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 ~~repository~~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 ~~of that covered entity's~~its Part D 340B claims with ~~dates~~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~~Program for covered Part D drugs billed to Medicare Part D (hereinafter, "Part D 340B claims"). ~~The 340B repository will allow~~ 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 ~~this data directly to CMS (~~, beginning with claims with a date of service on or ~~a~~after January 1, 2027, data elements associated with each claim for units of a

[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.

covered Part D drug billed to Medicare Part D and dispensed by such covered entity or its contractor~~), rather than through claims that dispensers submit to Part D plan sponsors.~~(s) (such as contract pharmacies) for which a manufacturer provides a discount under 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 ~~will~~would consider all data elements received by the 340B repository to be associated with Part D 340B claims~~; that is, CMS (or a contractor) would not further verify that submitted claims are eligible for discounted pricing under the 340B Program or that 340B discounts were provided on the units~~ 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 ~~to fill such claims. Rather, the~~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 ~~will serve solely to store these data. Under this process, CMS will require a~~ 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 ~~from covered entities that choose to submit data to the 340B repository~~) to certify that the data elements from all claims submitted to the 340B repository are from verified ~~Part D~~ 340B claims and, to the best of the ~~covered entity's~~340B provider's knowledge, ~~their submission includes~~its submissions include all Part D 340B claims for the ~~covered entity~~340B provider at the time of submission ~~with dates of service during~~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, ~~propose~~proposes and ~~adopt~~adopts a policy to use such data to exclude 340B units from rebate calculations, then units associated with ~~prescription drug event (~~PDE~~)~~ transactions that ~~match~~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. ~~During the testing period beginning in 2026, CMS will assess the usability of the data submitted to the 340B repository to remove 340B units from the total number of units used to calculate the total Part D inflation rebate amount in the future.~~

General Instructions

Overview

The purpose of this collection of information request is for CMS to receive, via submission ~~by each covered entity that chooses to submit data~~ to the 340B repository~~,~~ by each 340B provider,

certain data elements from all of that ~~covered entity's~~340B provider's Part D 340B claims with ~~dates~~a date of service during ~~the relevant~~ an applicable period. CMS ~~will assess the information collection process and the suitability of the data collected to remove 340B units from the Part D inflation rebate calculation in future program years. The 340B repository will allow covered entities that choose to submit data to submit such data directly to CMS (or a contractor) using the CMS-provided format. CMS established in the CY 2026 PFS final rule to require covered entities that choose to submit data to the~~ is proposing that 340B ~~repository during the testing period beginning in 2026~~providers would be required to submit ~~fields~~data elements specified by CMS ~~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. Covered entities that choose to submit data should submit data elements~~at proposed § 428.203(c) related to ~~all~~ Part D 340B claims with ~~dates~~a date of service on or after January 1, ~~2026. At a point in the future, CMS will provide a deadline that will allow sufficient time for covered entities to gather, validate, and submit the specified data to the 340B repository. CMS will provide the submission deadline(s) once the Medicare Prescription Drug Inflation Rebate collection of information request is approved by the Office of Management and Budget. During the rest of the testing period, CMS anticipates that covered entities will be expected to~~2027.

CMS would require that each 340B provider report data on a quarterly basis (though they may choose to submit more frequently) within ~~3 months of the end of a given~~one calendar quarter~~. For example, for~~ following the close of the relevant calendar quarter. Each 340B provider would submit 340B claims data with ~~dates~~a date of service ~~between October 1, 2026, through December 31, 2026, covered entities that choose to submit data elements from Part D 340B claims would submit~~during the ~~data~~applicable period directly to the 340B repository ~~no later than March 31, 2027~~using the CMS-specified format. The 340B units identified from these quarterly submissions ~~will~~would be used to ~~assess~~determine the ~~suitability~~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. ~~CMS also established~~

We expect that the 340B repository will be operational by Fall 2026 for voluntary submissions from covered entities ~~that choose~~, as we adopted in the CY 2026 PFS final rule. We strongly encourage covered entities to ~~submit~~ begin submitting data to the 340B repository ~~during the testing period must provide information identifying the covered entity, specifically~~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 ~~covered entity's 340B ID and name as designated in the~~ CY 2027 PFS proposed rule, all 340B ~~OPAIS database,[2] when submitting claim information to the 340B repository. In addition to this~~

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

~~identifying information, CMS established that covered entities that choose~~providers would be required to submit data ~~to the~~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 ~~repository during the testing period beginning in 2026 must submit~~providers would be required to submit all of the following data elements ~~from all Part D 340B claims dispensed during the relevant time period~~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 ~~will~~would use these data elements to match claims to PDE transactions and perform further analyses to assess the ~~suitability~~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,[3] 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

- ~~In the CY 2026 PFS final rule, CMS established that covered entities may begin submitting the fields specified by CMS~~ 340B providers would be required to submit Part D 340B claims data to the 340B repository ~~beginning in 2026 for Part D 340B claims to begin testing the usability of the 340B repository. This testing period will 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 will not use the data submitted during the testing period to remove units from the Part D inflation rebate calculations. CMS will not use data submitted to the 340B repository to remove units for the purpose of calculating 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 Part D 340B claim data elements by covered~~

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

~~entities to the 340B repository in future years in future rulemaking. CMS 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 will submit Part D 340B claims data to the 340B repository on a quarterly basis~~ using a ~~format~~ form and manner provided by CMS. CMS ~~will~~would receive and intake the claims data provided from the ~~covered entities~~340B providers as populated in the format and manner specified by CMS. CMS ~~will~~would match submitted claims data from ~~covered entities~~340B providers to PDE transactions stored in the ~~Drug Data Processing System (DDPS).~~CMS claims data system. Units associated with PDE transactions that ~~match~~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 and therefore would be assessed for ~~suitability~~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~~, those units for which a manufacturer provided a discount under the 340B Program~~.
- ~~In the CY 2026 PFS final rule, CMS established that covered entities that choose~~340B providers would be required to submit ~~the fields specified~~Part D 340B claims data to the 340B repository ~~must do so~~ within ~~3 months of the end of a given~~one calendar quarter~~.~~ following the close of the relevant calendar quarter. For example, for claims with ~~dates~~a date of service between October 1, ~~2026~~2027, through December 31, ~~2026, covered entities~~ 2027, 340B providers would ~~be allowed to~~ submit the data elements from Part D 340B claims to ~~CMS~~the 340B repository no later than March 31, ~~2027~~2028.
- ~~For covered entities that choose to submit claims data to the 340B repository, CMS will~~CMS would require ~~the covered entities to~~that 340B providers certify the accuracy and completeness of the data ~~submitted~~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 ~~the submission includes~~its data submissions will include all Part D 340B claims for the ~~covered entity~~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 ~~for the relevant period.~~ of Part D 340B claims. CMS ~~will~~would also require that the submitter ~~is~~certify that they are authorized to submit on behalf of the ~~covered entity. CMS intends to provide additional details related to the precise process for submission of Part D 340B claims data during the voluntary testing period as the 340B repository is developed. Interested parties provided feedback to CMS requesting that any developed data submission method be created in a way that is the least burdensome to covered entities.~~340B provider. CMS understands that ~~covered entities~~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 ~~covered entities~~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

~~covered entities that choose to submit Part D340B claims data during the testing period.~~340B providers.

- To ensure efficient matching between the Part D 340B claims data file and the PDE transactions, CMS ~~is considering applying~~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 ~~all data elements submitted by covered entities from Part D 340B claims~~340B providers.
- ~~Covered entities that choose to submit data to the~~ 340B ~~repository~~providers are required to submit data using the CMS-~~provided~~specified format.
- Questions about the Medicare Prescription Drug Inflation Rebate ~~program~~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~~here.
- Each set of data elements is derived from a Part D 340B claim. A ~~covered entity~~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.
- ~~Example response formats are indicated within each data element description in the example form.~~
- 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 ~~will~~would allow ~~covered entities that choose to submit data~~340B providers to arrange for ~~their~~ TPAs or other vendors contracted ~~vendors~~ with their associated covered entity to submit certain data elements to the 340B repository on their behalf. ~~Covered entities~~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 ~~covered entity~~340B provider submits Part D 340B claims data to the 340B repository, either directly or through a vendor, that is ~~either~~ (1) incomplete~~.~~, (2) is provided in an invalid format, and/or (~~2~~3) contains invalid data, CMS may inform the ~~covered entity~~340B provider of such error and request that the ~~covered entity~~340B provider resolve and resubmit the Part D 340B claims data in order to process the submission successfully.

- CMS ~~will~~would provide ~~covered entities that choose to submit data to the~~ 340B ~~repository~~providers with additional time to submit data to reflect a revision to the 340B determination of claims with ~~dates~~a date of service throughout an applicable period. A revision could ~~come in one of two forms: (1)~~be either a resubmission of data for a claim that the ~~covered entity~~340B provider previously submitted to the 340B repository in error or for a claim with errors in the requested data fields~~, or (2)~~. Another example of a revision could be a new submission of data for a claim for a drug that the ~~covered entity~~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 ~~will~~would provide ~~details~~technical instruction on the process and timing for ~~covered entities~~340B providers to submit revised data to the 340B repository ~~after the end of the reporting period in the~~ .

- 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. ~~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~~11-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 ~~will~~would indicate the type of data submission relative to previous submissions. ~~For example, "add" (A) for a new submission, or "remove" (R) to indicate that previously submitted claim was sent in error.~~
- Covered Entity Name: The ~~covered entity's~~ name of the covered entity associated with the 340B provider as reported in the 340B OPAIS database. If ~~the~~such covered entity does not have a registered name as listed in the 340B OPAIS database, the ~~covered entity~~340B provider should provide ~~their~~the legal business name ~~when submitting claims.~~of the associated covered entity.
- Covered Entity 340B ID: The ~~covered entity's~~ 340B ID of the covered entity associated with the 340B provider as reported in the 340B OPAIS database. ~~If the covered entity does not have a 340B ID, then the covered entity shall leave this field blank.~~

Certification

The certification of the data elements ~~submitted to the 340B repository should~~will be executed by (1) the chief executive officer (CEO) of the ~~covered entity~~340B provider, (2) the chief financial officer (CFO) of the ~~covered entity~~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 ~~covered entity~~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 ~~all~~ 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 ~~covered entity~~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 ~~to the 340B repository has changed or is otherwise inaccurate.~~ 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 ☐