

June 30, 2021

Boehringer Ingelheim Contract Pharmacy Policy Effective August 1, 2021

Dear 340B Covered Entity:

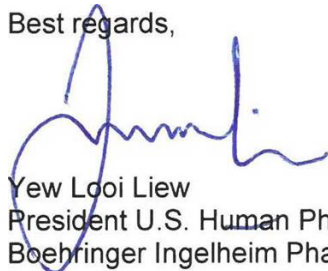
I am writing to inform you that Boehringer Ingelheim Pharmaceuticals, Inc. (BI) is altering its approach to distributing products purchased at the 340B price. For orders placed on or after August 1, 2021, except as provided below, BI will ship products purchased at the 340B price exclusively to locations registered as a 340B covered entity or their child site locations and will not facilitate shipment to commercial contract pharmacies.

To ensure that all 340B covered entities and their patients continue to have access to life-enhancing products purchased at the 340B price, BI will voluntarily apply the following general exceptions to its approach:

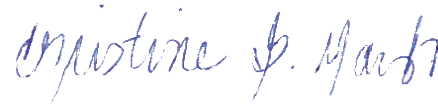
- First, any covered entity that does not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy location to receive and dispense 340B purchased products. BI is utilizing the 340B ESP™ platform to support this designation. 340B covered entities that do not have an in-house pharmacy, and have not already registered an account with 340B ESP™, can make their designations by visiting www.340besp.com/designations. Users that have registered an account with 340B ESP™ can designate a single contract pharmacy by navigating to the Entity Profile tab. If you have questions regarding the change in our 340B distribution model, please contact us at support@340Besp.com.
- Second, covered entities that are Federal grantees for medically underserved populations, and eligible for 340B participation under 42 U.S.C. § 256B(a)(4)(A)-(K), will remain eligible to place “Bill To / Ship To” replenishment orders of 340B priced drugs for their multiple pharmacies.
- Third, contract pharmacies that are wholly owned by a 340B hospital, or are under common ownership with a 340B health system, will remain eligible to receive “Bill To / Ship To” replenishment orders of 340B priced drugs. These pharmacies must be registered with HRSA as a contract pharmacy of their related 340B hospitals. To apply for a wholly owned contract pharmacy exemption, please reach out to support@340besp.com.

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 August 1, 2021 effective date. PHS contracts administered by our wholesalers will no longer support distribution of 340B purchased drugs to 340B contract pharmacies after August 1, 2021.

Best regards,



Yew Looi Liew
President U.S. Human Pharma
Boehringer Ingelheim Pharmaceuticals, Inc.



Christine Marsh
Senior Vice President, Market Access
Boehringer Ingelheim Pharmaceuticals, Inc.

Q: My covered entity has a contract pharmacy relationship with a pharmacy that is owned by our health system. Is this pharmacy excluded under BI's policy?

A: No, contract pharmacies that are wholly owned by the covered entity are not subject to BI's policy and covered entities may continue using all of their wholly owned contract pharmacies that are registered within the HRSA database. To apply for a wholly owned contract pharmacy exemption, please reach out to support@340besp.com.

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

A: No, under BI's policy, if a covered entity has an in-house pharmacy capable of purchasing at the 340B price and dispensing, the entity must use that pharmacy and cannot designate a contract pharmacy instead.

Q. How do I change my 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 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. How often can I change my contract pharmacy designation?

A. Covered entities may change its 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. 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. No. Similar to guidance provided by HRSA in 1996, BI's policy allows affected 340B covered entities to designate only a single contract pharmacy location. Contract pharmacy locations are registered individually on the HRSA database. 340B covered entities are permitted to designate only a single contract pharmacy location which corresponds to a single contract pharmacy registration with HRSA. The only exceptions to the above include Federal grantees in specified classes and contract pharmacies wholly owned by a 340B hospital or that have common ownership with a health system.

Q. Is BI 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 BI to manage its process with its wholesalers.

Q. If the contract pharmacy I want to designate doesn't have a HIN, how do I get one?

A: BI 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 do I ensure that my contract pharmacy designation takes effect on August 1, 2021?

A. For a covered entity's contract pharmacy designation to take effect on August 1st, its contract pharmacy selection needs to be made by Friday, July 16th. After July 16th, please allow 10 business days for the designation to take effect.

Q. How long does it take for my contract pharmacy designation to take effect if I make the designation after August 1, 2021?

A. You can designate a contract pharmacy after BI's policy goes into effect on August 1, 2021. If you designate after August 1, 2021, please allow 10 business days for the designation to take effect.

Q: Which products are subject to BI's policy?

A: BI's policy applies to all of its products except those distributed through specialty pharmacies (OFEV, Gilotrif, and Praxbind).