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October 29, 2021

**Notice to 340B Covered Entities  
Update to Boehringer Ingelheim Contract Pharmacy Policy  
Effective December 1, 2021**

Dear 340B Covered Entity:

I am writing to inform you that Boehringer Ingelheim Pharmaceuticals, Inc. (BI) is making an update to its 340B Program contract pharmacy policy that went into effect on August 1, 2021. As of August 1, BI ships certain products purchased at the 340B price exclusively to locations registered as a 340B covered entity or to their child site locations (“in-house”), and does not facilitate shipment to commercial contract pharmacies except under limited exceptions described in the policy.

The contract pharmacy policy currently in effect includes BI’s entire primary care portfolio. There will be no change to BI’s policy with respect to these products. In summary:

- BI continues to offer its products to covered entities for purchase at the 340B ceiling price in whatever quantities any covered entity requests.
- 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 products purchased at the 340B discount price.
- Covered entities that are Federal grantees 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 contract pharmacies.
- 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 pending approval. These pharmacies must be registered with HRSA as a contract pharmacy of their related 340B hospitals.

Effective December 1, 2021, BI will add its specialty product, OFEV, to the list of products subject to its 340B Program contract pharmacy policy. OFEV is subject to a limited distribution network that includes several specialty pharmacies approved by BI to purchase and dispense OFEV, and a number of in-house pharmacies that are capable of dispensing specialty care drugs.

In support of this change, and to ensure that all 340B covered entities and their patients continue to have access to OFEV at the 340B price, please note the following:

- First, for covered entities that have an in-house pharmacy capable of dispensing specialty care drugs, that in-house pharmacy must be used to dispense OFEV purchased at the 340B price.
  - For covered entities with an in-house pharmacy that is not capable of dispensing specialty products, each covered entity may designate one (1) specialty pharmacy from within BI’s limited distribution network for the sole purpose of dispensing OFEV to its patients.
  - For covered entities without an in-house pharmacy and that have previously designated a contract pharmacy for the distribution of primary care products, if that contract pharmacy is not in BI’s limited distribution network for OFEV, each covered entity may designate one (1) specialty pharmacy from within BI’s limited distribution network for the sole purpose of distributing OFEV to its patients.

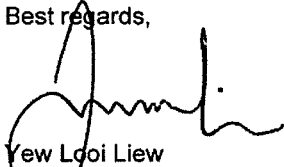
BI is utilizing the 340B ESP™ platform to support these designations. 340B covered entities that have not already registered an account with 340B ESP™, can make their designations by visiting [www.340besp.com/designations](http://www.340besp.com/designations).

Users that have registered an account with 340B ESP™ can designate a 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](mailto:support@340Besp.com).

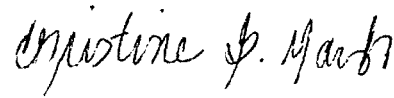
- Second, covered entities that are Federal grantees and eligible for 340B participation under 42 U.S.C. § 256b(a)(4)(A)-(K) will remain eligible to place “Bill To / Ship To” replenishment orders for OFEV at the 340B price for contract pharmacies within the BI limited distribution network for OFEV.
- Third, contract pharmacies that are wholly owned by a 340B hospital, or are under common ownership with a 340B health system (“wholly owned”), will remain eligible to receive “Bill To / Ship To” replenishment orders of 340B priced OFEV. Any wholly owned contract pharmacies that have an approved wholly owned contract pharmacy exemption for BI’s primary care products will remain eligible to do so and do not need to apply for an additional wholly owned contract pharmacy exemption for OFEV. Wholly owned contract 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 visit [www.340besp.com/wholly\\_owned\\_application](http://www.340besp.com/wholly_owned_application).

If you have any questions regarding BI’s updated 340B Program contract pharmacy policy, please reach out to [support@340besp.com](mailto:support@340besp.com).

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: Yes, contract pharmacies that are wholly owned by the covered entity are not subject to BI's policy. BI will allow "Bill To / Ship To" orders to be placed by covered entities for shipment to their wholly owned contract pharmacies that are registered within the HRSA database. To apply for a wholly owned contract pharmacy exemption, please visit [www.340besp.com/wholly\\_owned\\_application](http://www.340besp.com/wholly_owned_application).

**Q: I have an in-house pharmacy that is capable of 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 dispensing BI drugs, BI will only ship drugs purchased at the 340B ceiling price to the covered entity's in-house pharmacy and will not ship drugs to third-party contract pharmacies.

**Q: My covered entity has an in-house pharmacy that is capable of dispensing BI's primary care products but doesn't have the capability to dispense specialty products. Can my entity designate a contract pharmacy that is approved to purchase and dispense OFEV?**

A: Yes. Under BI's policy, a covered entity is eligible to designate a specialty pharmacy in BI's limited distribution network for OFEV if its in-house pharmacy doesn't have the capability to dispense specialty products.

**Q: My covered entity has an in-house pharmacy that is capable of dispensing BI's primary care and specialty products but doesn't use it to dispense BI products. Can my entity designate its preferred contract pharmacy to dispense BI's primary care and specialty products instead of using its in-house pharmacy?**

A: No. Under BI's policy, if a covered entity has an in-house pharmacy capable of dispensing both primary care and specialty products, the entity must use that pharmacy and cannot designate a contract pharmacy instead. BI's limited distribution network gives all covered entity-owned pharmacies the ability to purchase its specialty products at the 340B price. So as long as the covered entity owned pharmacy can dispense OFEV, the entity is not eligible to make any contract pharmacy designations.

**Q: My covered entity doesn't have an in-house pharmacy and is eligible to designate a contract pharmacy to continue accessing BI products. My entity designated a contract pharmacy that can dispense both primary care and specialty products but can't dispense OFEV. Can my entity designate another contract pharmacy that is approved to dispense OFEV?**

A: Yes. Covered entities are eligible to make a second contract pharmacy designation for OFEV only if their designated contract pharmacy is not approved to dispense OFEV and/or doesn't have the capability to dispense specialty products.

**Q. How do I change my contract pharmacy designation(s)?**

A. 340B covered entities can elect a single contract pharmacy every twelve (12) months. Changes to the single contract pharmacy can be made by visiting [www.340Besp.com/designations](http://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(s)?**

A. Covered entities may change their contract pharmacy designations 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. Can I designate all locations of the same pharmacy?**

A. No. Consistent with the statute, and 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 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 new contract pharmacy designation takes effect on December 1, 2021?**

A. For a covered entity's contract pharmacy designation to take effect on December 1<sup>st</sup>, its contract pharmacy selection needs to be made by Friday, November 12<sup>th</sup>. After November 12<sup>th</sup>, 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 designations after BI's updated policy goes into effect?**

A. A covered entity can make contract pharmacy designation(s) after BI's policy updated policy goes into effect on December 1, 2021. That designation will take up to 10 business days to take effect in the wholesalers' system.

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

A: BI's policy applies to all of its products except Gilotrif and Praxbind.