respondent	Instrument	Total Estimated Burden Hours	Hourly Wage Rate	Total Respondent Costs
Lawyer	340B Program Rebate Model Pilot Program Plan Submission	88	$176.00/ hour	$15,488
Accountant	Monthly purchase reports	264	$90.00/ hour	$23,760
Pharmacist	Covered Entities reporting claims data to third party platform	3,964,740	$132.00/hour	$523,345,680*
Estimated Total		**3,965,356**	**-**	**$523,384,928**

*****The 340B Program's size and scale, covering more than 15,000 covered entities, means that even modest operational changes produce large aggregate cost figures. That same size and scale is precisely why HRSA must retain the flexibility to implement the program in accordance with its statutory authority and refine program mechanisms in order to address program integrity challenges such as duplicate discounts and diversion. The limited scope of the Pilot affects only approximately 5 percent of total 340B sales while the remaining 95 percent continue under the existing upfront discount model, and the anticipated program integrity benefits are expected to outweigh the compliance costs. Moreover, even accounting for the full estimated burden, participation in the 340B Program remains a substantial financial benefit for covered entities.

14. Annualized Cost to the Federal Government

The total annualized cost to the Federal Government for this information collection is estimated to be $48,256. The GS-14 Pharmacist will also spend approximately 20% of their time annually reviewing incoming plan submissions, sales data and comments on the effectiveness of the Pilot. The hourly salary is $77.65, which is multiplied by 1.5 to account for overhead costs in the table below (bringing the total to $48,256)

Type of Federal Program Staff	Average Total Annual Burden Hours	Hourly Wage Rate*	Total Costs
Pharmacist GS-14, Step 5 average	416	$116	$48,256

*Wage rate is based on 2025 OPM Pay Schedule for Washington DC area Please note that this figure has been multiplied 1.5 times to account for benefits to Federal government workers.

15. Explanation for Program Changes or Adjustments

This is the initial clearance request; therefore, there are no changes or adjustments.

16. Plans for Tabulation, Publication, and Project Time Schedule Time Schedule

A manufacturer with an approved plan to participate in the Pilot will be identified on the OPA website. An evaluation of the Pilot may be displayed as a Program Update on the OPA website upon completion of the Pilot.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption is requested. The OMB number and Expiration date will be displayed on every page of every form/instrument.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.