



Amgen USA Inc.
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December 1, 2021

Dear Customer,

I am writing to inform you that Amgen Inc. (Amgen) is altering its policy regarding the offering of 340B discounts to contract pharmacies. Effective January 3, 2022, Amgen will provide products purchased at the 340B price exclusively to locations registered as a 340B covered entity or other locations designated in accordance with Amgen's policy, as described further below. Subject to the exceptions described below, pharmacies registered as contract pharmacies will no longer be eligible for Bill To / Ship To orders. Federal grantees will remain eligible to place Bill To / Ship To orders of drugs at the 340B price for their contract pharmacies.

To ensure all 340B covered entities can access Amgen products at the 340B price, 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. Amgen is utilizing the 340B ESP™ platform to support this designation. 340B covered entities that do not have an in-house pharmacy and haven't 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.

Covered entities may also elect to submit 340B claims through 340B ESP™ for all utilization dispensed through contract pharmacies. Any covered entity that elects to submit their 340B claims will be allowed to continue Bill To / Ship To orders for its contract pharmacies. Covered entities that are interested in submitting claims data will need to register an account with 340B ESP™ to get started.

Contract pharmacies that are wholly owned by a 340B hospital or have common ownership with a health system, will remain eligible to receive Bill To / Ship To orders of drugs purchased at the 340B price. These pharmacies must be registered with HRSA as a contract pharmacy of the 340B hospital. Furthermore, if a covered entity or health system is granted an exemption from Amgen's 340B distribution policy for its wholly owned contract pharmacy(ies), it may not also designate an independent contract pharmacy. To apply for a wholly owned contract pharmacy exemption, please visit www.340besp.com/wholly_owned_application.

In support of a smooth transition to our new 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 January 3, 2022 effective date. PHS contracts administered by our wholesalers will no longer support distribution of drugs purchased at the 340B price to 340B contract pharmacies after January 3, 2022.

Best regards,

Jennifer Norton
Vice President, US Value and Access

Frequently Asked Questions

- Q Which products are subject to Amgen's policy and will that change in the future (e.g. will Amgen extend this decision to medical benefit, physician administered products in the future)?**
- A** The current policy primarily applies to self-administered, pharmacy benefit Amgen products, specifically Repatha®, Enbrel®, Otezla®, and Aimovig®. The policy does not currently apply to medical benefit products and do not intend to change that in the future.
- Q If a covered entity has a contract pharmacy relationship with a pharmacy that is owned by the covered entity's health system, is this pharmacy subject to Amgen's policy?**
- A** No, contract pharmacies that are wholly owned by the covered entity are not subject to Amgen's policy and covered entities may continue using all of their wholly owned contract pharmacies. To apply for a wholly owned contract pharmacy exemption, please visit www.340besp.com/wholly_owned_application.
- Q If a covered entity has an in-house pharmacy that is capable of purchasing and dispensing Amgen drugs, but the entity doesn't currently use it to dispense Amgen drugs, can the entity designate one contract pharmacy instead?**
- A** No, under Amgen's policy, if a covered entity has an in-house pharmacy capable of dispensing products purchased at the 340B discount price to eligible patients then the covered entity must use that pharmacy and cannot designate a contract pharmacy instead.
- Q If a 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy, can the entity designate all locations of the same pharmacy?**
- A** Amgen's policy allows 340B covered entities to designate a single pharmacy location. 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. 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 How often can a 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 can a 340B covered entity change its 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 Is Amgen 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 Amgen to manage its process with its wholesalers.

Q **If the contract pharmacy a covered entity wants to designate doesn't have a HIN, how can one be obtained?**

A Amgen will not register a HIN on behalf of a covered entity, however if a covered entity needs guidance or more information on how to get a HIN assigned to a contract pharmacy, please reach out to support@340besp.com. If a covered entity tries to designate a contract pharmacy without a HIN in 340B ESP™, the system will notify it of this requirement and provide instructions for how to obtain a HIN.

Q **How does a covered entity ensure that its contract pharmacy designation takes effect on January 3, 2022?**

A For a covered entity's contract pharmacy designation to take effect on January 3, 2022, its contract pharmacy selection needs to be made by December 10, 2021. After December 10th, please allow 10 business days for the designation to take effect, though during holiday periods it may take slightly more time to process.

Q **How long does it take for a contract pharmacy designation to take effect if the covered entity makes the designation after January 3, 2022?**

A A covered entity can designate a contract pharmacy after Amgen's policy goes into effect on January 3, 2022. If a covered entity designates after January 3, 2022, please allow ten (10) business days for the designation to take effect.

Q **If a covered entity would like to submit 340B claims for its contract pharmacies and continue purchasing Amgen products at the 340B price, what does the entity need to do to begin submitting claims data?**

A 340B covered entities that wish to submit claims data under Amgen'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 claims for Amgen by navigating to the Claims Data Submission tab.

Q **What happens if a covered entity does not provide 340B contract pharmacy claims data by the required date?**

A If a covered entity elects not to submit claims data for its contract pharmacies, the covered entity will have the option to select a single contract pharmacy if it doesn't have an in-house pharmacy capable of dispensing products purchased at the 340B discount price OR may apply for a wholly owned contract pharmacy exemption to continue using its wholly owned contract pharmacies.

ADDENDUM 1

To supplement the Frequently Asked Questions section of this letter, Amgen provides the following Frequently Asked Questions on March 15, 2022.

Q Is there a limitation on how far back replenishment orders can be placed and still receive 340B pricing, once eligibility for our specialty contract pharmacies and/or contract pharmacy designations have been processed by our wholesaler?

A All contract pharmacy replenishment orders for all covered entities registered with 340B ESP™ will be honored for prescriptions dispensed to eligible 340B patients within forty-five (45) days of each data submission to 340B ESP™. Please allow for ten (10) days for the contract pharmacy designations to take effect with your wholesaler after your initial Amgen claims submission to 340B ESP™.

Q How extensive does my claims data need to be, in order to continue to have 340 priced drugs shipped to my contract pharmacies? If I submit data for some contract pharmacies, can I continue to receive 340B pricing for all of them?

A Amgen has provided the option to participate in the integrity program to give covered entities the ability to provide claims data (including commercial claims data and Medicare claims data) to Amgen. Under the program, covered entities may continue to ship drugs at the 340B price only to those contract pharmacies for which covered entities have provided claims data (including commercial claims data and Medicare claims data) as part of the program.

Q How do you intend to use the claims data if we provide it as part of the integrity program?

A This data is used solely to allow Amgen to identify potential duplicate discounts. Please refer to 340B ESP Terms of Use for more detailed information about how your data will be used.