

law enforcement matter. It has not scheduled any adjudicative items for discussion at this meeting.

#### Record of Commission's Vote

On July 29, 2025, Commissioners Ferguson, Holyoak, and Meador were recorded as voting in the affirmative to close this meeting for a non-adjudicative matter. By these votes, the Commission approved withholding from this meeting notice such information as is exempt from disclosure under 5 U.S.C. 552b(c).

#### Commission's Explanation of Closing

The Commission has determined that the meeting will be closed to the public pursuant to 5 U.S.C. 552b(c)(3), (4), (7)(A), and (10), and 552b(d)(4) and that the public interest does not require the meeting to be open to the public.

#### General Counsel Certification

The General Counsel has certified that the meeting may properly be closed for the above agenda matter, citing the following relevant exemptive provisions: 5 U.S.C. 552b(c)(3), (4), (7)(A), and (10).

#### Expected Attendees

Commission employees and consultants and the stenographer or court reporter preparing any necessary verbatim transcript may attend the closed meeting to the extent permitted under Rule 4.15(c)(1) of the Commission's Rules of Practice.

By direction of the Commission.

Joel Christie,

*Acting Secretary.*

[FR Doc. 2025-14648 Filed 7-30-25; 4:15 pm]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10846]

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

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice, correction.

**SUMMARY:** On June 20, 2025, CMS published a notice in the **Federal Register** that sought comment on a collection of information concerning CMS-10846 (OMB control number 0938-1451) entitled "Medicare Part D Manufacturer Discount Program." The point of contact information is

incorrectly listed in the last sentence within the last paragraph of the notice. This document corrects the error.

**FOR FURTHER INFORMATION CONTACT:** William N. Parham, III, (410) 786-4669.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the June 20, 2025, issue of the **Federal Register** (90 FR 26301), we published a Paperwork Reduction Act notice requesting a 60-day public comment period for the information collection request identified under CMS-10846, OMB control number 0938-1451, and titled "Medicare Part D Manufacturer Discount Program."

##### II. Explanation of Error

In the June 20, 2025 (90 FR 26301) notice, the point of contact information is incorrect. The incorrect language is located at the bottom of the left column on page 26302, "contact Maricruz Bonfante at (410-786-5086)" All of the other information contained in the June 20, 2025, notice is correct and remains unchanged. The related public comment period remains in effect and ends August 19, 2025.

##### III. Correction of Error

In FR Doc. 2025-11324 of June 20, 2025 (90 FR 26301), page 26302, the language at the bottom of the left column "[contact Maricruz Bonfante at (410-786-5086)]", is corrected to read as follows: (contact Beckie Peyton at (410) 786-1572 or [beckie.peyton@cms.hhs.gov](mailto:beckie.peyton@cms.hhs.gov))

William N. Parham, III,

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

[FR Doc. 2025-14525 Filed 7-31-25; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10680]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect

information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by September 30, 2025.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786-4669.

#### SUPPLEMENTARY INFORMATION:

##### Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement

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 compliant 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](mailto: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,<sup>1</sup> 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

<sup>1</sup> 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.”