Amgen USA Inc.
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MODIFIED AUGUST 26, 2026 TO REFLECT AN UPDATE TO AMGEN'S 340B PROGRAM INTEGRITY POLICY

Dear Valued Customer,

On May 15, 2026, Amgen communicated an update to its 340B Program Integrity Policy. This update included two changes:

- Effective June 1, under Amgen's updated policy, covered entities that wish to accept Amgen's offers of sale for 340B pricing must submit claims-level data for all 340B pharmacy and medical dispenses, including in-house pharmacy and contract pharmacy utilization, for all Amgen products to *www.340besp.com*. In addition, covered entities with an in-house pharmacy capable of dispensing 340B drugs to patients may no longer use contract pharmacy arrangements. Covered entities without an in-house pharmacy may designate a single contract pharmacy location.

- Beginning November 15, 2026, covered entities that wish to accept Amgen's offers of sale for 340B pricing must submit standard healthcare visit and service claims data for applicable 340B pharmacy and medical claims submitted through the 340B ESP platform. Claims-level data for pharmacy dispenses and medical claims must be submitted within 45 days of product dispense and 60 days of administration, respectively. This data includes standard, anonymized information about interactions between providers and patients resulting in the dispensing or administration of 340B-priced Amgen products. Additional details, including required data fields, field descriptions, file format, submission procedures, and platform instructions, will be available through 340B ESP in the FAQs section. Covered entities should refer to 340B ESP for the current operational requirements for submitting claims-level data.

Except as described in this notice, Amgen's policy will remain unchanged and is set forth below. Amgen reserves the right to further update or modify this policy at its discretion.

Amgen's Policy

Amgen will facilitate delivery of products purchased at the 340B price exclusively to locations registered as 340B covered entities or other locations designated in accordance with Amgen's policy, as described below. Subject to the following exceptions, pharmacies registered as contract pharmacies will not be eligible to receive Bill To / Ship To orders. Amgen's 340B policy will apply as described below in all states other than the states listed in **Attachment A.**

Effective June 1, 2026, covered entities that wish to accept Amgen's offers of sale for 340B pricing must submit claims-level data for all 340B pharmacy and medical dispenses for all Amgen products

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to *www.340besp.com*. Claims-level data for pharmacy dispenses and medical claims must be submitted within 45 days of product dispense and 60 days of administration, respectively. Failure to submit timely, complete, and accurate data as requested may be considered a rejection of Amgen's reasonable offer of 340B pricing.

A covered entity may elect to designate a single contract pharmacy location if it has no in-house pharmacy. The single contract pharmacy that a covered entity elects to designate must be registered on the HRSA OPAIS database and be within 40 miles of the covered entity's parent site or grantee site (as listed in the HRSA database). Amgen will allow the use of a contract pharmacy for covered entities without an in-house pharmacy beyond the 40-mile radius where a covered entity shows that there is no contract pharmacy that can receive and dispense Amgen's drugs within a 40-mile radius of the covered entity's parent or grantee site (as listed in the HRSA database).

Covered entities that do not currently submit data can do so by registering an account at *www.340besp.com* and navigating to the Entity Profile tab. Please complete the registration promptly to be ready to submit data within the above timeline for dispenses made on or after June 1, 2026.

Sincerely,

David Zimmer
Vice President, US Value & Access
Amgen Inc.

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Frequently Asked Questions

1. **Q Which products are subject to Amgen's policy?**
   A Amgen's 340B policy applies to all of its products. Refer to ESP™ platform Product List for a List of Amgen's products subject to this policy.

2. **Q If a covered entity has a contract pharmacy relationship with a pharmacy that is wholly owned or under common ownership with the covered entity's health system, is this pharmacy subject to Amgen's policy?**

   A A covered entity may elect to designate a single contract pharmacy location if it has no in-house pharmacy. The single contract pharmacy that the covered entity elects to designate must be registered on the HRSA OPAIS database and be within 40 miles of the covered entity's parent site or grantee site (as listed in the HRSA database). Amgen will allow the use of a contract pharmacy for covered entities without an in-house pharmacy beyond the 40-mile radius where a covered entity shows that there is no contract pharmacy that can receive and dispense Amgen's drugs within a 40-mile radius of the covered entity's parent site or grantee site (as listed in the HRSA database).

   Effective June 1, 2026, regardless of whether a covered entity elects to utilize an in-house pharmacy or a contract pharmacy, all covered entities must submit claims-level data for all 340B pharmacy and medical dispenses for all Amgen products to *www.340besp.com*. Failure to submit timely, complete, and accurate data as required will be considered a rejection of Amgen's reasonable offer of 340B pricing.

3. **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, a covered entity that has an in-house pharmacy capable of dispensing 340B purchased drugs to its patients cannot designate a contract pharmacy location. A covered entity may only elect to designate a single contract pharmacy location if it has no in-house pharmacy. The single contract pharmacy that a covered entity elects to designate must be registered on the HRSA OPAIS database and be within 40 miles of the covered entity's parent site or grantee site (as listed in the HRSA database). Amgen will allow the use of a contract pharmacy for covered entities without an in-house pharmacy beyond the 40-mile radius where a covered entity shows that there is no contract pharmacy that can receive and dispense Amgen's drugs within a 40-mile radius of the covered entity's parent site or grantee site (as listed in the HRSA database).

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4. **Q What happens if a covered entity does not have an in-house pharmacy that is capable of purchasing and dispensing Amgen drugs and does not have a contract pharmacy within the 40-mile radius of the parent site, or grantee site as listed in the HRSA database?**

   A Amgen will allow the use of a contract pharmacy beyond the 40-mile radius if a covered entity shows that (1) it lacks an in-house pharmacy capable of purchasing and dispensing Amgen's drugs and (2) there is no contract pharmacy capable of receiving and dispensing Amgen's drugs within a 40-mile radius of the covered entity's parent site, or grantee site as listed on the HRSA database.

5. **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 contract pharmacy location. Contract pharmacy locations are registered individually on the HRSA database and eligible 340B covered entities are permitted to designate a single contract pharmacy location which corresponds to a single contract pharmacy registration with HRSA.

6. **Q How can a 340B covered entity change its contract pharmacy designation?**

   A Covered entities may change their contract pharmacy designations once every twelve (12) months (from the date of first designation) or more often if the designated contract pharmacy is terminated from the HRSA OPAIS database. 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.

7. **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.

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

   A Amgen cannot register a HIN on behalf of a covered entity or contract pharmacy. 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 the covered entity of this requirement and provide instructions for how to obtain a HIN.

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9. **Q How many days does it take for a contract pharmacy designation made by a covered entity to take effect?**

   A Please allow 10 business days for a covered entity's contract pharmacy designation to take effect.

10. **Q What are the requirements for submitting 340B claims data?**

    A All claims-level data for pharmacy dispenses and medical claims are required to be submitted within 45 days of product dispense and 60 days of administration, respectively. Please see www.340Besp.com for additional details on submitting claims data, including the limited set of required data fields. Failure to submit timely, complete, and accurate data as requested will be considered a rejection of Amgen's reasonable offer.

11. **How will Amgen use 340B claims level data that CEs submit through the ESP™ Platform?**

    A 340B claims level data submitted by 340B CEs will be used to identify and deduplicate Maximum Fair Price (MFP) discounts and determine eligibility for certain replenishment orders under the policy.

12. **Q Is there a limitation on how far back replenishment orders can be placed and still receive 340B pricing, once eligibility for our contract pharmacy designation has 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™.

13. **Q If a covered entity with an in-house pharmacy currently uses a contract pharmacy, how do they update their designation to comply with Amgen's policy after June 1, 2026?**

    A No action is required from the covered entity. Beginning June 1, 2026 contract pharmacy claims will no longer be accepted for a covered entity with an in-house pharmacy. Covered entities will continue to be able to submit claims for their in-house pharmacy. If you have any questions, please contact support@340besp.com.

14. **Q Where can covered entities find the requirements and submit standard healthcare visit and service claims data?**

    A Covered entities should refer to the 340B ESP platform for operational submission

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details, including required fields, file formats, templates, and technical instructions. Operational or technical questions may be directed to 340B ESP support at support@340besp.com.

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Attachment A

Arkansas: Effective April 2, 2024, contract pharmacy arrangements between 340B covered entities located in Arkansas and contract pharmacies located in Arkansas are exempt from Amgen's 340B policy. Covered entities in Arkansas do not need to submit claims-level data for their in-house or contract pharmacies in Arkansas.

Maryland: Effective July 1, 2024, contract pharmacy arrangements between 340B covered entities located in Maryland and contract pharmacies located in Maryland are exempt from Amgen's 340B policy. Covered entities in Maryland do not need to submit claims-level data for their in-house or contract pharmacies in Maryland.

Mississippi: Effective July 1, 2024, contract pharmacy arrangements between 340B covered entities located in Mississippi and contract pharmacies located in Mississippi are exempt from Amgen's 340B policy. Covered entities in Mississippi do not need to submit claims-level data for their in-house or contract pharmacies in Mississippi.

Missouri: Effective August 28, 2024, contract pharmacy arrangements between 340B covered entities located in Missouri and contract pharmacies located in Missouri are exempt from Amgen's 340B policy. Covered entities in Missouri do not need to submit claims-level data for their in-house or contract pharmacies in Missouri.

Nebraska: Effective April 9, 2025, contract pharmacy arrangements between 340B covered entities located in Nebraska and contract pharmacies located in Nebraska are exempt from Amgen's 340B policy. Covered entities in Nebraska do not need to submit claims-level data for their in-house or contract pharmacies in Nebraska.

Vermont: Effective June 1, 2025, contract pharmacy arrangements between 340B covered entities located in Vermont and contract pharmacies located in Vermont are exempt from Amgen's 340B policy. Covered entities in Vermont do not need to submit claims-level data for their in-house or contract pharmacies in Vermont.

Tennessee: Effective June 2, 2025, contract pharmacy arrangements between 340B covered entities located in Tennessee and contract pharmacies located in Tennessee are exempt from Amgen's 340B policy. Covered entities in Tennessee do not need to submit claims-level data for their in-house or contract pharmacies in Tennessee.

South Dakota: Effective July 1, 2025, contract pharmacy arrangements between 340B covered entities located in South Dakota and contract pharmacies located in South Dakota are exempt from Amgen's 340B policy. Covered entities in South Dakota do not need to submit claims-level data for their in-house or contract pharmacies in South Dakota.

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Hawaii: Effective July 1, 2025, contract pharmacy arrangements between 340B covered entities located in Hawaii and contract pharmacies located in Hawaii are exempt from Amgen's 340B policy. Covered entities in Hawaii do not need to submit claims-level data for their in-house or contract pharmacies in Hawaii.

Oregon: Effective February 17, 2026, contract pharmacy arrangements between 340B covered entities located in Oregon and contract pharmacies located in Oregon are exempt from Amgen's 340B policy. Covered entities in Oregon do not need to submit claims-level data for their in-house or contract pharmacies in Oregon.

Louisiana: Effective August 1, 2026, contract pharmacy arrangements between 340B covered entities located in Louisiana and contract pharmacies located in Louisiana are exempt from Amgen's 340B policy. Covered entities in Louisiana do not need to submit claims-level data for their in-house or contract pharmacies in Louisiana.

Minnesota: Effective August 1, 2026, contract pharmacy arrangements between 340B covered entities located in Minnesota and contract pharmacies located in Minnesota are exempt from Amgen's 340B policy. Covered entities in Minnesota do not need to submit claims-level data for their in-house or contract pharmacies in Minnesota.