

UPDATE

Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer) is updating its 340B Program contract pharmacy policies

Notice to 340B Covered Entities: Effective December 2, 2024

Dear 340B Covered Entity:

Boehringer strongly supports the 340B program and is committed to maintaining and strengthening its mission for the patients we serve today and into the future. At the same time, Boehringer is concerned with the well-documented program integrity issues. We remain committed to the 340B program and believe this initiative will further strengthen the program and support its core mission to ensure patients have access to the medications they need.

I am writing to inform you that Boehringer is updating its 340B Program contract pharmacy policies. **Effective December 2, 2024, Boehringer will require the submission of claims data on 340B utilization filled at contract pharmacies for all covered entity types.** All specified claims data must be submitted on the 340B ESP™ platform within 45 days of the date of dispense.

- Our policy change applies to all covered entity types that do not have in-house pharmacy dispensing capabilities and have designated contract pharmacy location(s) per the 340B ESP™ platform. The FAQs below provide additional information on Boehringer's 340B policy.

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

Best regards,

DocuSigned by:

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Timmo Andersen
President U.S. Human Pharma
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Frequently Asked Questions

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

A: Boehringer's policy applies to all products attached in [Exhibit A](#) hereto. In addition, the list of applicable NDCs can be found at [What NDCs do we look for? | 340B ESP – Help Center](#).

Q: What covered entity types are included in Boehringer's policy?

A: All covered entity types are subject to Boehringer's 340B contract pharmacy policy.

Q: What is an in-house ('entity-owned') pharmacy?

A: An in-house ('entity-owned') pharmacy is a pharmacy that is 100% owned by the 340B covered entity and listed as shipping addresses of the entity.

Q: My covered entity does not have in-house dispensing capabilities. Does my covered entity need to submit claims data for access to its designated contract pharmacy location(s)?

A: Yes. Any 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 products purchased at the 340B price provided the covered entity submits limited claims data for that contract pharmacy location. The designated contract pharmacy must be registered on the HRSA OPAIS database as a contract pharmacy, located within a forty (40) mile radius of the covered entity parent site, and cannot be a central fill pharmacy. A wholly owned pharmacy may instead be designated as the single contract pharmacy location to receive and dispense 340B purchased primary care brands provided the covered entity submits limited claims data for that contract pharmacy location. The contract pharmacy must be registered on the HRSA OPAIS database as a contract pharmacy, located within forty (40) miles of the covered entity parent site and is not a central fill pharmacy.

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

A: Any covered entity that does not have an in-house pharmacy capable of dispensing specialty products may also designate one (1) specialty pharmacy from within Boehringer's limited distribution network for the sole purpose of receiving and dispensing OFEV at the 340B price to its patients provide the covered entity submits limited claims data for that specialty pharmacy location. A wholly owned pharmacy may instead be designated as a single contract pharmacy location to receive and dispense OFEV purchased at the 340B price provide the covered entity submits limited claims data for that specialty pharmacy location and it meets the contract pharmacy requirements as registered on the HRSA OPAIS database as a contract pharmacy and is not a central fill pharmacy.

Q: My covered entity was previously exempt from Boehringer's 340B contract pharmacy policy, is my entity required to submit claims data?

A: If your entity was previously exempt from Boehringer's policy, please reach out to support@340Besp.com for claims data requirements for your entity.

Q: My covered entity has an in-house pharmacy capable of dispensing Boehringer products. Is my covered entity required to submit claims data?

A: No, while submission of claims data is not required for 340B product dispensations at in-house pharmacies, covered entities may voluntarily submit claims level data for Boehringer products purchased at the 340B price and dispensed through their in-house pharmacies.

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

A: Yes, contract pharmacies that are wholly owned by the covered entity are subject to Boehringer's policy. A wholly owned pharmacy may be designated as the single contract pharmacy location provided it meets the contract pharmacy requirements as registered on the HRSA OPAIS database as a contract pharmacy of the

entity, is located within a forty (40) mile radius of the covered entity parent site, is not a central fill pharmacy, and the covered entity submits limited claims data for that contract pharmacy location.

Q: Does the pharmacy's location that I would like to designate as my contract pharmacy designation need to be within a forty (40) mile radius of my covered entity's parent location?

A: Yes, under Boehringer's policy, with the exception of OFEV, the single contract pharmacy designation that a covered entity has chosen to distribute Boehringer products must be within a forty (40) mile radius of the covered entity's parent location.

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

A: No. Similar to guidance provided by HRSA in 1996, Boehringer's policy allows 340B covered entities to designate only a single contract pharmacy location within forty (40) miles of the covered entity. Contract pharmacy locations are registered individually on the HRSA 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: Does Boehringer permit an entity to designate a single contract pharmacy that collectively replenishes Boehringer products based on the dispensing activity of other non-designated contract pharmacy locations?

A: No. Boehringer expects 340B products to be shipped directly to the same contract pharmacy location(s) in which the 340B product was dispensed to an eligible patient.

Q: Is Boehringer 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 for a covered entity to designate it as its single contract pharmacy. This information is important for Boehringer to manage its process with its wholesalers. Boehringer 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 December 2, 2024?

A: If your covered entity wishes to designate a contract pharmacy, please allow up to ten (10) business days for the designation to take effect.

Q: What are the requirements for submission of 340B claims data?

A: Boehringer is utilizing Second Sight Solutions' 340B ESP™ platform (www.340Besp.com) to support claims collection on behalf of all entity types. Claims data must be submitted within forty-five (45) days of the date of dispense for the contract pharmacy to continue to access 340B pricing for all Boehringer products in Exhibit A. Please see 340B ESP™ for additional details on submitting claims data, including the limited set of required data fields.

Q: How often can my covered entity change its contract pharmacy designation?

A: 340B covered entities can elect a single contract pharmacy every twelve (12) months from the date of designation or more often if the designated contract pharmacy relationship is terminated from HRSA OPAIS database. Changes to the single 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.

Exhibit A

ADALIMUMAB-ADBIM®

APTIVUS®

ATROVENT®

COMBIVENT®RESPIMAT®

CYLTEZO®

GLYXAMBI®

JARDIANCE®

JENTADUETO®

JENTADUETO XR®

MICARDIS®

MICARDIS HCT®

OFEV®

PRADAXA®

SPIRIVA® HandiHaler®

SPIRIVA® RESPIMAT®

STIOLTO® RESPIMAT®

STRIVERDI® RESPIMAT®

SYNJARDY®

SYNJARDY XR®

TRADJENTA®

TRIJARDY XR®

VIRAMUNE XR®