

NOTICE REGARDING BRISTOL MYERS SQUIBB 340B PRACTICE

October 6, 2023

Dear Valued 340B Customer,

This notice describes updates to BMS's 340B practice that will become applicable to all 340B covered entity types.

Effective November 1, 2023, BMS will recognize up to **three** designated 340B contract pharmacy locations for each 340B covered entity that does not have its own entity-owned pharmacy (as described in the FAQs below): one for certain of our covered outpatient drugs (non-IMiDs), a second for our immunomodulatory drugs (IMiDs) (Revlimid®, Pomalyst®, and Thalomid®), and a third for Camzyos®. BMS will continue to offer 340B prices on drugs sold to covered entities and delivered to their entity-owned pharmacies, in compliance with applicable law. To ensure transparency and program integrity at designated contract pharmacies, BMS 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 BMS or an authorized distributor.

Non-IMiDs. BMS will permit each covered entity that lacks its own entity-owned pharmacy to select and utilize a single designated contract pharmacy location for non-IMiD products (excluding Camzyos®). The non-IMiD contract pharmacy location selected by the covered entity need not be the same pharmacy as the IMiD or Camzyos® contract pharmacy location, although it may be.

IMiDs. 340B covered entities that are not already part of the IMiD limited distribution network will have the option to access the IMiDs at 340B prices through one in-network IMiD-designated specialty contract dispensing pharmacy location per applicable covered entity. This update does not amend or expand the IMiD limited distribution network of pharmacies and will not affect access to the IMiDs for any patient. Patients receiving IMiDs will still be able to receive their medications from the same dispensaries. Entities that choose to access IMiDs at 340B prices at an IMiD-designated specialty contract pharmacy location will submit claim information to BMS directly. Only one 340B purchase may occur on a single eligible IMiD prescription. Multiple 340B requests on a single prescription will not be allowed.

Camzyos®. 340B covered entities that are not already part of the Camzyos® limited distribution network will have the option to access Camzyos® at 340B prices through one in-network Camzyos®-designated specialty contract dispensing pharmacy location per applicable covered entity.

Contract Pharmacy Designations. Covered entities must make contract pharmacy designations at least 15 calendar days in advance of the date of their first purchase under this practice. Contract pharmacy designations may be made by visiting <https://www.340besp.com/designations>.

Questions regarding these 340B practice updates may be submitted to BMS340B@bms.com.

BMS remains committed to working with covered entities to protect the integrity of the 340B program and to help ensure that uninsured and low-income patients can access the medications they need at the 340B price. BMS will continue to apply its practice as circumstances require to fulfill applicable legal obligations and support practice requirements.

BMS 340B Update Frequently Asked Questions

- 1. Q: What if my covered entity does not have a pharmacy capable of purchasing and dispensing BMS products?**
A: BMS will allow a covered entity to designate up to three contract pharmacies upon attestation and availability of auditable records sufficient to support that the covered entity does not have an entity-owned pharmacy capable of purchasing and dispensing the applicable BMS 340B drugs. The ability to designate a contract pharmacy does not in any way extend this pricing to entities or individuals that do not meet program eligibility. Covered entities are responsible for ensuring that their particular contracting arrangements and operations conform to the requirements of all applicable laws and regulations. Upon request, participating covered entities will provide copies of their contract pharmacy service agreements to BMS.
- 2. Q: What does BMS consider to be auditable records sufficient to support that a covered entity does not have a pharmacy capable of purchasing and dispensing BMS's 340B drugs?**
A: BMS will consider information from auditable records that BMS determines is sufficient to support that a covered entity does not have an entity-owned pharmacy capable of purchasing and dispensing the applicable BMS 340B drugs, along with the entity's attestation.
- 3. Q: What is an "entity-owned pharmacy"?**
A: An "entity-owned pharmacy" is a pharmacy that is 100% owned by the covered entity, is capable of dispensing the applicable BMS 340B covered outpatient drugs, is licensed or permitted by the state, and is not listed on OPAIS as a contract pharmacy for the entity. This may include but is not limited to a specialty pharmacy, retail pharmacy, central fill pharmacy, etc. Such a pharmacy may be listed as a ship-to address on OPAIS. Any pharmacy that does not meet the definition of entity-owned pharmacy (including a partially entity-owned pharmacy, a pharmacy owned by an entity other than the covered entity, including a parent or affiliated corporation other than the 340B covered entity, etc.) may receive 340B drugs only if it is designated as the contract pharmacy for that entity. Merely listing a non-entity owned pharmacy (i.e., a contract pharmacy) as a ship-to address on OPAIS does not confer entity-owned status on the pharmacy.
- 4. Q: What are a few examples of BMS 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, BMS expects covered entities, including those that use contract pharmacies, to maintain auditable records that confirm program integrity. 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 (e.g., 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)).
- 5. Q: Are any covered entity types exempt from the requirements of this practice?**
A: No. BMS's 340B practice applies to all covered entity types, effective November 1, 2023. Any prior exemptions will not apply.
- 6. Q: Which wholesale distributors may establish arrangements with 340B covered entities for a non-IMiD designated contract pharmacy?**
A: Distribution arrangements for the non-IMiD designated contract pharmacy may be established with any licensed

wholesaler or distributor that is authorized by BMS to distribute BMS non-IMiD products.

7. Q: How do I change my contract pharmacy designation?

A: Covered entities may designate contract pharmacies every calendar year. Covered entities with contract pharmacy arrangements terminated mid-year may designate replacement contract pharmacies. Changes to designated contract pharmacies can be made by visiting <https://www.340besp.com>.

8. Q: Will BMS require that pharmacies have HIN assignments to be designated as contract pharmacies?

A: Yes. A contract pharmacy must have a HIN assigned for a covered entity to designate it as a contract pharmacy.

9. Q: If the contract pharmacy I want to designate does not have a HIN, how do I obtain one?

A: BMS cannot register a HIN on behalf of any pharmacy. However, if you need guidance or more information on how to get a HIN assigned to your contract pharmacy, please reach out to BMS340B@bms.com. If you try to designate a contract pharmacy location without a HIN in 340B ESP™, the system will notify you of this requirement and provide instructions on how to obtain a HIN.

10. Q: How will the limited distribution specialty pharmacy network for Revlimid®, Pomalyst®, and Thalomid® (the “IMiDs”) function with 340B contract pharmacies?

A: Details about 340B contract pharmacies within the IMiD limited distribution specialty pharmacy network include:

- **In-network specialty contract pharmacies:** The limited distribution specialty pharmacy locations that may serve as 340B contract pharmacies to dispense Revlimid®, Pomalyst®, and Thalomid® can be found at <https://www.340besp.com/designations> during the designation process. No other pharmacies may serve as IMiD-designated specialty contract pharmacies.
- **In-network 340B-owned pharmacies:** A 340B covered entity that is already part of the IMiD limited distribution network may continue to purchase IMiDs directly from BMS. These entity-owned pharmacies may not serve as IMiD-designated specialty contract pharmacies for any other covered entity.
- **Distribution:** Revlimid®, Pomalyst®, and Thalomid® are directly shipped from BMS to the specialty pharmacy network. Contract pharmacy orders will be facilitated via drop ship exclusively by AmerisourceBergen Corporation.
- **Information:** Information submission includes: 340B ID, covered entity name, prescription ID, dispense date, NDC, quantity, contract pharmacy name, HIN and DEA number. BMS will provide a submission template to the covered entity upon finalization of the covered entity’s IMiD-designated specialty contract pharmacy request.

11. Q: Why will the existing limited distribution network for Revlimid®, Pomalyst®, and Thalomid® remain closed/limited?

A: Revlimid®, Pomalyst®, and Thalomid® may cause birth defects or embryo-fetal death. At the direction of the FDA, Celgene implemented a Risk Evaluation and Mitigation Strategy (“REMS”) for these products. The REMS mandates that only a trained network of providers subject to contractual agreement with BMS/Celgene may dispense the product. Additionally, the REMS requires BMS/Celgene to engage in rigorous training, certification, auditing, and monitoring activities. To satisfy its ongoing REMS obligations in a manner that optimizes both patient safety and access, Celgene adopted a limited distribution network of specialty pharmacies, hospitals, and clinics that are authorized to purchase and dispense these three products. The network remains sufficient to meet patient needs to access the products.

12. Q: Our 340B covered entity pharmacy is not currently included in the IMiD limited distribution network. Does this change mean that our 340B covered entity pharmacy is now approved to dispense these medicines?

A: No. This change has no effect on which pharmacies are included in the IMiD limited distribution network. Our

practice permits non-network covered entities to designate one IMiD specialty 340B contract pharmacy location.

13. Q: Our entity-owned pharmacy is capable of purchasing and dispensing 340B-priced drugs, but we do not use it to dispense BMS drugs, or we otherwise prefer to utilize a contract pharmacy. May we, nevertheless, designate contract pharmacies?

A: No. If a covered entity has an entity-owned pharmacy capable of purchasing at the 340B price and dispensing, the entity may not designate a contract pharmacy for Non-IMiDs. If a covered entity has an entity-owned pharmacy that is part of the IMiD network, the entity may not designate an IMiD specialty contract pharmacy. Similarly, if a covered entity has an entity-owned pharmacy that is part of the Camzyos® network, the entity may not designate a Camzyos® specialty contract pharmacy.

14. Q: After designating an IMiD specialty contract pharmacy with 340B ESP™, should I submit any additional information through the 340B ESP platform?

A: No. After designating a new IMiD specialty contract pharmacy location and providing the email address of the entity staff who will submit IMiD claims-level data, BMS will provide a claims submission template (Excel file format) to the entity. The entity should email the completed template to BMSCelgene340BRX@web.bms.com prior to each order (once the security protocols, described below, are in place).

15. Q: What kind of security is in place when I share the requested IMiD information with BMS directly (by emailing a file to BMSCelgene340BRX@web.bms.com), and what documentation can you provide to assure that?

A: Before emailing a file, BMS and the covered entity will need to use a point-to-point encryption (Transport Layer Security Wrapper) process that establishes the registered covered entity email domain and the BMS Destination (Amazon Loading Dock Service). BMS will also use Domain-based Message Authentication, Reporting, and Conformance (DMARC), Sender Policy Framework (SPF) and Domain Key Identified Mail (DKIM) to ensure emails received are from a registered covered entity domain and that messages are not altered in transit between the sending and recipient servers. Covered entities will also be asked to password protect all Excel file attachments. The password will be shared with the covered entity during the email onboarding process.

16. Q: May my 340B covered entity purchase IMiD products at the 340B price for dispensing at an IMiD-designated specialty contract pharmacy location without submitting the information requested?

A: No. BMS needs the claim-level detail (including the dispense date) to determine whether each IMiD contract pharmacy order complies with BMS's 340B practice.

17. Q: For IMiDs, if my covered entity's entity-owned pharmacy is a part of the existing limited distribution network (and can purchase IMiDs directly from BMS at the 340B price), is it necessary to submit the requested information to BMS?

A: No. Only covered entities making a new contract pharmacy designation must submit the IMiD information.

18. Q: My 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy (e.g., six different Accredo pharmacy locations). May I designate all locations of the same pharmacy as contract pharmacies?

A: No. Eligible 340B covered entities may designate a single contract pharmacy location for non-IMiDs, a single specialty contract pharmacy location for IMiDs, and a single contract pharmacy location for Camzyos®. Contract pharmacy locations are registered individually on the HRSA database by name and physical location. To ensure transparency and program integrity, BMS 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 BMS or an authorized distributor.

19. Q: Does BMS 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 Last Modified: 11/10/2014.

20. Q: How long does it take for my IMiD specialty contract pharmacy designation to take effect in AmerisourceBergen Corporation's purchasing system such that my covered entity may place a contract pharmacy order?

A: Please allow 10-15 business days for your contract pharmacy designation to take effect. For customers that are new to AmerisourceBergen Corporation, you will need to request that your 340B Third Party Administrator(s) work through their established process to request a new account setup for your designated contract pharmacy. AmerisourceBergen Corporation anticipates new account requests will be completed and communicated to your 340B Third Party Administrator(s) approximately 15 days after the receipt of all required documentation.

21. Q: May a covered entity order a full package at 340B pricing through an IMiD-designated specialty contract pharmacy, if the covered entity only has claims-level data to support use of a partial package?

A: No. BMS provides discounts and sells products based upon full package sizes only.

22. Q: If two covered entities attempt to order a 340B discounted drug to replace the same prescription number, how will BMS respond?

A: Multiple 340B requests on a single prescription (same prescription ID number) will not be allowed. BMS will honor the first 340B discount request received and deny all subsequent requests.

23. Q: Is there a timeframe limitation in placing a 340B replenishment order to an IMiD-designated specialty contract pharmacy?

A: BMS will accept and process contract pharmacy replenishment orders that have corresponding claims-level data submitted within 60 days of the contract pharmacy's date of dispense.

24. Q: Does BMS 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, BMS 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 BMS or an authorized distributor.

25. Q: Our covered entity successfully placed a 340B order that was sent to our designated IMiD specialty contract pharmacy. We subsequently determined that the patient was not actually 340B eligible, but the 340B-purchased drug was shipped to, and is now incorporated into, the third-party contract pharmacy's inventory. Since the contract pharmacy has paid us for the 340B drug, what actions should we take next, given the discrepancy?

A: The covered entity should adhere to the HRSA guidance for Entity Self-Disclosures.