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July 31, 2026

Dear 340B Covered Entity,

We write to inform you that effective August 31, 2026, Genentech is updating its 340B policy as set forth below. As the 340B landscape continues to evolve, Genentech remains firmly committed to the original mission of the 340B program. To strengthen program integrity, expand transparency, and support the accurate deduplication of statutory rebates—including Medicaid and Medicare Inflation Reduction Act Maximum Fair Price (MFP) obligations—we are implementing standard industry business practices across our portfolio. Please note HEMLIBRA® (emicizumab-kxwh) and Evrysdi® (risdiplam) continue to be excluded from our 340B contract pharmacy policy and are excluded from the changes below.

**Summary of Key Policy Changes**

- **Universal Claims Data Submission:** Genentech is expanding its claims-level data (CLD) collection requirements. Submission of 340B claims data will now be mandatory for **all Covered Entity (CE) types** across all utilization channels, encompassing both **pharmacy benefit** and **medical benefit** products. This includes all 340B dispenses and administrations from entity in-house pharmacies, any outpatient facilities, and designated contract pharmacies.
- **Inclusion of Grantees:** Federal grantee covered entities, previously excluded or exempted under our prior contract pharmacy policy, are **now fully subject to all requirements of this updated policy**, including universal claims data submission.
- **Contract Pharmacy Geographic Limitation:** To support localized patient care and programmatic transparency, any designated contract pharmacy must be located **within a 40-mile radius** of the associated Covered Entity's registered location.

**Updated Policy Details**

**1. Data Requirements for all 340B Dispenses & Administrations**

All covered entities must submit complete and accurate claims-level data (CLD) elements for all 340B utilization for applicable covered outpatient drugs. This includes utilization for all dispenses and administrations for all CE types across all utilization channels, including but not limited to entity-owned pharmacies, any outpatient facilities and any eligible, designated contract pharmacies. Data must be submitted within 45 calendar days of the date of dispense or service via the 340B ESP™ platform. Failure to provide timely and complete data may result in a suspension of access to 340B pricing for applicable products until the outstanding data is validated.

**2. Contract Pharmacy**

For covered entities that utilize contract pharmacy arrangements, Genentech will facilitate bill-to/ship-to distribution of 340B purchased products subject to the following criteria:

- Covered Entities: Genentech’s policy will be expanded to include Federal Grantees[1].

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- Geographic Radius: Covered entities that do not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients must designate a single contract pharmacy location within 40 miles of the Covered Entity's registered physical address. Covered entities that have already designated a single contract pharmacy that is within 40 miles do not need to redesignate.
- Data Submission: Covered entities must submit complete CLD for all 340B utilization through the contract pharmacy within 45 calendar days of the dispense date.

The remaining elements of Genentech's policy regarding contract pharmacies continue to be applicable. Including the below:

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. Only one covered entity may claim the 340B discount on a given dispense.

**3. Data Submission Protocol**

Genentech utilizes the 340B ESP™ platform (administered by Second Sight Solutions) as the **only accepted method** for covered entities to register accounts, manage contract pharmacy designations, and securely upload required claims data. Covered entities that have not submitted claims for Genentech’s policy in the past can register at 340BESP.com. In addition, Genentech has updated the FAQ section of our 340B policy, provided below.

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: Why is Genentech expanding its 340B policy requirements?**

A: Universal claims-level data (CLD) collection provides the necessary transparency to confirm 340B eligibility, prevent unlawful diversion, and fulfill statutory mandates to eliminate duplicate discounts across Medicaid, Medicare Part D, and Inflation Reduction Act Maximum Fair Price (MFP) frameworks.

**Q: My covered entity is a federal grantee. Does this policy apply to us?**

A: Yes. Under the updated policy, federal grantees (eligible under 42 U.S.C. § 256b(a)(4)(A)-(K)) are no longer exempt. Grantees must comply with all terms, including the 40-mile contract pharmacy geofence and mandatory CLD submissions for both in-house and contract pharmacies. Grantees that wish to submit 340B claims under Genentech's policy can do so by registering an account at www.340BESP.com. Covered entities that have registered an account with 340B ESP™ can submit 340B claims for Genentech by navigating to the Claims Data Submission tab.

**Q: What products are subject to this policy, and does it include medical benefit drugs?**

A: This policy applies to Genentech's entire portfolio of covered outpatient drugs (except for HEMLIBRA® (emicizumab-kxwh) and Evrysdi® (risdiplam); covered entities may voluntarily submit claims for these products). The requirement has expanded to cover **both pharmacy benefit and medical benefit utilization** (dispenses via a pharmacy as well as administrations in a clinical or medical setting). An up-to-date list of Genentech's products and Genentech's policy can be found on the 340BESP.com website.

**Q: How is the 40-mile contract pharmacy geofence calculated?**

A: The designated contract pharmacy location must be physically located within 40 miles of the Covered Entity (or child site) utilizing that contract pharmacy. Compliance with this geographic boundary will be validated through the HRSA OPAIS database and the 340B ESP™ platform during the designation process.

**Q: What happens if our covered entity fails to submit the required claims data within the 45-day window?**

A: Covered entities that fail to accurately and completely submit the required data elements within 45 calendar days of the date of service/dispense will be deemed non-compliant. Non-compliance may result in a temporary suspension of access to 340B pricing for the applicable products until the missing data is fully submitted and validated.

**Q: We only dispense Genentech products through our entity-owned, in-house pharmacy. Are we impacted?**

A: Yes. Previously, in-house pharmacies were not required to submit data. Effective with this policy update, all covered entities must submit CLD via 340B ESP™ for all in-house pharmacy dispenses and administrations to maintain uninterrupted access to 340B pricing.

**Q: What specific data elements are required for our submissions?**

A: The required data encompasses standard, routine information routinely gathered by covered

entities and third-party administrators during standard replenishment workflows. A list of required data elements can be viewed at the following links:

- Pharmacy Claims Data Table: www.340besp.com > FAQ > 'Pharmacy Claims Data Table'
- Medical Claims Data Table: www.340besp.com > FAQ > 'Medical Claims Data Table'

**Q: How do we register or submit our data?**

A: Covered entities must register and manage their accounts online at **www.340BESP.com**. Technical questions regarding registration, templates, or file uploads can be directed to **support@340besp.com**.

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

A. As of Aug 31, 2026, all eligible 340B covered entities are subject to Genentech's contract pharmacy policy.

**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 does a covered entity ensure its contract pharmacy designation will be in effect on the effective date?**

A. Covered entities must take action by August 22, 2026 in order for contract pharmacy locations to take effect on the effective date (August 31, 2026). 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. 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. 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 in-house pharmacy or contract pharmacy 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 covered entities?**

A: The claims data submission requirement applies to all 340B dispenses of a covered entity. All specified claims data must be submitted within 45 calendar days of the date of dispense to your covered entity's patient. Please submit claims data within the specified time period to ensure your covered entity or designated contract pharmacy location remains eligible to receive 340B priced medicines. If purchases for the covered entity or designated contract pharmacy location exceed conforming claims submitted according to this policy, this may result in the covered entity or 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: 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.

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**Q: What happens if my 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 covered entity or 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. If applicable, 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 calendar 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.

**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)).