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August 5, 2022

Notice to 340B Covered Entities: Update to Boehringer Ingelheim Contract Pharmacy Policy Effective September 1, 2022

Dear 340B Covered Entity:

I am writing to inform you that Boehringer Ingelheim Pharmaceuticals, Inc. (BI) is updating its 340B Program contract pharmacy policy that went into effect on August 1, 2021 (Primary Care) and December 1, 2021 (OFEV), respectively.

Effective September 1, 2022, except as provided below, BI will no longer offer voluntarily 340B discounts on shipments of BI product to contract pharmacies of Federal grantee covered entities enrolled in the 340B Program as a Consolidated Health Center Program (CH/CHC covered entity type). At this time, for all other Federal grantee types, aside from CH/CHC covered entity type, BI will continue to voluntarily honor 340B discounts on shipments of BI products to contract pharmacies of covered entities with multiple contract pharmacy arrangements. Further, this update does not alter BI's existing limitations on multiple contract pharmacy arrangement shipments for hospital covered entity types.

To ensure that all 340B CH/CHC covered entity types 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 CH/CHC covered entity that does not have an in-house pharmacy capable of dispensing primary care 340B purchased products to its patients may designate a single contract pharmacy location to receive and dispense 340B purchased products. If covered entities have an in-house pharmacy that is not capable of dispensing specialty products, each such covered entity may also designate one (1) specialty pharmacy from within Bl's limited distribution network for the sole purpose of dispensing OFEV to its patients. Bl 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, for any CH/CHC covered entity type that provides specified 340B contract pharmacy claims data through the 340B ESP™ platform, such entity may continue to purchase BI products at the 340B discounted price and have such discounted product shipped to those contract pharmacies that are registered on the HRSA website as a contract pharmacy of the entity and identified in the submitted contract pharmacy claims data.
- Third, contract pharmacies that are wholly owned by a 340B covered entity or are under common ownership with a 340B health system, may apply for an exemption to remain eligible to receive "Bill To / Ship To" replenishment orders of 340B priced products. These pharmacies must be registered with HRSA as a contract

pharmacy of their related 340B covered entity. To request a wholly owned contract pharmacy exemption, please reach out to support@340besp.com. If such request is approved, the wholly owned pharmacy will become eligible for "Bill To / Ship To" replenishment orders.

The contract pharmacy policy currently in effect includes BI's entire primary care portfolio and its specialty product OFEV. 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 products.

Covered entities that are non-CH/CHC covered entity type Federal grantees and are eligible for 340B participation under 42 U.S.C. § 256b(a)(4)(B)-(K) will remain eligible to place "Bill To / Ship To" replenishment orders of 340B priced products for their contract pharmacies.

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. 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.

BI is utilizing the 340B ESP™ platform to support claims collection on behalf of CH/CHC entity type. This entity type that wishes to submit 340B claims under BI's policy can do so by registering an account at www.340Besp.com. Users that have registered an account with 340B ESP™ can begin submitting 340B claims for BI by navigating to the Claims Data Submission tab. 340B claims must be submitted within forty-five (45) days of the date of dispense in order for the contract pharmacy to remain eligible to receive 340B purchased products.

If you have any questions regarding BI's updated 340B Program contract pharmacy policy, please reach out to support@340besp.com.

Best regards,

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President U.S. Human Pharma

Boehringer Ingelheim Pharmaceuticals, Inc.

Christine Marsh

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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 ("inhouse"), 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 <u>not</u> 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 <u>not</u> 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. 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.

- 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.

If you have any questions regarding BI's updated 340B Program contract pharmacy policy, please reach out to support@340besp.com.

Best regards,

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