Appendix A: 340B Repository Data Elements Collection Instructions

In accordance with Section 1860D-14B of the Social Security Act ("the Act"), for each 12-month applicable period, starting with the applicable period beginning October 1, 2022, a manufacturer of a Part D rebatable drug will owe a rebate, to be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund, if the annual manufacturer price exceeds the inflation-adjusted payment amount. As defined in Section 1860D-14B(g)(1) of the Act, a "Part D rebatable drug" means, with respect to an applicable period, a drug or biological described at section 1860D-14B(g)(1)(C)[1] that is a covered Part D drug as defined under section 1860D-2(e). A drug approved under an abbreviated new drug application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) is only subject to the Part D drug inflation rebate if it meets certain sole source criteria described at sections 1860D-14B(g)(1)(C)(ii)(I)–(IV) of the Act. As described in section 1860D-14B(g)(1)(B), the definition of a Part D rebatable drug does not include a drug or biological if, as determined by the Secretary, the "average annual total cost" for such drug or biological under Part D for a year per individual that uses such a drug or biological is less than the applicable threshold.
Section 1860D-14B(b)(1)(B) of the Act requires that beginning with plan year 2026, CMS shall exclude from the total number of units for a Part D rebatable drug, with respect to an applicable period, those units for which a manufacturer provides a discount under the 340B Program. Because this requirement starts after the first quarter of the applicable period that begins on October 1, 2025, the exclusion of 340B units will only apply for the last three quarters of this applicable period. That is, CMS will exclude 340B units starting on January 1, 2026.

As described in the CY 2026 Physician Fee Schedule (PFS) proposed rule, CMS proposed to establish a repository (hereinafter, "340B repository") and allow 340B covered entities (hereinafter "covered entities") to optionally submit to the 340B repository data elements from all claims with dates of service during the relevant period which the covered entity determined utilized a drug for which the manufacturer provides a discount under the 340B program for all covered Part D drugs billed to Medicare Part D (hereinafter "Part D 340B claims"). The 340B repository would allow covered entities to submit this data to CMS (or a contractor), rather than through claims that dispensers submit to Part D plan sponsors. CMS would consider all data elements received by the 340B repository to be associated with Part D 340B claims; that is, the 340B repository would not further verify the 340B status of a claim but rather would serve solely to store these data. Under this process, CMS intends to require a certification from covered entities that choose to submit data to the 340B repository that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the covered entities' knowledge, their submission includes all Part D 340B claims for the covered entity at

[1] A drug or biological described in section 1860D-14B(g)(1)(C) is a drug or biological that, as of the first day of the applicable period involved is: (1) a drug approved under a New Drug Application (NDA) under section 505(c) of the FD&C Act; (2) a drug approved under an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act that meets certain criteria in section 1860D-14B(g)(1)(C)(ii); or (3) a biological licensed under section 351 of the Public Health Service (PHS) Act.

the time of submission with dates of service during the relevant period. If we determine that the data reported to the repository is usable and reliable and, in the future, propose and finalize a policy to use such data to exclude 340B units from rebate calculations, then units associated with PDE transactions that match to data elements stored in the 340B repository would be considered those for which the manufacturer provided a discount under the 340B Program. For data submitted during the testing period beginning in 2026, CMS would assess the usability of this data to remove 340B units from the total number of units used to calculate the total rebate amount in the future.

General Instructions

Overview

The purpose of this Information Collection Request (ICR) is for CMS to receive, via submission by covered entities that choose to submit data to the 340B repository, data elements from all Part D 340B claims with dates of service during the relevant period. CMS would assess the suitability of the data collected and the information collection process to obtain data to remove 340B units from the Part D drug inflation rebate calculation in future program years. The 340B repository would allow covered entities that choose to participate to submit this data directly to CMS (or a contractor) using the proposed collection form. CMS has proposed in the CY 2026 PFS proposed rule to allow covered entities participating in the 340B repository during the testing period beginning in 2026 to voluntarily submit the fields specified by CMS on a quarterly basis to the 340B repository by a date announced in the future, which would be no sooner than 3 months after the date on which the 340B repository is available to receive submissions from covered entities. CMS proposed that covered entities that choose to submit data would report data elements related to all Part D 340B claims with dates of service on or after January 1, 2026. At a point in the future, if the CY 2026 PFS proposed rule is finalized, CMS would provide a deadline that CMS believes would be necessary to allow sufficient time for covered entities to gather, validate, and submit the specified data to the 340B repository. CMS would provide the submission deadline(s) once the Medicare Prescription Drug Inflation Rebate ICR is finalized. During the rest of the testing period, CMS anticipates that covered entities will be expected to report data within 3 months of the end of a given calendar quarter. For example, for claims with dates of service between October 1, 2026, through December 31, 2026, covered entities would be allowed to submit data elements from Part D 340B claims to CMS no later than March 31, 2027. The 340B units identified from these quarterly submissions would be used to assess the suitability of the data for future use to remove 340B units from the total number of units and the total rebate amount specified in the Preliminary Rebate Report and Rebate Report detailed at § 428.401(b) and (c), respectively. CMS also proposed that covered entities that choose to submit data to the 340B repository during the testing period provide information identifying the covered entity, such as the covered entity's 340B ID and name as designated in the 340B OPAIS

database,[2] when submitting claim information to the 340B repository. In addition to this identifying information, CMS proposed that covered entities that choose to submit data to the 340B repository during the testing period beginning in 2026 submit the following data elements from Part D claims for covered Part D drugs that are purchased under the 340B Program and dispensed to Medicare Part D beneficiaries: (1) Date of Service (that is, the date the prescription was filled by the pharmacy); (2) Prescription or Service Reference Number; (3) Fill Number (that is, the code indicating whether the prescription is an original or a refill; if a refill, the code indicates the refill number); (4) Dispensing Pharmacy NPI; and (5) NDC-11. CMS proposed to use these data elements to match claims to PDE transactions and perform further analyses to assess the suitability of the data for future use in removing 340B units from Part D drug inflation rebate calculations.

Submission Method

- In the CY 2026 PFS proposed rule, CMS proposed to allow covered entities to begin submitting the fields specified by CMS to the 340B repository beginning in 2026 for Part D 340B claims to begin testing the usability of the 340B repository. This testing period would provide data for CMS to conduct usability testing for the 340B repository and allow covered entities to develop and test processes for submitting data elements to the 340B repository. CMS would not use the data submitted for user testing to remove units from Part D inflation rebates unless and until a policy to do so is proposed and finalized. Many covered entities are providers and suppliers regulated by CMS under Title XVIII of the Social Security Act, including hospitals receiving Disproportionate Share Hospital (DSH) payments, Critical Access Hospitals (CAHs) and Federally Qualified Health Centers (FQHCs). CMS will address the possibility of mandatory reporting of data elements by covered entities in the 340B repository in future years in future rulemaking and recommends that covered entities take advantage of the testing period beginning in 2026 to prepare for future policy development related to 340B repository reporting.
- Covered entities that choose to submit data to the 340B repository during the testing period would submit Medicare Part D 340B claims data to the 340B repository on a quarterly basis using the provided collection form. CMS would receive and intake the claims data provided from the covered entities as populated on the collection form. CMS would match submitted claims data from covered entities to PDE transactions stored in the Drug Data Processing System (DDPS). Units associated with PDE transactions that match to data elements stored in the 340B repository would be considered those for which the manufacturer provided a discount under the 340B Program and therefore would be assessed for suitability for future use in removing from the total number of units used to calculate the total rebate amount.

[2] The 340B Office of Pharmacy Affairs Information System (340B OPAIS) database is accessed at https://340bopais.hrsa.gov/home.

- In the CY 2026 PFS proposed rule, CMS proposed for covered entities that choose to submit the fields specified to the 340B repository to do so within 3 months of the end of a given calendar quarter. For example, for claims with dates of service between October 1, 2026, through December 31, 2026, covered entities would be allowed to submit data elements from Part D 340B claims to CMS no later than March 31, 2027.
- For covered entities that choose to submit claims data to the 340B repository, CMS would require the covered entities to certify the accuracy and completeness of the data submitted, that the data elements submitted to the 340B repository are from claims that have been verified as 340B claims and, to the best of their knowledge, the submission includes all Part D 340B claims for the covered entity at the time of submission for the relevant period and attest that the submitter is authorized to submit on behalf of the covered entity. As stated in the CY 2026 PFS proposed rule, CMS is exploring approaches to confirming completeness and accuracy of data submission to the 340B repository and is soliciting comments on methods to review and ensure the accuracy of reported data. Additionally, CMS is soliciting comments on whether 340B covered entities would prefer to submit 340B claims data using a standardized and formatted 340B data collection form template or to submit data using a flat file output based on file layout instruction provided by CMS.
- To ensure efficient matching between the 340B file and the PDE data, CMS is considering applying field specific validation based on PDE record standards to ensure that collected data elements align with the corresponding data elements in the PDE.
- CMS will append a submission timestamp to transmitted 340B claims data files to assist in records management, downstream processing, and de-duplication of submissions, as needed.

Additional Instructions

- The instructions in this section apply to all data elements submitted by covered entities from Part D 340B claims.
- Covered entities that choose to submit data to the 340B repository are required to submit data on the 340B Repository Data Elements Collection Form.
- Questions about the Medicare Prescription Drug Inflation Rebate program should be sent to IRARebateandNegotiation@cms.hhs.gov. Additional information regarding the Medicare Prescription Drug Inflation Rebate Program can be found on CMS' website here.
- Each set of data elements are derived from a 340B Medicare Part D drug claim. A covered entity may batch multiple sets of data elements, including from different 340B pharmacies contracted with the covered entity, into a single file of data elements to submit to the 340B repository.

- Response formats are indicated within each data element description in this ICR.
- CMS understands that covered entities typically contract with vendors, such as 340B third-party administrators (TPAs), to determine 340B eligibility of claims using data provided by covered entities and their contract pharmacies. CMS would allow covered entities that choose to participate to arrange for their TPAs or other contracted vendors to submit certain data elements to the 340B repository on their behalf. Covered entities are ultimately responsible for the accuracy of the submission of data elements to the 340B repository, even if a covered entity has an arrangement with a contracted entity to submit on its behalf.
- In instances where the covered entity submits Part D 340B claims data to the repository that is either (1) incomplete or (2) contains invalid data, CMS may inform the covered entity of such error and request that the covered entity resolve and resubmit the Part D 340B claims data in order to process the submission successfully.
- CMS is proposing to provide covered entities that choose to submit data to the 340B repository with additional time to submit data to reflect a revision to the 340B determination of claims with dates of service throughout an applicable period. A revision could come in one of two forms: (1) resubmission of data for a claim that the covered entity previously submitted to the 340B repository in error or for a claim with errors in the requested data fields, or (2) new submission of data for a claim for a drug that the covered entity had previously determined was not purchased under the 340B Program, but later identified was purchased under such program. CMS will provide details on the process and timing for covered entities to submit revised data to the 340B repository after the end of the reporting period in the future.

Definitions

- Claim Date of Service: This data element is the date the prescription was filled by the pharmacy.
- Prescription or Service Reference Number: This data element is the unique prescription number that is assigned to the claim by the pharmacy.
- Fill Number: This data element is the code indicating whether the prescription is an original or a refill; if a refill, the code indicates the refill number.
- Dispensing Pharmacy NPI: This data element is the NPI of the pharmacy that dispensed the Medicare Part D claim. The Dispensing Pharmacy NPI should be numeric only and not include any dashes embedded within the number.
- NDC-11: This data element is the National Drug Code (NDC), provided in an eleven-digit format, for the dispensed product. The NDC-11 should not include dashes embedded within the number.
- Claim Record Indicator: The claim record indicator on the submission form would default to "add" (A) when submitting claims. When submitting a record to reverse a

previously submitted claim record, the covered entity shall update the claim record indicator on the form to "remove" (R) to indicate that previously submitted claim was sent in error.

- 340B Name: The covered entity's name as reported in the 340B OPAIS database.
- 340B ID: The covered entity's 340B ID as reported in the 340B OPAIS database.

Certification

The certification of the 340B Repository Data Elements form should be executed by (1) the chief executive officer (CEO) of the covered entity, (2) the chief financial officer (CFO) of the covered entity, (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority as an authorized representative of the covered entity to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

Certification Statement

I hereby certify, to the best of my knowledge, that the information included in the data elements transmitted in this submission is complete and accurate and was prepared in good faith and after reasonable efforts. I attest that the data elements submitted to the 340B repository are from claims that have been verified as 340B claims and, to the best of my knowledge, the submission includes all Part D 340B claims for the covered entity at the time of submission for the relevant period. I understand that the information contained in this submission is being provided to and will be relied upon by CMS for purposes of implementing the Medicare Prescription Drug Inflation Rebate Program, in accordance with section 1860D-14B of the Social Security Act. I agree to transmit revised data elements if I become aware that any information submitted in this form has changed or is otherwise inaccurate.

Yes ☐