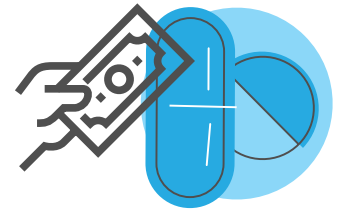


Medicare Part D Claims Data 340B Repository FAQs:

Frequently Asked Questions for 340B Covered Entities and Third-Party Administrators



This Frequently Asked Questions (FAQs) document contains information intended to support covered entities and third-party administrators (TPAs) as they engage with the Medicare Part D Claims Data 340B Repository (340B repository). The 340B repository will open for submissions on October 1, 2026.

For more information, please see the CMS [Medicare Inflation Rebate Program page](#), the [340B Repository Companion Guide](#), the [Calendar Year 2026 Physician Fee Schedule Final Rule](#), and the [Calendar Year 2027 Physician Fee Schedule Proposed Rule](#). If you do not see the answer to your question within this document, rulemaking, or additional resources available on the Medicare Inflation Rebate Program landing page, please email IRAREbateandNegotiation@cms.hhs.gov with your question, and CMS will provide you with a response or direct you to a relevant resource.

Background

Question: What is the Medicare Part D Claims Data 340B Repository?

Under the Medicare Part D Inflation Rebate Program, a manufacturer must pay CMS a rebate—equal to the product of a rebatable drug's per unit rebate amount and the total units dispensed under Part D of that drug—if the price of the rebatable drug rises faster than inflation. CMS is required by statute to remove 340B units from Part D inflation rebate calculations beginning January 1, 2026.

Currently, CMS is using a claims-based methodology to identify 340B units to remove from Part D inflation rebate calculations. The 340B repository would test if data collected from covered entities could be used to more accurately identify 340B units. The 340B repository will receive data elements from Part D 340B claims from covered entities (or their TPAs and other partners) to test whether CMS could in the future use these data elements to identify 340B units to remove from Part D

inflation rebate calculations. At this time, data collected will be used for analytical purposes; CMS will not use data from the 340B repository in Part D inflation rebate calculations unless and until we propose and finalize a policy to do so.

Question: As a covered entity, do I have to enroll in the 340B repository? What are the consequences if a covered entity does not enroll in the 340B repository?

The 340B repository is voluntary for covered entities in 2026. Covered entities are encouraged but not required to enroll and submit data to the 340B repository for claims with a date of service in 2026. Voluntary participation will enable CMS to start testing data quality and completeness and will allow covered entities to develop and refine their submission processes to prepare for a potential future participation requirement.

In the [Calendar Year 2027 Physician Fee Schedule Proposed Rule](#), CMS proposed to require that Medicare providers and suppliers that are covered entities submit data to the 340B repository beginning for claims with a date of service on or after January 1, 2027. If CMS' proposal is finalized, participation in the 340B repository would be required as a condition of continued enrollment in the Medicare program for providers and suppliers that are covered entities. If finalized, CMS would reserve the right to revoke, in accordance with existing § 424.535(a)(10), a currently enrolled provider or supplier's Medicare enrollment and any corresponding provider agreement or supplier agreement for failure to comply with the requirements to submit data to the 340B repository in accordance with proposed § 424.516(f)(4). In 2027, CMS would continue to test the data submitted to the 340B repository for potential future use in Part D inflation rebate calculations. CMS will not use the data to remove 340B units from Part D inflation rebate calculations unless and until a policy to do so is proposed and finalized.

Account Creation

Question: What do I need to know about creating an account for the 340B repository?

1. Landing page

The individual who creates an account within the 340B repository must be (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 or contractor with the 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).

2. CMS account, if needed

To create an account for the first time, users will begin on the 340B repository website. The first step will be to create an account with Login.gov, ID.me, or the CMS Identity Management (CMS IDM) system, using Remote Identity Proofing (RIDP). If a user already has a Login.gov, ID.me, or CMS IDM account, then they will not need to create a second account. Information needed during these account creation processes may include first and last name, date of birth, home address, phone number, and an email address.

3. Finish your 340B repository account

To complete their 340B repository account, covered entities will be required to provide one or more covered entity 340B ID(s) for which they will submit data. If reporting for a child site of a covered entity and no 340B ID is available in Office of Pharmacy Affairs Information System (OPAIS) for the child site, the covered entity parent 340B ID should be used. Covered entity users can edit this 340B ID list at any time.

TPA or other partner users will provide the name of the TPA or other partner organization with which they are associated.

Note: Users should create only one account, even if submitting data for more than one covered entity. When creating a user profile, users can select all appropriate 340B IDs for which they will submit data. When submitting data, claims from multiple 340B IDs may be submitted in separate files or in one file.

Detailed, step-by-step instructions will be provided in the 340B Repository User Guide, which CMS plans to make available prior to October 1, 2026.

Question: Do I need an invitation from CMS to create an account in the 340B repository?

Covered entities, TPAs, or other partners interested in submitting Part D 340B claims data in the 340B repository do not need an invitation to create an account in the 340B repository. To begin the account creation process, a covered entity or TPA user may visit the 340B repository website any time on or after October 1, 2026.

Question: How should covered entities with multiple 340B IDs create their accounts in the 340B repository? What about TPAs and other partners with delegated authority to submit data for multiple covered entities?

Users should only create one 340B repository account, even if submitting data for multiple 340B IDs.

During the account creation process, the covered entity user will be required to select at least one 340B ID for which they will submit data but may designate multiple 340B IDs. At least the covered entity parent 340B ID should be named; the user may also select applicable child 340B IDs, however, an exhaustive list of all child 340B IDs is not necessary. The 340B ID list in the account can be edited at any time.

A user submitting data for a TPA or other partner on behalf of multiple covered entities should only create one 340B repository account. TPAs and other partners will provide their organization name as part of completing account set up.

Question: I already have an account for the Medicare Transaction Facilitator. Do I need to create a new account with the 340B repository?

Yes. While the Medicare Transaction Facilitator (MTF) and the 340B repository both use CMS IDM for authentication, they are separate systems with distinct purposes, and users will need to complete a separate 340B account creation process for the 340B repository. However, if a user already has a CMS IDM account —

whether for the MTF or any other CMS program — they do not need to create a new CMS IDM account. They may use their existing CMS IDM username and password to log in to the 340B repository to create their 340B repository account.

Submitting Claims

Question: Which claims should I submit to the 340B repository and how often?

Covered entities (or their TPAs or other partners) should submit claims for all 340B dispenses that were covered and paid for by a Medicare Part D plan with dates of service on or after January 1, 2026. This is regardless of whether the drug was dispensed at an in-house pharmacy or contract pharmacy, and regardless of whether the drug is a Part D rebatable drug. To identify dispenses covered and paid for by a Medicare Part D plan, covered entities may use the BINs/PCNs for Medicare Part D plans that CMS posts on its [website](#).

Covered entities (or their TPAs or other partners) should report to the 340B repository at least on a quarterly basis (though they may choose to submit more frequently) within one calendar quarter following the close of the relevant calendar quarter. For example, for claims with a date of service between October 1, 2026, through December 31, 2026, a covered entity should submit data elements from such claims to the 340B repository no later than March 31, 2027. The repository website is available at any time for claims submissions and corrections.

Question: How does a covered entity submit a claim into the 340B repository?

More information on claims data submissions, including data elements and formats accepted can be found in the [340B Repository Companion Guide](#).

Question: My covered entity's Part D drugs are dispensed by contract pharmacies and identified as 340B by a TPA. Does my covered entity still need to submit claims for those dispenses?

Yes. Your covered entity should submit claims for all 340B dispenses that were covered and paid for by a Medicare Part D plan, regardless of whether the drug was dispensed at an in-house pharmacy or contract

pharmacy. Your covered entity may designate a TPA or other partner with delegated authority to submit data to the 340B repository on its behalf.

Question: I use a TPA or other partner to process my 340B claims data. How will this work with the 340B repository?

The 340B repository is designed to accommodate covered entities that use a TPA or other partner and allows them submit Part D 340B claims data on the covered entities' behalf. Covered entities do not need to identify their TPA or other partner within the 340B repository. A TPA will create its own 340B repository account and may submit data on behalf of one or more covered entities. CMS encourages TPAs to communicate with their associated covered entities to facilitate consistent data entry and successful submissions in the system. A TPA must have delegated authority as an authorized representative of the covered entity to submit and certify the data submitted to the 340B repository on behalf of the covered entity.

TPAs may submit Part D 340B claims data for multiple covered entities in a single file upload, as the system supports batch submissions containing claims across multiple 340B IDs in one .xlsx or .csv file. Each claim row must include the appropriate covered entity 340B ID to ensure accurate attribution.

Other Frequently Asked Questions

Question: How does the 340B repository relate to the potential HRSA Rebate Pilot Program?

The 340B repository is for the Medicare Part D Inflation Rebate Program.

CMS' 340B repository and the HRSA 340B Rebate Pilot are distinct. The 340B repository is part of a comprehensive effort involving a larger scope of drugs than the pilot to assess use of the 340B repository to exclude 340B units from Part D inflation rebate calculations. We have designed the 340B repository to minimize burden on covered entities to the extent possible, and we will coordinate with HRSA to reduce covered entities' data reporting burden, where feasible.

Question: Will my 340B repository submissions affect how much my hospital, clinic, and/or contract pharmacies are paid for dispensing 340B drugs?

The Medicare Part D Inflation Rebate Program invoices manufacturers for rebatable drugs if their drug prices increase faster than the rate of inflation. Although CMS needs information about your Part D 340B claims to administer the Medicare Part D Inflation Rebate Program, the 340B repository does not impact hospital, clinic, or pharmacy payment for drugs purchased through the 340B Program.

Question: Will CMS share data that I submit to the 340B repository with others?

CMS designed the 340B repository to create a direct, confidential link between covered entities (or their TPAs) and CMS. 340B repository data will not be shared outside of CMS; that is, CMS will not share the data with entities such as manufacturers and Part D plans.

Question: How is CMS removing 340B units from Part D inflation rebate calculations while it tests the 340B repository data?

CMS has adopted a claims-based methodology known as the “Prescriber-Pharmacy Methodology” to remove 340B units from Part D inflation rebate calculations beginning in 2026. Under this methodology, CMS removes 340B units from the Part D inflation rebate calculations by evaluating whether a Prescription Drug Event (PDE) record is potentially 340B-eligible based on (1) the affiliation of the National Provider Identifier (NPI) of the prescriber associated with that PDE record with a registered covered entity, and (2) the designation of the dispensing pharmacy associated with that PDE record as a 340B contract pharmacy.

CMS will not use data from the 340B repository in Part D inflation rebate calculations unless and until we propose and finalize a policy to do so.