funds was offered to these recipients with the intent to offer the remaining 19 PMHCA award recipients with the same level of funding through annual supplements in FY 2024 and FY 2025.

HRSA will offer supplemental funding for all 29 PMHCA U4A current award recipients in a manner that ensures all 29 award recipients are offered the same total amount of funding over a 3-year timeframe. If PMHCA current award recipients decline supplemental funding, that declined funding will be distributed among remaining recipients as allowable. The intended date of supplemental funding is September 30, 2025, to September 29, 2026, which falls within the current period of performance. In FY 2025, annual appropriation funds for PMHCA award recipients will be tracked separately from concurrent PMHCA awards.

PMHCA program award recipients will continue to expand the reach and capacity of PMHCA programs started in FY 2022 to provide training and tele-consult support to pediatric primary care providers and providers in other settings, including emergency departments and educational agencies and schools. The above activities are within the original scope of the PMHCA program (HRSA–22–121, and HRSA–21–122).

Thomas J. Engels,

Administrator.

[FR Doc. 2025–15033 Filed 8–6–25; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

340B Program Notice: Application Process for the 340B Rebate Model Pilot Program; Correction

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Announcement of application process for the 340B Rebate Model Pilot Program and request for public comment; Correction.

SUMMARY: The U.S. Department of Health and Human Services (HHS) Health Resources and Service Administration (HRSA), Office of Pharmacy Affairs (OPA), which administers the 340B Drug Pricing Program (340B Program), is issuing this Notice to announce the availability of a 340B Rebate Model Pilot Program as a voluntary mechanism for qualifying drug manufacturers to effectuate the 340B ceiling price on select drugs to all covered entities, and to collect comments on the structure and application process of the 340B Rebate Model Pilot Program, as outlined in this Notice. OPA will consider comments received but is under no obligation to respond to or act on the comments. This Notice is effective immediately as published, unless revised by a future notice. OPA reserves the right to issue revisions or addenda to this Notice at a later date (including, but not limited to, revisions or addenda informed by public comment).

DATES: Submit comments no later than September 8, 2025.

ADDRESSES: Electronic comments should be submitted *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions on the website for submitting comments. Include the HHS Docket No. HRSA–2025–14619 in your comments. All comments received will be posted without change to *https://www.regulations.gov.* Please do not include any personally identifiable or confidential business information you do not want publicly disclosed.

FOR FURTHER INFORMATION CONTACT: Chantelle Britton, Director, Office of Pharmacy Affairs, HRSA, 5600 Fishers Lane, Mail Stop 14W52, Rockville, MD 20857; email: *340Bpricing@hrsa.gov;* telephone 301–594–4353.

SUPPLEMENTARY INFORMATION: OPA has received inquiries from manufacturers related to different proposed rebate models for the 340B Program, primarily to address 340B and Maximum Fair Price (MFP) deduplication,[1] but also to facilitate other aims such as the prevention of 340B Medicaid duplicate discounts and diversion.

A ''rebate'' for purposes of this pilot program, means a reimbursement made from the manufacturer to the covered entity in the amount of the standard acquisition cost (*i.e.,* wholesale acquisition cost) of a covered outpatient drug less the statutory 340B ceiling price as defined at section 340B(a)(1) of the Public Health Service Act (PHSA).

Whereas the 340B Program has traditionally operated as an upfront discount program (*i.e.,* a covered entity purchases a covered outpatient drug at the discounted 340B price), under a rebate model, a covered entity would pay for the drug at a higher price upfront and then later receive a post-purchase rebate that reflects the difference between the higher initial price and the 340B 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 prices].'' As the Department has previously informed stakeholders, implementing a rebate model without Secretarial approval would violate section 340B(a)(1) of the PHSA.

Due to the significant amount of feedback received from (or on behalf of) manufacturers and covered entities regarding implementation of rebate models, and in light of the fact that rebate models could fundamentally shift how the 340B Program has operated for over 30 years, OPA is inviting certain drug manufacturers, that meet the criteria described below, to apply for participation in a voluntary 340B Rebate Model Pilot Program for a minimum of 1 year. OPA is introducing this pilot program to test the rebate model on a select group of drugs (as described below) in a methodical and thoughtful approach to ensure a fair and transparent 340B rebate model process for all stakeholders involved. OPA is also implementing this pilot to better understand the merits and shortcomings of the rebate model from stakeholders' perspectives, and to inform OPA consideration of any future 340B rebate models consistent with the 340B statute and the Administration's goals.

The scope of this voluntary 340B Rebate Model Pilot Program will be limited to the NDC–11s included on the CMS Medicare Drug Price Negotiation Selected Drug List,[2] regardless of payer.

[1] As stated in Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2026, ''in accordance with section 1193(d)(1) of the Social Security Act, the Primary Manufacturer of a selected drug is not required to provide access to the Maximum Fair Price (MFP) for a selected drug to MFP-eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the (Public Health Service (PHS)) Act if the selected drug is subject to an agreement described in section 340B(a)(1) of the PHSA and the 340B ceiling price (defined in section 340B(a)(1) of the PHS Act is lower than the MFP for such selected drug. Under section 1193(d)(2) of the Social Security Act, the Primary Manufacturer is required to provide access to the MFP to 340B covered entities in a deduplicated amount to the 340B ceiling price if the MFP for the selected drug is lower than the 340B ceiling price for the selected drug.''

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

The first call to submit plans for OPA review is for the manufacturers with Medicare Drug Price Negotiation Program (MDPNP) Agreements with CMS for initial price applicability year 2026.[3] Manufacturer plans for participation in the 340B Rebate Model Pilot Program should be submitted to *340BPricing@hrsa.gov* no later than September 15, 2025. Approvals will be made by October 15, 2025, for a January 1, 2026, effective date. Manufacturers may not implement plans without first receiving approval in accordance with section 340B(a)(1) of the PHSA. OPA may announce a call for plans from manufacturers with MDPNP Agreements for other applicability years, at a later time.

After assessment of the pilot, which will include OPA's evaluation of data and reports received from the participating manufacturers on the effectiveness of the model and covered entity and other stakeholder feedback, OPA may consider expanding the rebate pilot to other drugs purchased under the 340B Program. Additional information about manufacturer reporting and stakeholder feedback opportunities will be provided in the future.

Manufacturer plans for the 340B Rebate Model Pilot Program should include the criteria outlined below. Manufacturer plans that exceed or go beyond these criteria should include detailed justification and will be subject to additional review by OPA prior to implementation. OPA will review submitted plans and notify manufacturers if they are approved to participate in the 340B Rebate Model Pilot Program. Submitted plans should not exceed 1,000 words and should address all of the criteria below. OPA reserves the right to revoke approval of a manufacturer plan at any time if a manufacturer is not in compliance with the criteria outlined in the ''Rebate Model Pilot Program Criteria'' below.

OPA is seeking public comment on all aspects of this Notice and the 340B Rebate Model Pilot Program. Specifically, commenters are encouraged to include supporting data and sources underpinning any factual claims. Commenters should also consider the following questions when providing comment on this Notice and the Pilot Program:

- Are there any additional flexibilities to maximize efficiency and efficacy for participating manufacturers that should be considered in the pilot design?
- Are there any additional safeguards to mitigate adverse, unintended impacts for covered entities that should be considered in the pilot design?
- Are there any additional data or reporting elements that should be required to improve implementation and evaluation of the pilot?
- Are there any potential implementation issues not yet sufficiently accounted for in the pilot design (*e.g.,* logistical or administrative burdens)?

Rebate Model Pilot Program Criteria

General Requirements

1. Plan should include assurances that all costs for data submission through an Information Technology (IT) platform be borne by the manufacturer and no additional administrative costs of running the rebate model shall be passed onto the covered entities.

2. Plan should allow for 60 calendar days' notice to covered entities and other impacted stakeholders before implementation of a rebate model, with instructions for registering for any IT platforms.

3. Plan should allow for covered entities to order the selected drugs under existing distribution mechanisms (*e.g.,* 340B wholesaler accounts with pre-rebate prices loaded) to ensure purchases flow through existing infrastructure.

4. Plan should provide a technical assistance/customer service component and ensure that opportunities to engage with the manufacturer in good faith regarding questions or concerns are made available to covered entities through both the IT platform and a point of contact at the manufacturer.

5. Plan should 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.

6. Plan should ensure that the IT platform has mechanisms in place to protect patient identifying information, which is required to be maintained in a manner consistent with the Health Insurance Portability and Accountability Act of 1996 and any other applicable privacy and data security laws.

Reporting Requirements

7. Plan should ensure that covered entities are allowed to submit and report data (as detailed below) for 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.

8. Plan should ensure that the IT platform will have the capacity to receive data that will filter and use only the data required to effectuate the rebate (*e.g.,* if drugs other than selected drugs under the MDPNP are submitted, the platform will be able to identify and discard unneeded data).

9. Plan should 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.

10. A manufacturer should agree to provide OPA with periodic reports consistent with the information outlined in this Notice, in a format and manner specified by OPA (instructions forthcoming). Such reports should detail data on purchases provided through rebates, information related to claim delays and denials, and other information that may evaluate the effectiveness of the rebate model.

Rebates

11. Plan should specify if rebates are paid at the package level, or at the unit level.

12. Plan should ensure that all rebates are paid to the covered entity (or denied, with documentation in support) within 10 calendar days of data submission.

13. Plan should ensure that 340B rebates are not denied based on 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.,* deduplication for MFP or 340B rebate provided to another covered entity on the same claim). If a manufacturer has concerns regarding diversion or Medicaid duplicate discounts, the manufacturer should raise those concerns directly with OPA or utilize the 340B statutory mechanisms, such as audits and administrative dispute resolution (ADR), for addressing such issues. Covered entities are also afforded opportunities to raise concerns with OPA if there are issues with rebate delays and denials, or any other administrative or logistical issues emerging through implementation of the rebate model.

14. Plan should ensure that 340B rebates are only paid on sales of drugs selected under the MDPNP, regardless of payer.

[3] The Fact Sheet for Negotiated Prices for Applicability Year 2026 includes the list of Primary Manufacturers with selected drugs, available at *https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf.*

Data

15. All data requested as part of the Plan should be limited to only the following readily available pharmacy claim fields:

a. Date of Service
b. Date Prescribed
c. RX number
d. Fill Number
e. 11 Digit National Drug Code (NDC)
f. Quantity Dispensed
g. Prescriber ID
h. Service Provider ID
i. 340B ID
j. Rx Bank Identification Number (BIN)
k. Rx Processor Control Number (PCN)

Thomas J. Engels,

Administrator.

[FR Doc. 2025–14998 Filed 8–6–25; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB No. 0915–0327—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than October 6, 2025.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information collection request title for reference.

Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB No. 0915–0327—Revision.

Abstract: Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service (PHS) Act, which instructs HHS to enter into a Pharmaceutical Pricing Agreement (PPA) with manufacturers of covered outpatient drugs. Manufacturers are also required by section 1927(a)(5)(A) of the Social Security Act to enter into agreements with the Secretary of HHS (Secretary) that comply with section 340B of the PHS Act if they participate in the Medicaid Drug Rebate Program. When a drug manufacturer signs a PPA, it is opting into the 340B Drug Pricing Program (340B Program), and it agrees to the statutory requirement that prices charged for covered outpatient drugs to covered entities will not exceed statutorily defined 340B ceiling prices. When an eligible covered entity voluntarily decides to enroll and participate in the 340B Program, it accepts responsibility for ensuring compliance with all provisions of the 340B Program, including all associated costs. Covered entities that choose to participate in the 340B Program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) of the PHS Act prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) of the PHS Act prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the covered entity.

Need and Proposed Use of the Information: To ensure the ongoing responsibility to administer the 340B Program while maintaining efficiency, transparency, and integrity, HRSA developed a process of registration for covered entities to enable it to address specific statutory mandates. Specifically, section 340B(a)(9) of the PHS Act requires HRSA to notify manufacturers of the identities of covered entities and of their status pertaining to certification and annual recertification in the 340B Program pursuant to section 340B(a)(7) and the establishment of a mechanism to prevent duplicate discounts as outlined at section 340B(a)(5)(A)(ii) of the PHS Act.

In addition, section 340B(a)(1) of the PHS Act requires each participating manufacturer to enter into an agreement with the Secretary to offer covered outpatient drugs to 340B covered entities.

Finally, section 340B(d)(1)(B)(i) of the PHS Act requires the development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities.

HRSA is requesting approval for existing information collections. HRSA notes that the previously approved collections are mostly unchanged, except some forms have been revised to increase program efficiency and integrity. Below are descriptions of each form and any resulting revisions that are captured in both the registration and pricing component of the 340B Office of Pharmacy Affairs Information System (OPAIS).

Enrollment/Registration/Recertification

To enroll and certify the eligibility of federally funded grantees and other safety net health care providers, HRSA requires covered entities to submit administrative information (*e.g.,* shipping and billing arrangements, Medicaid participation), certifying information (*e.g.,* Medicare Cost Report information, documentation supporting the hospital's selected classification), and attestation from appropriate grantee-level or entity-level authorizing officials and primary contacts. To maintain accurate records, HRSA requests entities submit modifications to any administrative information that they submitted when initially enrolling into the Program. Covered entities participating in the 340B Program have an ongoing responsibility to immediately notify HRSA in the event of any change in eligibility for the 340B Program. Covered entities must comply with the statutory mandates of the Program and, at least annually, they need to certify the accuracy of the information provided and continued maintenance of their eligibility.

Registration and annual recertification information is entered into the 340B OPAIS by covered entities and verified by HRSA staff according to 340B Program requirements. The following forms are being revised:

(1) 340B Registration, Recertification and Change Requests for Shipping Address: HRSA is providing additional clarification for covered entities to complete the shipping address section in 340B OPAIS to improve transparency and assist in determining the exact shipping address location and relationship to the covered entity. The