

January 14, 2022

Dear Valued 340B Customer,

In November 2019, Bristol Myers Squibb (BMS) acquired Celgene Corporation, and with it Revlimid®, Pomalyst®, and Thalomid® (the “IMiD” products). Since that time, BMS has made progress integrating our complex business operations consistent with our vision of transforming patients’ lives. As part of our integration efforts, BMS has developed a coordinated, enterprise-wide approach to the company’s distribution practices. This approach complies with the 340B statutory requirements, supports the intent of the 340B program, strengthens program integrity, and will not affect patient access to prescribed medications. This letter describes how the company will achieve integration while continuing to support the 340B program.

**Beginning March 1, 2022, BMS will recognize up to two designated 340B contract pharmacy locations per 340B hospital that lacks an entity-owned pharmacy. One for IMiDs, and a second for non-IMiD products.** 340B grantees may continue to utilize multiple 340B contract pharmacy locations for non-IMiD products, without restriction, and may utilize a single contract pharmacy for the IMiDs. 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.

**IMiDs.** Revlimid®, Pomalyst®, and Thalomid® may cause birth defects or embryo-fetal death. The IMiDs are subject to strict FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) programs that require registration and tracking of patients on these medications, mandatory physician education before prescribing, and dispensing only at certified pharmacies. To satisfy its ongoing REMS obligations in a manner that optimizes patient safety and access, Celgene, and now BMS, have long operated a limited distribution network of pharmacies—including a number of covered entities—consistent with the plan posted on the HRSA website and discussions with HRSA. As a voluntary measure, as of March 1, 2022, 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 pharmacy location per covered entity. This change does not amend or expand the IMiD limited distribution network of pharmacies and will not disrupt access to the IMiDs for any patient. Patients receiving IMiDs before the change will still be able to receive their medications from the same dispensaries after the change. Entities that choose to access IMiDs at 340B prices at an IMiD-designated specialty contract pharmacy location will in claim information to BMS directly. This will ensure customary business practices and program integrity are maintained, which will support supply chain stability during the transition to the integrated distribution approach. Contract pharmacy prescription dispense dates for the IMiDs must occur after the start of the distribution practice (March 1, 2022). Only one 340B purchase may occur on a single eligible IMiD prescription. Multiple 340B requests on a single prescription will not be allowed. Additional details about the process are addressed in the attached FAQs.

**Non-IMiDs.** Beginning March 1, 2022, BMS will permit each hospital covered entity that lacks an entity-owned pharmacy to utilize a single designated contract pharmacy location for non-IMiD products.<sup>1</sup> The non-IMiD contract

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<sup>1</sup> 340B hospitals will be eligible to designate all wholly owned entities as contract pharmacy locations. BMS assumes that contract pharmacies are not owned by covered entities, absent evidence to the contrary.

pharmacy location need not be the same pharmacy as the IMiD contract pharmacy location, although it can be, at the covered entity's discretion. No claim information submission is necessary for non-IMiDs.

**Contract Pharmacy Designations.** Covered entities must make contract pharmacy designations at least 15 days in advance of the date of their first purchase under this practice (for example, designate a contract pharmacy location by February 15 for a March 1, 2022 purchase). Contract pharmacy designations may be made by visiting [www.340besp.com/designations](http://www.340besp.com/designations).

Questions regarding these integration changes may be submitted to [BMS340B@bms.com](mailto:BMS340B@bms.com).

BMS considers the 340B program to be a critical part of America's health care safety net. BMS also recognizes, however, that the program is evolving and has become increasingly complex for stakeholders to navigate. Accordingly, BMS invites covered entities, HRSA, and others to partner with BMS to consider and test potential solutions to the challenges that face 340B. Such models may include extending 340B pricing directly to uninsured and vulnerable patients at the point of sale, sharing data to prevent diversion and duplicate discounts, or exploring third party contract pharmacy models that align with state and federal law. Stakeholders interested in partnering with BMS in pursuit of these common goals may submit ideas to [340BCollaborative@bms.com](mailto:340BCollaborative@bms.com).

Best Regards,

*Steven Pieri*

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## BMS 340B Update Frequently Asked Questions

- 1. Q: My covered entity hospital has a contract pharmacy relationship with a pharmacy that is wholly owned by our health system. Is this pharmacy considered an entity-owned pharmacy and therefore not subject to restriction?**

A: Yes. Hospital covered entities may continue to use wholly owned contract pharmacies to fill 340B prescriptions for their eligible patients. All pharmacies that are wholly owned by health systems may be utilized as contract pharmacies by 340B hospitals in the system, but no additional contract pharmacy designation for non-IMiDs would be permitted.
- 2. 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 wholesaler or distributor that carries BMS non-IMiD products.
- 3. 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 <http://www.340Besp.com>.
- 4. 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 in order for a covered entity to designate it as its contract pharmacy.
- 5. Q: If the contract pharmacy I want to designate doesn't have a HIN, how do I get one?**

A: BMS 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 [BMS340B@bms.com](mailto: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 for how to obtain a HIN.
- 6. 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 [www.340besp.com/designations](http://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 effective March 1, 2022.
  - **Information:** Information submission includes: 340B ID, covered entity name, prescription ID, dispense date, NDC, quantity, contract pharmacy name, HIN & 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. BMS will re-evaluate the need for information submission after 340B purchasing patterns are clearly established and the integrated distribution practice has transitioned to a normal business activity.

- **Prospective Only:** No contract pharmacy orders will be honored for dispenses prior to March 1, 2022.

**7. 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.

**8. 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. The change permits non-network covered entities to designate one IMiD specialty 340B contract pharmacy location.

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

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

**10. 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 claim data, BMS will provide a claims submission template (EXCEL format) to the entity. The entity should email the completed template to [BMSCelgene340BRX@web.bms.com](mailto:BMSCelgene340BRX@web.bms.com) prior to each order (once the security protocols, described below, are in place).

**11. 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](mailto:BMSCelgene340BRX@web.bms.com)), and what documentation can you provide to assure that?**

A: Prior to 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 DKIM (Domain Key Identified Mail) to ensure emails received are from a registered covered entity domain. DKIM is an email security standard designed to make sure messages aren't altered in transit between the sending and recipient servers. It uses public-key cryptography to sign email with a private key as it leaves a sending server. Covered entities will also be asked to password protect all excel attachments. The password will be shared with the covered entity during the email onboarding process.

**12. 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 or not each IMiD contract pharmacy order complies with BMS' updated distribution practices.

**13. Q: My covered entity had 340B eligible IMiD transactions in 2021 that we would like to replenish on March 1, 2022. Is that utilization eligible for a 340B replenishment order at the IMiD-designated specialty contract pharmacy?**

A: No. BMS's distribution practice permitting IMiD 340B contract pharmacy applies solely to prescriptions with dispense dates on or after the effective date of March 1, 2022. Prescription dispense dates that occurred prior to the effective date are not eligible for contract pharmacy orders at the 340B price. This applies to all covered entities and will be monitored.

**14. 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.

**15. 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, and a single specialty contract pharmacy location for IMiDs. The limited distribution specialty pharmacy locations that may serve as 340B contract pharmacies to dispense Revlimid®, Pomalyst®, and Thalomid® can be found at [www.340besp.com/designations](http://www.340besp.com/designations) during the designation process. No other pharmacies may serve as IMiD-designated specialty contract pharmacies. Contract pharmacy locations are registered individually on the HRSA database by name and physical location.

**16. 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.

## BMS Addendum 1

To supplement the Frequently Asked Questions section of this letter, BMS provides the following  
Frequently Asked Questions  
May 2022

1. **Q: How do I designate my contract pharmacy for CAMZYOS?**

A: As a voluntary measure, 340B covered entities that are not already part of the CAMZYOS limited distribution network will have the option to access the product at a 340B price through one in-network CAMZYOS designated specialty contract dispensing pharmacy location per covered entity by visiting <https://340besp.com/designations>. No claim information submission is necessary for CAMZYOS. Please submit 340B-specific questions to [bms340b@bms.com](mailto:bms340b@bms.com).

2. **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 data to support a partial package?**

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

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

A: As stated in our January 14, 2022, letter, multiple 340B requests on a single prescription (same prescription ID number) will not be allowed. BMS will honor the first 340B discount request and deny the subsequent requests.

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

A: Effective July 1, 2022, BMS will accept and process contract pharmacy replenishment orders that have corresponding claims data submitted within 60 days of the contract pharmacy's date of dispense.

5. **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.

6. **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 continue to adhere to the HRSA guidance for Entity Self-Disclosures.