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May 19, 2025

Dear 340B Covered Entity,

We write to inform you that effective May 31, 2025, Genentech is updating its 340B contract pharmacy policy as set forth below. Updates will become applicable to hospital covered entities; there is no change for federal grantee[1] covered entities. Hospital covered entities with an existing single contract pharmacy designation will not need to redesignate.

1. Claims data submission.
A hospital covered entity without an in-house outpatient pharmacy may designate one contract pharmacy location. Genentech will facilitate bill to/ ship to orders of 340B priced medicines to that location only, provided that the covered entity submits limited claims data on 340B utilization for such contract pharmacy location.

2. Redistribution of 340B drug.
Covered entities may ship 340B drugs only through Genentech-authorized distribution channels and only to the location of actual dispense of the 340B drug. Any drug product subject to other, non-transparent arrangements affecting a 340B drug (including but not limited to "banking" orders outside of the reasonable window, virtual return, alternative distribution models, consolidated replenishment, central fill, or virtual credit) falls outside of this policy and Genentech does not consider qualified as a 340B drug and may result in chargeback reversal or other action.

These updates reflect the inclusion of standard business practices that support 340B program integrity. We also believe product integrity is essential to ensuring patient safety, and Genentech works with its authorized distributors to ensure that our medicines are handled appropriately as they are stored, transported, and distributed throughout the supply chain.

In addition, Genentech has updated the FAQ section of our 340B contract pharmacy policy, provided below. All other aspects of our policy remain the same as in our previous policy letter that became effective May 1, 2024.

Best regards,

Suzie Tam Porter

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Vice President Channel & Contract Management

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

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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). An 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[1] 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.

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.

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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.

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.

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. 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. Users that have registered an account with 340B ESP™ can submit 340B claims for Genentech by navigating to the Claims Data Submission tab.

Q: What are the requirements for submission of claims data for hospital covered entities?

A: The claims data submission requirement applies to hospital covered entities without an in-house outpatient pharmacy that designate one contract pharmacy location. All specified claims data must be submitted within 45 days of the date of dispense to your covered entity's patient. Please submit claims data within the specified time period to ensure your designated contract pharmacy location remains eligible to receive 340B priced medicines. If purchases for the designated contract pharmacy location exceed conforming claims submitted according to this policy, this may result in the designated contract pharmacy losing eligibility to receive 340B priced medicines. The 340B ESP™ platform requires claims uploads on the 1st and 16th of every

month. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform. Please see 340B ESP™ at www.340BESP.com for additional details on submitting claims data, including the limited set of required data fields.

Q: How will Genentech use the 340B claims data that covered entities provide through 340B ESP™?

A: Contract pharmacy claims data uploaded by 340B covered entities may be used to identify and resolve certain ineligible rebates (including in Medicaid, Medicare Part D, TRICARE, commercial payer rebates, and multiple 340B rebate requests on a single dispense), determine compliance with Genentech's 340B integrity initiative, and determine eligibility for placing certain 340B orders under the policy. Only one covered entity may claim the 340B discount on each 340B-eligible dispense.

Q: What happens if my hospital covered entity is unable to provide claims data in conformance with Genentech's policy?

A: Failure to provide claims data in conformance with the requirements of this policy may result in the designated contract pharmacy losing eligibility to receive 340B priced medicines. If you encounter challenges in submitting conforming claims data, please reach out to 340B ESP™ with questions. Please also ensure that your covered entity's contract pharmacy administrator is aware of these policy requirements and takes any appropriate steps to assist with the submission of claims data. Specified claims data must be submitted within 45 days of the date of dispense to the covered entity's patient.

Q: Does Genentech permit an entity to tally dispensing activity from non-designated contract pharmacy locations and then, based on that tallying, place subsequent orders to be shipped to a different, single designated contract pharmacy or entity-owned location?

A: No. Contract pharmacy designations are specific to a location registered individually on the HRSA database by name and physical location, and 340B dispensing activity must occur at this location in order for the location to receive 340B drugs. Per the 340B statute, covered entities may not resell or otherwise transfer 340B covered outpatient drugs to a person who is not a patient of the covered entity. For reference, please also view HRSA/Apexus FAQ 1341.

Q: Does Genentech permit an entity to designate a single contract pharmacy 'replenishment' location, include dispensing activity from several other non-designated contract pharmacy locations of the same organization, and then create replenishment orders based on all the dispensing activity to a single replenishment location?

A: No. Contract pharmacy designations are specific to a location registered individually on the HRSA database by name and physical location. To ensure transparency and program integrity, Genentech expects that all dispensing to 340B eligible patients will occur at the properly designated contract pharmacy location(s), and that 340B drugs will be shipped directly to that location either by Genentech or an authorized distributor.

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Q: What are a few examples of Genentech program integrity expectations, aligned with the 340B statute?

A: To support covered entity stewardship of 340B discounts, and consistent with obligations under the 340B statute, Genentech expects covered entities, including those that use contract pharmacies, to maintain auditable records that confirm program integrity and to request or otherwise seek 340B pricing in a transparent manner. For example, the records should reflect that:

a. Diversion does not occur (i.e., 340B-eligible individuals receive 340B drugs used in connection with a service received at an OPAIS-registered entity location, only one 340B discount is claimed per 340B-eligible patient transaction, entities do not otherwise transfer the 340B drug to a person who is not a patient of the entity, and the covered entity complies with all applicable laws, including distribution laws, etc.).

b. Prohibited 340B duplication does not occur (i.e., an entity does not request a 340B discount or cause a 340B discount to be given on a transaction that is subject to a Medicaid rebate (including all types of Medicaid)).