



NOTICE TO 340B COVERED ENTITIES
REGARDING UPDATES TO TEVA PHARMACEUTICALS USA, INC.
340B PROGRAM INTEGRITY INITIATIVE

May 20, 2024

Dear Covered Entity Customer,

I am writing to inform you of changes to Teva Pharmaceuticals USA, Inc. ("Teva") contract pharmacy policy under the 340B Program Integrity Initiative that became effective July 5, 2023.

Effective May 20, 2024, Teva is updating the list of products included in our contract pharmacy policy under the 340B Program Integrity Initiative to include Simlandi. Please refer to Attachment A for an updated product listing. Please note that since this product list may be updated from time to time by Teva, please visit www.340BESP.com for a current list of applicable NDC's included in Teva's contract pharmacy policy under the 340B Program Integrity Initiative. Teva will no longer be providing additional notification for product changes to our contract pharmacy policy.

If you have questions regarding these changes, please contact support@340Besp.com.

Thank you.



June 8, 2023

Dear Covered Entity Customer,

I am writing to inform you that Teva Pharmaceuticals USA, Inc. ("Teva") is altering its approach to distributing medicines purchased at the 340B price. Teva will continue to ship medicines purchased at the 340B price to locations registered as a 340B covered entity or child site location. However, effective July 5, 2023, pharmacies registered as contract pharmacies for hospitals will no longer be eligible for Bill To / Ship To replenishment orders, except as provided below.

Teva remains committed to the original mission of the 340B program to provide low income and indigent patients' access to affordable medications. At the same time, Teva has grown concerned with participation of for-profit contract pharmacies and the increase in diversion of 340B purchased medicines and duplicate discounts that has accompanied growth in contract pharmacy arrangements. We believe this policy will help strengthen the 340B program through increased focus on 340B program integrity and transparency, and will not reduce patient access to Teva medicines under the 340B program.

Effective July 5, 2023:

- Any covered entity enrolled in the 340B Program as a hospital that has an in-house outpatient pharmacy will no longer be eligible to have 340B-discounted product shipped to contract pharmacies, including contract pharmacies that are wholly-owned by a 340B hospital. 340B-discounted products will only be shipped to the in-house outpatient pharmacy.
- To ensure that all 340B covered entities can access Teva medicines at the 340B price, any covered entity hospital that does not have an in-house pharmacy capable of dispensing 340B-discounted Teva product to its eligible patients may designate a single contract pharmacy location. Covered entity hospitals that qualify to designate a single contract pharmacy location may do so under two conditions:
 1. The contract pharmacy is physically located within 40 miles of the covered entity hospital's parent site, and
 2. The covered entity submits 340B claims data for the designated contract pharmacy location.

Teva is utilizing 340B ESP™ to support the designation of contract pharmacies and the submission of 340B claims data. For a covered entity's contract pharmacy designation to take effect on July 5, 2023, the designation should be made by June 18, 2023.



All federal grantee covered entities are exempt from this policy and may continue to obtain 340B pricing through an unlimited number of contract pharmacies and are not required to submit claims data.

In support of a smooth transition to our new distribution model, 340B covered entities should work with their contract pharmacy administrators and wholesalers to process any outstanding Bill To / Ship To replenishment orders in advance of the July 5, 2023 effective date.

If you have questions regarding the change in our 340B distribution model, please contact support@340Besp.com.

Best Regards,

A handwritten signature in black ink, appearing to read "Thomas Rainey". The signature is fluid and cursive, with the first name "Thomas" and last name "Rainey" clearly distinguishable.

Thomas Rainey
Senior Vice President, US Market Access



Frequently Asked Questions

Q: Which medicines are subject to Teva's policy?

A: Teva's policy applies to all products included in Attachment A. Teva will notify covered entities when additional products are added and of other changes to the product list.

Q: Under what circumstances can a 340B covered entity hospital designate a single contract pharmacy?

A: Only those 340B covered entity hospitals that are not capable of dispensing Teva medicines to patients for subsequent self-administration are eligible to designate a single contract pharmacy location. Covered entities that meet this criterion may designate a single contract pharmacy location that is physically located within 40 miles of the covered entity hospital's parent site and must submit 340B claims data through 340B ESP for all 340B purchases that are shipped to the designated contract pharmacy.

Q: I have an in-house pharmacy that is capable of purchasing and dispensing Teva medicines, but I don't use it to dispense Teva medicines. Can I designate a contract pharmacy instead?

A: No. If a covered entity has an in-house pharmacy capable of purchasing Teva medicines at the 340B price and dispensing the medicines to patients, the entity must use that pharmacy and may not designate a contract pharmacy instead.

Q. How do I make my contract pharmacy designation?

A. Teva is utilizing 340B ESP to support single contract pharmacy designations and 340B claim submissions. Registered users can navigate to the Entity Profile tab to make their contract pharmacy designation. Please allow 10 business days for contract pharmacy designations to be reflected with your wholesaler.

Q. My 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy (e.g. six different Accredo pharmacy locations). Can I designate all locations of the same pharmacy?

A. Teva's policy allows eligible 340B covered entities to designate only a single contract pharmacy location. Contract pharmacy locations are registered individually on the HRSA database and 340B covered entities are permitted to designate only a single contract pharmacy location which corresponds to a single contract pharmacy registration with HRSA.

Q. How do I ensure that my contract pharmacy designation takes effect on July 5, 2023?

A. For a covered entity's contract pharmacy designation to take effect on July 5, 2023, the designation should be made by June 18, 2023. After June 18, 2023, please allow 10 business days for the designation to take effect.

Q. What if my 340B covered entity hospital does not have a contract pharmacy location within 40 miles of my parent site?



A. 340B covered entity hospitals that do not have a contract pharmacy location registered with HRSA that is within 40 miles of its parent site may contact support@340besp.com to find an acceptable alternative pharmacy.

Q: How do I change my 340B contract pharmacy designation?

A: Changes to the single contract pharmacy location can be made by logging into your 340B ESP account and navigating to the Entity Profile tab. Covered entities may change their contract pharmacy designation once every twelve (12) months (from the date of first designation) or more often if the designated contract pharmacy relationship is terminated from the HRSA OPAIS database.

Q: How do I submit 340B claims data originating from my single contract pharmacy location designation?

A: 340B covered entities that have made a single contract pharmacy location designation will utilize 340B ESP to submit 340B claims data. Claims data must be submitted within 45 days of the date of dispense and will be compared with 340B purchases made for the single contract pharmacy designation to ensure all 340B claims are submitted in a timely manner.

Q: How will Teva use the 340B claims data submitted to 340B ESP?

A: Teva will utilize 340B claims data to identify and withhold payment of ineligible rebates claimed by Medicaid, Medicare Part D plans and commercial payers. Teva will also utilize 340B claims data to ensure 340B covered entity hospitals that have elected to make a single contract pharmacy designation are complying with Teva's policy.



ATTACHMENT A

APPLICABLE PRODUCTS	EFFECTIVE DATE
ACTIQ®	7/5/2023
ADDERALL®	7/5/2023
ADIPEX-P®	7/5/2023
AIRDUO RESPICLICK®	7/5/2023
AIRDUO® DIGIHALER®	7/5/2023
AJOVY®	7/5/2023
AMRIX®	7/5/2023
ARMONAIR® DIGIHALER®	7/5/2023
AYGESTIN®	7/5/2023
AZILECT®	7/5/2023
BENDEKA®	7/5/2023
CINQAIR®	7/5/2023
COPAXONE®	7/5/2023
FENTORA®	7/5/2023
FIORICET®	7/5/2023
GABITRIL®	7/5/2023
GALZIN®	7/5/2023
GRANIX®	7/5/2023
LOESTRIN®	7/5/2023
LOSEASONIQUE®	7/5/2023
MIRCETTE®	7/5/2023
NUVIGIL®	7/5/2023
PREFEST®	7/5/2023
PROAIR®	7/5/2023
PROGLYCEM®	7/5/2023
PROVIGIL®	7/5/2023
QNASL®	7/5/2023
QUARTETTE®	7/5/2023
QVAR REDIHALER®	7/5/2023
SEASONIQUE®	7/5/2023
SYNRIBO®	7/5/2023
TREANDA®	7/5/2023
TREXALL®	7/5/2023
TRISENOX®	7/5/2023
UZEDY®	7/5/2023
ZIAC®	7/5/2023
AUSTEDO®	11/6/2023
AUSTEDO XR®	11/6/2023
ALVAIZ®	4/8/2024
SIMLANDI®	5/20/2024