

Dear 340B Covered Entity,

I am writing to inform you that Genentech is updating its 340B contract pharmacy policy. This decision was made after careful assessment of the landscape, and Genentech's updated policy does not change product access to Genentech medicines for eligible covered entities and patients.

**What is changing for hospital covered entities?** Effective **May 1, 2024**, except for the limited exceptions described below or in the attached FAQs, Genentech will limit 340B pricing exclusively to:

- Locations registered in the Health Resources & Service Administration (HRSA) database as a 340B covered entity or child site location affiliated with that covered entity
- A **single** contract pharmacy location registered in HRSA database, designated by the 340B Covered Entity or child site, in cases where the covered entity does not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients

This change is applicable to the Genentech portfolio of medicines that is adjudicated through a retail or specialty pharmacy, and will not apply to Hemlibra and Evrysdi. Genentech encourages voluntary submission of claims to support program transparency.

**What is changing for federal grantee<sup>1</sup> covered entities?** There is **no change** for **federal grantee** covered entities<sup>1</sup>. Federal grantees will remain eligible to place Bill To / Ship To replenishment orders of 340B priced drugs for their contract pharmacies. No action is required by federal grantees as it relates to Genentech's 340B contract pharmacy policy.

Genentech is utilizing the 340B ESP™ platform to support this designation and claims submission. 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](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).

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<sup>1</sup> Federal grantees eligible for 340B participation under 42 U.S.C. § 256b(a)(4)(A)-(K)



*A Member of the Roche Group*

**Non-grantee covered entities must take action by April 22nd, 2024 in order for contract pharmacy location designations to take effect on the effective date (May 1st, 2024) of the policy.**

Please allow up to 10 business days for the designation to take effect for selections made after May 1st, 2024.

In support of a smooth transition to our updated contract pharmacy policy, 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 May 1st, 2024 effective date.

Best regards,

*Suzie Tam Porter*

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Vice President Channel & Contract Management

## Frequently Asked Questions

### **Q: Which products are covered under Genentech's new contract pharmacy policy?**

A. Genentech's new contract pharmacy policy applies to all Genentech products with the exception of HEMLIBRA® (emicizumab-kxwh) and Evrysdi® (risdiplam). Up to-date list of Genentech's products and Genentech's policy can be found on <https://help.340besp.com/en/articles/4455011-what-ndcs-do-we-look-for>.

### **Q: Which covered entities are subject to Genentech's new contract pharmacy policy?**

A. All eligible 340B covered entities, with the exception of federal grantees such as Ryan White program grantees, hemophilia centers etc. (eligible for 340B participation under 42 U.S.C. § 256b(a)(4)(A)-(K)), are subject to this new contract pharmacy policy.

### **Q. My covered entity is a federal grantee, does my covered entity have to change the way we order 340B drugs for the contract pharmacies that we currently use?**

A. No, federal grantees<sup>1</sup> are exempt from Genentech's updated policy. Federal grantees will remain eligible to place Bill To / Ship To replenishment orders of 340B priced drugs for their contract pharmacies

### **Q. My 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy company. Can my entity designate all locations of the same pharmacy company?**

A. If a hospital covered entity does not have in-house dispensing capabilities, only a single contract pharmacy location can be designated via the Designations form on [www.340besp.com/designations](http://www.340besp.com/designations).

### **Q. If a covered entity has an in-house pharmacy that is capable of purchasing and dispensing Genentech products, but doesn't currently use it to dispense Genentech products, can that entity designate one contract pharmacy instead?**

A. No. Under Genentech's policy, if a covered entity has an in-house pharmacy capable of dispensing all of GNE's 340B products included in this policy, then the entity must use that pharmacy and cannot designate a contact pharmacy instead.

**Q. How often can a covered entity change its contract pharmacy location designation?**

A. A covered entity can change its contract pharmacy location designation once every 12 months from the date of designation.

A covered entity may change its contract pharmacy location designation within a 12-month period only if the designated contract pharmacy location is terminated as a contract pharmacy of the covered entity from the 340B OPAIS database. Changes to the single contract pharmacy can only be made by visiting [www.340Besp.com/designations](http://www.340Besp.com/designations).

**Q. How would a covered entity change its contract pharmacy location designation?**

A. Changes to a contract pharmacy location designation can be made at [www.340besp.com/designations](http://www.340besp.com/designations).

**Q. How does a covered entity ensure its contract pharmacy designation will be in effect on May 1st?**

A. Covered entities must take action by April 22nd, 2024 in order for contract pharmacy location designations to take effect on the effective date (May 1st, 2024) of the policy. Please allow 10 business days for the designation to take effect post policy update.

If a hospital covered entity does not have in-house dispensing capabilities, it may complete the form to designate a single contract pharmacy location at [www.340besp.com/designations](http://www.340besp.com/designations).

**Q. Is Genentech requiring covered entities to have a HIN registered for the contract pharmacy that they designate?**

A. Yes, a contract pharmacy must have a Health Industry Number (HIN) assigned to it in order for a covered entity to designate it as its single contract pharmacy. This information is important for Genentech to manage its process with its wholesalers.

**Q. If the contract pharmacy my covered entity wants to designate doesn't have a HIN, how does my entity get one?**

A: Genentech 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](mailto:support@340besp.com).



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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: My covered entity would like to submit 340B claims for its contract pharmacies and continue purchasing Genentech products at the 340B price. What does our entity need to do to begin submitting 340B claims?**

A: 340B covered entities that wish to submit 340B claims under Genentech's policy can do so by registering an account at [www.340Besp.com](http://www.340Besp.com). Users that have registered an account with 340B ESP™ can submit 340B claims for Genentech by navigating to the Claims Data Submission tab.

Although we encourage claim submission to support 340B program integrity, doing so does not change application of the Genentech contract pharmacy policy.