



**Notice to 340B Covered Entities of
Implementation of Astellas Pharma US, Inc.'s
Contract Pharmacy Policy for Xtandi®
Effective September 1, 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, Astellas Pharma US, Inc. (“Astellas”) is implementing a policy regarding contract pharmacies’ eligibility to receive Xtandi® products at the 340B discount price. The new policy will take effect as of September 1, 2023 (“Policy Effective Date”).

Under the policy, Astellas will continue to distribute all NDCs of Xtandi® 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 Xtandi® products purchased at the 340B discount price to contract pharmacies, meaning that Astellas will no longer facilitate “Bill To/Ship To” orders of Xtandi® 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 Xtandi® 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 Astellas will facilitate “Bill To/Ship To” orders of Xtandi® 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 340B contract pharmacy database.




Any 340B covered entity that does not have an in-house pharmacy capable of dispensing Xtandi® 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>. Astellas 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>.

In order for single contract pharmacy designations to take effect as of the Policy Effective Date, **340B covered entities must take action by August 18, 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,

DocuSigned by:

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Lei Ding
Senior Vice President, Market Access and Commercial Capabilities
Astellas Pharma US, Inc.



Frequently Asked Questions

Q: Which products are subject to Astellas' contract pharmacy policy?

A: Astellas' contract pharmacy policy applies to all NDCs of Xtandi®.

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

A: Yes, contract pharmacies that are wholly owned by the covered entity are subject to Astellas' policy. However, a wholly owned contract pharmacy can be designated as the entity's single contract pharmacy, so long as the covered entity does not have an in-house pharmacy.

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

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

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

A. No. Astellas' 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 database and 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. Changes to the contract pharmacy designation can only be made by visiting 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. Please allow 10 business days for the eligible contract pharmacy designation to take effect.



Q. Is Astellas 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 that contract pharmacy as its single contract pharmacy. This information is important for Astellas to manage its process with its wholesalers.

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

A: Astellas 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 contract pharmacy designation takes effect on September 1, 2023?

A. For a covered entity's eligible contract pharmacy designation to take effect on September 1, 2023, the covered entity must designate a single contract pharmacy by **August 18, 2023**.

Q. How long does it take for my covered entity's contract pharmacy designation to take effect if we do not register by August 18, 2023?

A. Covered entities can take action to comply with Astellas' policy after it goes into effect on September 1, 2023. After September 1, 2023, please allow 10 business days for the eligible contract pharmacy designation to take effect.