and associated materials (see **ADDRESSES**).

CMS–10680—Electronic Visit Verification Compliance Survey

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

**Information Collections**

1. *Title of Information Collection:* Electronic Visit Verification Compliance Survey; *Type of Information Collection Request:* Extension without change of a currently approved collection; *Use:* The web-based survey will allow states to self-report their progress in implementing electronic visit verification (EVV) for personal care services (PCS) and home health care services (HHCS), as required by section 1903(l) of the Social Security Act. CMS will use the survey data to assess states' compliance with section 1903(l) of the Act and levy Federal Medical Assistance Percentage (FMAP) reductions where necessary as required by 1903(l) of the Act.

The survey will be disseminated to all 51 state Medicaid agencies (including the District of Columbia) and the Medicaid agencies of five US territories. States will be required to complete the survey in order to demonstrate that they are complaint with Section 1903(l) of the Act by reporting on their EVV implementation status for PCS provided under sections 1905(a)(24), 1915(c), 1915(i), 1915(j), 1915(k), and Section 1115 of the Act; and HHCS provided under 1905(a)(7) of the Act or under a demonstration project or waiver (*e.g.,* 1915(c) or 1115 of the Act).

The survey will be a live form, meaning states will have the ability to update their 1903(l) compliance status on a continuous basis. As FMAP reductions are assigned quarterly per 1903(l) of the Act, states who are not in compliance will be asked to review their survey information on a quarterly basis to ensure it is up-to-date and to update their survey responses as needed until they come into compliance. *Form Number:* CMS–10680 (OMB control number: 0938–1360); *Frequency:* On occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Number of Responses:* 336; *Total Annual Hours:* 504. (For questions regarding this collection contact Ryan Shannahan at 410–786–0295.)

**William N. Parham, III,**

*Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2025–14524 Filed 7–31–25; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

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

**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.

**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 2, 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–_____ 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

[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.''

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.

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

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

[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*.

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.

*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. 2025–14619 Filed 7–31–25; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–0361.

**Proposed Project: 988 Suicide and Crisis Lifeline and Crisis Services Program Evaluation—New Package**

The Substance Abuse and Mental Health Services Administration (SAMHSA) 988 & Behavioral Health Crisis Coordinating Office (BHCCO) is requesting clearance for the new data collection associated with the evaluation of the SAMHSA 988 Suicide and Crisis Lifeline and Crisis Services Program Evaluation (988 Suicide and Crisis Lifeline Evaluation). The collection of this information is critical to successfully oversee the operational response and quality of service through the 988 Suicide and Crisis Lifeline to ensure connections to care for individuals in suicidal crisis or emotional distress contacting in for 988 phone, chat, and text support for connecting local, state/territory, and national outcomes and monitoring contractual obligations for current and future 988 grant programs.

In 2020, Congress designated the three-digit number 9–8–8 for the Suicide and Crisis Lifeline, and the Suicide and Crisis Lifeline transitioned to the 3-digit number in July 2022. As a part of the federal government's commitment to addressing the mental health and opioid crises in America, unprecedented federal resources have been invested to expand crisis centers in support of 988. Since its launch in July 2022, the 988 Suicide & Crisis Lifeline has answered over 10 million contacts (SAMHSA, 2024). Progress recognized in 2023 continues in all areas including crisis line features, crisis center supports, and funding. In FY2024, nearly $500 million was allocated for new funding opportunities to support the 988 Lifeline Administrator and other grantees at the state, territorial, Tribal, and center levels, as part of the commitment to strengthen crisis care nationally. In Section 1103(a)(2)(B) of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328), Congress called for enhanced program evaluation, including performance measures to assess program response and improve readiness and performance of the service, including review of each contact to ensure timely connection of service and quality provision in line with evidence-based care. To meet the standards and requirements set forth in the statute, ongoing communication of key outcomes within this OMB request must be received and reviewed to ensure connection and quality of care through the 988 Suicide and Crisis Lifeline.

The information collected will be used by SAMHSA to conduct an evaluation of the 988 Suicide and Crisis Lifeline and Crisis Services, to ensure individuals in suicidal, mental health, and/or substance use crisis can contact 988 Suicide and Crisis Lifeline and are connected to crisis centers providing evidence-based care and receiving critical resource referral and linkage, including opportunities for mobile crisis support, crisis receiving and stabilizing facilities, peer respite centers, and withdrawal management services. The purpose of the 988 Lifeline and Crisis Services Program Evaluation is to assess the implementation and expansion of the 988 Lifeline in the U.S. The evaluation will provide SAMHSA, grantees, and other interested parties with the information needed to strengthen the Behavioral Health Crisis Services Continuum (BHCSC) for all people in crisis. The evaluation utilizes multiple studies to conduct the evaluation of the 988 Lifeline and Crisis Services across a 5-year period. The 988 Lifeline and Crisis Services Program Evaluation includes three levels: system-level, client-level, and impact. Embedded within each of the three evaluation levels are inquiries into differences in utilization of 988 Lifeline and BHCSC services and outcomes.

The System-level Evaluation examines the characteristics, collaborations, and structures of the crisis services infrastructure within states, territories, and Tribal jurisdictions that support improved client outcomes. The Systems-level Evaluation includes two studies: the System Composition and Collaboration Study and the System-Level Service Utilization Study. The System Composition and Collaboration Study examines the structure of the 988 Lifeline and the BHCSC at the national, state, territory, and Tribal levels, and the extent to which crisis service agencies work together. The System-level Service Utilization Study