

September 11, 2023

**Notice to 340B Covered Entities of
Implementation of Jazz Pharmaceuticals'
Contract Pharmacy Policy
Effective October 9, 2023**

Dear 340B Covered Entity:

In an effort to uphold the integrity of the 340B program and address the risk of duplicate discounts and diversion, Jazz Pharmaceuticals is implementing a policy regarding contract pharmacies' eligibility to receive products at the 340B discount price. The new policy will take effect as of October 9, 2023 ("Policy Effective Date"). This policy will be applicable for EPIDIOLEX® only at this point in time. The applicable NDC's are: 70127-0100-10 and 70127-0100-60.

Under the policy, Jazz Pharmaceuticals will continue to distribute products purchased at the 340B discount price to locations registered as a 340B covered entity or child site on HRSA's OPAIS database, consistent with the 340B statute. Subject to the exceptions set forth herein, commencing on the Policy Effective Date, 340B covered entities will not be permitted to direct delivery of EPIDIOLEX products purchased at the 340B discount price to contract pharmacies, meaning that Jazz Pharmaceuticals will no longer facilitate "Bill To/Ship To" orders of EPIDIOLEX products purchased at the 340B discount price to contract pharmacies.

Exceptions:

- Federal grantee covered entities are excluded from the policy and will remain eligible to direct delivery of EPIDIOLEX products purchased at the 340B discount price to their respective contract pharmacies. Accordingly, there is no action required by federal grantees with respect to this policy.

Any covered entity that does not have an in-house pharmacy capable of dispensing 340B products to its patients may designate a single contract pharmacy location per the instructions below, and Jazz Pharmaceuticals will facilitate "Bill To/Ship To" orders of EPIDIOLEX products purchased at the 340B discount price to such designated contract pharmacy location only. The designated contract pharmacy location must be registered in the HRSA OPAIS 340B contract pharmacy database.

Any 340B covered entity that does not have an in-house pharmacy capable of dispensing products purchased at the 340B discount price to its patients must designate a single contract pharmacy location by completing the online form at <https://www.340besp.com/designations>.



jazzpharmaceuticals.com

Jazz Pharmaceuticals is utilizing the 340B ESP™ platform to support the contract pharmacy designation process. Covered entities that have not already registered an account with 340B ESP™, must make their designations by visiting <https://www.340besp.com/designations>. Covered entities that have already registered an account with 340B ESP™ must designate a contract pharmacy by navigating to the Entity Profile tab at <https://www.340besp.com>.

Contract pharmacies that are wholly owned by the covered entity (or have common ownership with the entity) will not be able to access 340B pricing unless the covered entity does not have an in-house pharmacy, and the wholly owned pharmacy is designated as the single contract pharmacy through the 340B ESP™ platform.

In order for single contract pharmacy designations to take effect as of the Policy Effective Date, **340B covered entities must take action by September 29th, 2023.**

In support of a smooth transition to this policy, 340B covered entities should work with their contract pharmacy administrators and wholesalers to process any outstanding “Bill To/Ship To” orders in advance of the Policy Effective Date.

Please refer to the attached FAQ for additional information. If you have further questions regarding this policy or utilization of the 340B ESP™ platform, please contact **support@340besp.com**.

Sincerely,

A handwritten signature in cursive script that reads 'Ernie Ross'.

Ernie Ross
Senior Vice President, Market Access



- a. *Federal grantees are eligible for 340B participation under 42 U.S.C. § 256b(a)(4)(A)-(K). Grantee 340B Covered Entities are: Black Lung Clinics Program; Consolidated Health Center Program; Title X funded Family Planning; Tribal Contract/Compact with IHS (P.L. 93-638); Federally Qualified Health Center Look-Alikes; Comprehensive Hemophilia Treatment Center; Native Hawaiian Health Care Program; Ryan White Clinics; Sexually Transmitted Diseases; Tuberculosis, and Urban Indian.*
- b. *The term “340B covered entity”, refers to those entities eligible for participation in the 340B drug discount program under 42 U.S.C. §256b(a)(4)(L)-(O).*

Frequently Asked Questions

Q: Which products are subject to Jazz Pharmaceuticals' policy?

A: Jazz Pharmaceuticals' contract pharmacy policy applies to EPIDIOLEX products. The NDC's are 70127-0100-10 and 70127-0100-60.

Q: My covered entity has a contract pharmacy relationship with a pharmacy that is owned by our health system. Is this pharmacy subject to Jazz Pharmaceuticals' policy?

A: Yes, contract pharmacies that are wholly owned by the covered entity are subject to Jazz Pharmaceuticals' policy. However, a wholly owned can be designated as a singular contract pharmacy.

Q: My covered entity has an in-house pharmacy that is capable of purchasing and dispensing Jazz Pharmaceuticals' drugs, but my entity doesn't use it to dispense Jazz Pharmaceuticals' drugs. Can my entity designate one contract pharmacy instead?

A: No, under Jazz Pharmaceuticals' policy, if a covered entity has an in-house pharmacy capable of dispensing 340B purchased products to eligible patients then the covered entity must use that pharmacy and cannot designate a contract pharmacy instead.

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

A. No. Jazz Pharmaceuticals' policy allows qualifying 340B covered entities (i.e., covered entities without an in-house pharmacy) to designate a single contract pharmacy location. Contract pharmacy locations are registered individually on the HRSA OPAIS 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 often can my covered entity change its contract pharmacy designation?

A. 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 does my covered entity change its contract pharmacy designation?

A. 340B covered entities can elect a single contract pharmacy every twelve (12) months. Changes to the single contract pharmacy can only be made by visiting <https://www.340besp.com/designations>. Users that have registered an account with 340B ESP™ can navigate to the Entity Profile tab to make their contract pharmacy designation.

Q. Is Jazz Pharmaceuticals requiring covered entities to have a HIN registered for the contract pharmacy that they designate?

A. Yes, a contract pharmacy must have a HIN assigned to it in order for a covered entity to designate it as its single contract pharmacy. This information is important for Jazz Pharmaceuticals to manage its process with its wholesalers.

Q. If the contract pharmacy my covered entity wants to designate doesn't have a HIN, how does my entity get one?

A: Jazz Pharmaceuticals will not register a HIN on your behalf, however if you need guidance or more information on how to get a HIN assigned to your contract pharmacy, please reach out to support@340besp.com. If you try to designate a contract pharmacy without a HIN in 340B ESP™, the system will notify you of this requirement and provide instructions for how to obtain a HIN.

Q. How does my covered entity ensure that its eligible contract pharmacy locations take effect on October 9th, 2023?

A. For a covered entity's eligible contract pharmacy locations to take effect on October 9th, 2023, the entity must designate by September 29th, 2023. After September 29th, please allow 10 business days for the eligible contract pharmacy locations to take effect.