340B Repository Data Elements Reporting 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) of the Act. 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, the Centers for Medicare & Medicaid Services (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 provided 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 Calendar Year (CY) 2026 Physician Fee Schedule (PFS) final rule (90 FR 49748-49755), CMS adopted its proposal to establish a Medicare Part D Claims Data 340B Repository (hereinafter, "340B repository") and allow 340B covered entities (hereinafter, "covered entities") to optionally submit to the 340B repository data elements from all its Part D 340B claims with a date of service during the relevant period which the covered entity determined utilized a drug for which the manufacturer provided a discount under the 340B Program for covered Part D drugs billed to Medicare Part D (hereinafter, "Part D 340B claims"). In the CY 2027 PFS proposed rule, CMS is proposing at § 428.203(c) to require all Medicare providers and suppliers that are covered entities as defined at 42 CFR 10.3 (hereinafter collectively "340B providers" unless otherwise noted) to submit, beginning with claims with a date of service on or after January 1, 2027, data elements associated with each claim for units of a covered Part D drug billed to Medicare Part D and dispensed by such covered entity or its contractor(s) (such as contract pharmacies) for which a manufacturer provides a discount under

[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) of the Act; or (3) a biological licensed under section 351 of the Public Health Service (PHS) Act.

the 340B Program to such covered entity. Such reporting would fulfill a 340B provider's obligation to provide access to documentation relating to covered Part D drugs written or ordered by such 340B provider as a condition of continued enrollment in Medicare, as we are proposing at § 424.516(f)(4) in accordance with our authorities in sections 1842(h)(9) and 1866(a)(1)(X) of the Act. CMS would consider all data elements received by the 340B repository to be associated with Part D 340B claims consistent with the 340B provider requirement to certify the accuracy of such submissions. CMS intends to analyze the data submitted to the 340B repository to determine if they could be used reliably in the future to remove 340B units from Part D inflation rebate calculations in accordance with section 1860D-14B(b)(1)(B) of the Act. We would match the stored data elements in the 340B repository to prescription drug event (PDE) transactions for each Part D rebatable drug dispensed during the applicable period and would evaluate 340B repository data for: (1) data integrity, and (2) submission frequency and completeness across covered entity types and geographies. We also propose, as part of every submission, to require 340B providers (or an individual or contractor with the delegated authority as an authorized representative of the 340B provider to perform the certification) to certify that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the 340B provider's knowledge, its submissions include all Part D 340B claims for the 340B provider at the time of submission for the relevant period. 340B providers or their authorized representative would be required to certify the completeness and accuracy of the data submitted and to certify that the submitter is authorized to submit on behalf of the 340B provider.

If CMS determines that the data reported to the 340B repository is usable and reliable and, in the future, proposes and adopts a policy to use such data to exclude 340B units from rebate calculations, then units associated with PDE transactions that are matched to data elements stored in the 340B repository would be considered those for which the manufacturer provided a discount under the 340B Program.

General Instructions

Overview

The purpose of this collection of information request is for CMS to receive, via submission to the 340B repository by each 340B provider, certain data elements from all of that 340B provider's Part D 340B claims with a date of service during an applicable period. CMS is proposing that 340B providers would be required to submit data elements specified by CMS at proposed § 428.203(c) related to Part D 340B claims with a date of service on or after January 1, 2027.

CMS would require that each 340B provider report data on a quarterly basis (though they may choose to submit more frequently) within one calendar quarter following the close of the relevant calendar quarter. Each 340B provider would submit 340B claims data with a date of service during the applicable period directly to the 340B repository using the CMS-specified format. The 340B units identified from these quarterly submissions would be used to determine the reliability of the submitted data for future use to remove 340B units from the total number of units used to

calculate the total rebate amount specified in the Preliminary Rebate Report and Rebate Report detailed at § 428.401(b) and (c), respectively.

We expect that the 340B repository will be operational by Fall 2026 for voluntary submissions from covered entities, as we adopted in the CY 2026 PFS final rule. We strongly encourage covered entities to begin submitting data to the 340B repository voluntarily in 2026 to test operational processes.

Beginning with claims with a date of service on or after January 1, 2027, as proposed in the CY 2027 PFS proposed rule, all 340B providers would be required to submit data elements set forth in proposed § 428.203(c) from their Part D 340B claims for all covered Part D drugs billed to Medicare Part D. Specifically, under the proposed § 428.203(c), 340B providers would be required to submit all of the following data elements associated with each claim for units of a covered Part D drug billed to Medicare Part D and dispensed by the covered entity associated with such 340B provider or its contractor(s) (such as contract pharmacies) for which a manufacturer provides a discount under the 340B Program to such covered entity: (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 would use these data elements to match claims to PDE transactions and perform further analyses to assess the reliability of the data for future use in removing 340B units from Part D inflation rebate calculations. CMS may also use these data elements to conduct other internal program analyses, such as those related to the Medicare Drug Price Negotiation Program.

In addition, under proposed § 428.203(c), a 340B provider must submit its 340B ID and name as designated in the 340B Office of Pharmacy Affairs Information System (OPAIS) database,[2] when submitting claim information.

Finally, under proposed § 428.203(c)(4), a 340B provider must resubmit data to the 340B repository that is either incomplete or contains invalid data.

Submission Method

- 340B providers would be required to submit Part D 340B claims data to the 340B repository using a form and manner provided by CMS. CMS would receive and intake the claims data provided from the 340B providers as populated in the format and manner specified by CMS. CMS would match submitted claims data from 340B providers to PDE transactions stored in the CMS claims data system. Units associated with PDE transactions that are matched to data elements stored in the 340B repository would be

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

considered those for which the manufacturer provided a discount under the 340B Program and therefore would be assessed for reliability for future use in effectuating the statutory directive at section 1860D-14B(b)(1)(B) of the Act to exclude 340B units from the total number of units for a Part D rebatable drug, with respect to an applicable period.

- 340B providers would be required to submit Part D 340B claims data to the 340B repository within one calendar quarter following the close of the relevant calendar quarter. For example, for claims with a date of service between October 1, 2027, through December 31, 2027, 340B providers would submit the data elements from Part D 340B claims to the 340B repository no later than March 31, 2028.
- CMS would require that 340B providers certify the accuracy and completeness of the data they submit to the 340B repository, that the data elements submitted to the 340B repository are from claims that have been verified as Part D 340B claims, and, to the best of their knowledge, that its data submissions will include all Part D 340B claims for the 340B provider with a date of service during the relevant time period. 340B providers would attest to this certification statement at the time of submission of Part D 340B claims. CMS would also require that the submitter certify that they are authorized to submit on behalf of the 340B provider. CMS understands that 340B providers manage, store, and report their 340B claims data using different systems and methods, and CMS intends to develop a submission method that allows 340B providers to submit Part D 340B claims data using a standardized format, based on file layout instructions provided by CMS, or via another submission method not outlined here that is determined to provide a less burdensome method to 340B providers.
- To ensure efficient matching between the Part D 340B claims data file and the PDE transactions, CMS will apply field-specific validation based on PDE record standards to ensure that collected data elements align with the corresponding data elements in the PDE transaction.
- CMS will maintain data on transmitted Part D 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 340B providers.
- 340B providers are required to submit data using the CMS-specified format.
- 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 is derived from a Part D 340B claim. A 340B provider may batch multiple sets of data elements, including from different 340B pharmacies contracted with the associated covered entity, into a single file of data elements to submit to the 340B repository.

- 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 340B providers to arrange for TPAs or other vendors contracted with their associated covered entity to submit certain data elements to the 340B repository on their behalf. 340B providers are ultimately responsible for the accuracy of the submission of data elements to the 340B repository, even if a 340B provider's associated covered entity has an arrangement with a contracted entity to submit on its behalf. CMS may ask a TPA for additional information, such as an up-to-date list of the 340B IDs for the covered entities associated with the 340B providers for which the TPA submits Part D 340B claims data.
- When reporting for a child site of the covered entity associated with the 340B provider, if the child site's 340B ID is not available in the OPAIS database, the 340B provider should enter the parent site's 340B ID in the 340B ID field of the 340B repository.
- In instances where the 340B provider submits Part D 340B claims data to the 340B repository, either directly or through a vendor, that is (1) incomplete, (2) is provided in an invalid format, and/or (3) contains invalid data, CMS may inform the 340B provider of such error and request that the 340B provider resolve and resubmit the Part D 340B claims data in order to process the submission successfully.
- CMS would provide 340B providers with additional time to submit data to reflect a revision to the 340B determination of claims with a date of service throughout an applicable period. A revision could be either a resubmission of data for a claim that the 340B provider previously submitted to the 340B repository in error or for a claim with errors in the requested data fields. Another example of a revision could be a new submission of data for a claim for a drug that the 340B provider had previously determined was not purchased under the 340B Program but later identified was purchased under such program after the end of the reporting period. CMS would provide technical instruction on the process and timing for 340B providers to submit revised data to the 340B repository.
- CMS would provide further specifications in future technical instruction that would include, but is not limited to, the specific formatting descriptions of data elements submitted by 340B providers from Part D 340B claims to the 340B repository.
- When a 340B provider submits a Part D 340B claim to the 340B repository, the 340B provider would indicate through a Claim Record Indicator field if the submitted Part D 340B claim is a new Part D 340B claim to be added to the 340B repository or if it is a previously submitted claim that should be removed. If a 340B provider determines that a previously submitted claim is not 340B-eligible or otherwise needs to be changed, the 340B provider should use the Claim Record Indicator to flag the previously submitted claim for removal from the 340B repository.

Definitions

- 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 340B Part D claim.
- NDC-11: This data element is the National Drug Code (NDC), provided in an 11-digit format, for the dispensed product.
- Claim Record Indicator: The claim record indicator on the submission would indicate the type of data submission relative to previous submissions.
- Covered Entity Name: The name of the covered entity associated with the 340B provider as reported in the 340B OPAIS database. If such covered entity does not have a registered name as listed in the 340B OPAIS database, the 340B provider should provide the legal business name of the associated covered entity.
- Covered Entity 340B ID: The 340B ID of the covered entity associated with the 340B provider as reported in the 340B OPAIS database.

Certification

The certification of the data elements will be executed by (1) the chief executive officer (CEO) of the 340B provider, (2) the chief financial officer (CFO) of the 340B provider, (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual or contractor with the delegated authority as an authorized representative of the 340B provider 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 Part D 340B claims and, to the best of my knowledge, the submission includes all Part D 340B claims for the 340B provider 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. I further certify that I am (1) the chief executive officer (CEO) of the 340B provider, (2) the chief financial officer (CFO) of the 340B provider, (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual or contractor with the delegated authority as an authorized representative of the 340B provider to perform the certification on behalf of one of the

individuals mentioned in (1) through (3) and am authorized to submit the data elements in this submission on behalf of such 340B provider.

Yes ☐