



Dear Valued Customer,

Bayer is writing to notify you that it has modified its approach to providing products to contract pharmacies at the 340B price. Bayer supports the 340B program and its intended mission of supporting safety net healthcare providers in providing vulnerable patients with access to medical care and medications. Unfortunately, the program has strayed far from its original purpose and the current use of contract pharmacies is beyond the parameters of the statutory scheme, as the U.S. Court of Appeals for the Third Circuit has held. Bayer is concerned with the integrity issues that arise from contract pharmacy arrangements, and we believe meaningful improvements are needed to ensure that safety net providers and vulnerable patients come first.

The following additional conditions will be added to the Bayer 340B Policy effective June 1, 2023:

- The Bayer drug Adempas will be added to the list of Bayer products covered by the new Bayer 340B Policy.
- Any covered entity that does not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy location (including wholly owned) for delivery of 340B-priced drugs as long as the location of the single contract pharmacy is within 40 miles of the covered entity parent site. The covered entity may voluntarily provide claims data for the designated contract pharmacy through 340B ESP™.
- Covered entities that wish to dispense Bayer's product Adempas (subject to FDA REMs requirements) may designate an additional contract pharmacy location in Bayer's limited distribution system, for the purposes of dispensing Adempas only. The covered entity may voluntarily provide claims data for the designated contract pharmacy through 340B ESP™.
- Federal grantees will continue to be provided Bill To / Ship To replenishment orders of 340B-priced drugs for their contract pharmacies.

Bayer is utilizing the 340B ESP™ platform to support the contract pharmacy designation process. 340B covered entities that haven't already registered an account with 340B ESP™, can make their designations by visiting www.340besp.com/designations. Users that have registered an account with 340B ESP™ can designate a contract pharmacy by navigating to the Entity Profile tab.

Entities that have already registered and designated a contract pharmacy will need to re-designate a contract pharmacy if the original contract pharmacy is beyond the 40 miles radius of the covered entity parent site.

Covered Entities must take action by May 18, 2023 in order for single contract pharmacy designations to take effect on the effective date of the policy.

Covered entities that are submitting 340B claims will need to register an account with 340B ESP™ and it is requested that the 340B claims are submitted within 45 days of the dispense date.

In support of a smooth transition to our new policy, 340B covered entities should work with their contract pharmacy administrators and wholesalers to process any outstanding Bill To / Ship To replenishment orders in advance of the June 1, 2023 effective date. PHS contracts administered by our wholesalers will no longer support provision of drugs purchased at the 340B price to contract pharmacies after May 31, 2023.

Bayer Healthcare Pharmaceuticals Inc.

Effective April 1, 2024:

Arkansas-based covered entities will be able to place Bill to/Ship to replenishment orders through contract pharmacies located within Arkansas. Dispensing of Bayer's product Adempas (subject to FDA REMs requirements) must follow the FDA REMs requirement and be part of Bayer's limited distribution system.

Effective June 24, 2024:

Bayer Healthcare is adding the product, Nubeqa, to the 340B Contract Pharmacy policy.

Frequently Asked Questions

Q: Which products are not subject to Bayer's policy at this time?

A: Aliqopa, Jivi, Kerendia, Kogenate, Kovaltry, Kyleena, Lampit, Mirena, Skyla, Xofigo.

Q: What happens if a covered entity does not have an in-house pharmacy capable of dispensing Bayer products?

A: Bayer will allow the designation of a single contract pharmacy within 40 miles of any non-grantee covered entity's parent site. The designated contract pharmacy may voluntarily submit claims.

Q: My covered entity has a contract pharmacy relationship with a pharmacy that is wholly owned by our health system. Is this pharmacy subject to Bayer's policy?

A: Any non-grantee covered entity that lacks an in-house pharmacy capable of dispensing Bayer drugs may elect to designate one contract pharmacy location registered on the HRSA OPAIS database that is within 40 miles of the covered entity's parent site, regardless of ownership interest, as its single contract pharmacy location.

Q: My covered entity has an in-house pharmacy that is capable of purchasing and dispensing Bayer drugs, but my entity doesn't use it to dispense Bayer drugs. Can my entity designate one contract pharmacy instead?

A: No, under Bayer's policy, if a covered entity has an in-house pharmacy capable of dispensing 340B-priced products to eligible patients, then the covered entity must use that pharmacy and cannot designate a contract pharmacy instead.

Q. My 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy (e.g., six different Accredo pharmacy locations). Can my entity designate all locations of the same pharmacy?

A. No. Bayer's policy allows qualifying 340B covered entities (i.e., covered entities without an in-house pharmacy) to designate a single contract pharmacy location. Contract pharmacy locations are registered individually on the HRSA database and 340B covered entities are permitted to designate only a single contract pharmacy location which corresponds to a single contract pharmacy registration with HRSA.

Q. How often can my covered entity change its contract pharmacy designation?

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

Q. How does my covered entity change its contract pharmacy designation?

A. 340B covered entities can elect a single contract pharmacy every twelve (12) months. 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.

Q. Is Bayer 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 Bayer 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: Bayer 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. How does my covered entity ensure that its eligible contract pharmacy locations take effect on June 1, 2023?

A. For a covered entity's eligible contract pharmacy locations to take effect on June 1, 2023, the entity must designate by May 18, 2023. After May 18, 2023, please allow 10 business days for the eligible contract pharmacy locations to take effect.

Q. How long does it take for my covered entity's eligible contract pharmacy locations to take effect after June 1, 2023?

A. Covered entities can take action to comply with Bayer's policy after it goes into effect on June 1, 2023. After May 18, 2023, please allow 10 business days for the eligible contract pharmacy locations to take effect.

Q: I have designated my single contract pharmacy and now I would like to submit claims for that pharmacy. What does our entity need to do to begin submitting 340B claims?

A: 340B covered entities submitting 340B claims under Bayer's policy can do so by registering an account at www.340Besp.com. Users that have registered an account with 340B ESP™ can begin submitting 340B claims for Bayer by navigating to the Claims Data Submission tab. Claims submitted voluntarily can be used to monitor for and avoid duplicate discounts.

Q: How many days from the date of a drug's dispense does my covered entity have to submit the corresponding claims data?

A: Bayer is requesting Covered Entities electing to comply with Bayer's updated contract pharmacy policy to submit claims within 45 days of the eligible claim's date of service.

Policy Changes Related to Adempas

Q: Can a covered entity dispense Adempas to any contract pharmacy?

A: No, Adempas is a specialty product with FDA REMS requirements and can only be distributed to specialty pharmacies through our limited distribution network.

Q: How will the limited distribution specialty pharmacy network for Adempas function with 340B contract pharmacies?

A: Details about 340B contract pharmacies within the Adempas limited distribution network include:

In-network specialty contract pharmacies: The limited distribution locations that may serve as 340B contract pharmacies to dispense Adempas can be found at www.340besp.com/designations during the designation process. No other pharmacies may serve as Adempas designated contract pharmacies.

Q: Our 340B covered entity pharmacy is not currently included in the Adempas 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 Adempas limited distribution network.

Q: Does the pharmacy's location that I would like to designate for distribution of Adempas need to be within 40 miles of my covered entity's location?

A: No. Bayer does not require the single contract pharmacy designation that a covered entity has chosen to distribute Adempas to be within 40 miles of the covered entity's location.

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

A: Bayer requires covered entities to designate one contract pharmacy location to purchase Adempas at the 340B price. Once designated, Bayer is requesting covered entities to provide claims data for replenishment orders placed at that location through the 340B ESP platform.



Dear Valued Customer,

Bayer, like other pharmaceutical manufacturers, is modifying its approach to providing products to contract pharmacies at the 340B price. Bayer supports the 340B program and its intended mission of supporting safety net healthcare providers in providing vulnerable patients with access to medical care and medications. Unfortunately, the program has strayed far from its original purpose and the current use of contract pharmacies is beyond the parameters of the statutory scheme. Bayer is concerned with the integrity issues that arise from contract pharmacy arrangements, and we believe meaningful improvements are needed to ensure that safety net providers and vulnerable patients come first.

Effective March 1, 2023, Bayer will provide products purchased at the 340B price only to locations registered as a 340B covered entity or child site location affiliated with that covered entity. Contract pharmacies will not be provided Bill To / Ship To replenishment orders, subject to exceptions noted below. Bayer will voluntarily allow the following exemptions for select Bayer products¹:

- Federal grantees will be provided Bill To / Ship To replenishment orders of 340B-priced drugs for their contract pharmacies.
- Contract pharmacies that are wholly owned by a 340B hospital or have common ownership with a health system, will be provided Bill To / Ship To replenishment orders of 340B priced drugs. These pharmacies must be registered with HRSA as a contract pharmacy of the 340B hospital. To apply for a wholly owned contract pharmacy exemption, please visit www.340besp.com/wholly_owned_application.
- Any covered entity that does not have an in-house pharmacy capable of dispensing 340B-priced drugs to its patients may designate a single contract pharmacy location. Bayer is utilizing the 340B ESP™ platform to support this designation. 340B covered entities that do not have an in-house pharmacy and haven't already registered an account with 340B ESP™, can make their designations by visiting www.340besp.com/designations. Users that have registered an account with 340B ESP™ can designate a contract pharmacy by navigating to the Entity Profile tab. If you have questions regarding the change in our 340B distribution model, please contact us at support@340Besp.com.
- Covered entities may also elect to submit 340B claims through 340B ESP™ for all utilization dispensed through contract pharmacies. Any covered entity that elects to submit its 340B claims will be allowed to continue Bill To / Ship To replenishment orders for its contract pharmacies. Covered entities that are interested in submitting 340B claims will need to register an account with 340B ESP™ and must submit the 340B claims within 45 days of the dispense date.

In support of a smooth transition to our new policy, 340B covered entities should work with their contract pharmacy administrators and wholesalers to process any outstanding Bill To / Ship To replenishment orders in advance of the March 1, 2023, effective date. PHS contracts administered by our wholesalers will no longer support provision of drugs purchased at the 340B price to contract pharmacies after February 28, 2023.

Bayer Healthcare Pharmaceuticals Inc.

¹See FAQ on following pages for more information on select Bayer products.

Frequently Asked Questions

Q: Which products are not subject to Bayer's policy at this time?

A: Adempas, Aliqopa, Jivi, Kerendia, Kogenate, Kovaltry, Kyleena, Lampit, Mirena, Skyla, Nubeqa, Xofigo.

Q: Which products are subject to Bayer's policy?

A: Bayer's contract pharmacy policy applies to specific Bayer products. Covered entities may access the complete list of NDCs at <http://help.340besp.com/en/articles/4455011-what-ndcs-do-we-look-for>.

Q: My covered entity has a contract pharmacy relationship with a pharmacy that is owned by our health system. Is this pharmacy subject to Bayer's policy?

A: No, contract pharmacies that are wholly owned by the covered entity are not subject to Bayer's policy and covered entities can ship drugs purchased at the 340B price to all of their wholly owned contract pharmacies. To apply for a wholly owned contract pharmacy exemption, please visit www.340besp.com/wholly_owned_application.

Q: My covered entity has an in-house pharmacy that is capable of purchasing and dispensing Bayer drugs, but my entity doesn't use it to dispense Bayer drugs. Can my entity designate one contract pharmacy instead?

A: No, under Bayer's policy, if a covered entity has an in-house pharmacy capable of dispensing 340B-priced products to eligible patients, then the covered entity must use that pharmacy and cannot designate a contract pharmacy instead.

Q. My 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy (e.g., six different Accredo pharmacy locations). Can my entity designate all locations of the same pharmacy?

A. No. Bayer's policy allows qualifying 340B covered entities (i.e., covered entities without an in-house pharmacy) to designate a single contract pharmacy location. Contract pharmacy locations are registered individually on the HRSA database and 340B covered entities are permitted to designate only a single contract pharmacy location which corresponds to a single contract pharmacy registration with HRSA.

Q. How often can my covered entity change its contract pharmacy designation?

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

Q. How does my covered entity change its contract pharmacy designation?

A. 340B covered entities can elect a single contract pharmacy every twelve (12) months. 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.

Q. Is Bayer 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 Bayer to manage its process with its wholesalers.

Frequently Asked Questions (continued)

Q. If the contract pharmacy my covered entity wants to designate doesn't have a HIN, how does my entity get one?

A: Bayer 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. How does my covered entity ensure that its eligible contract pharmacy locations take effect on March 1, 2023?

A. For a covered entity's eligible contract pharmacy locations to take effect on March 1, 2023, the entity must designate or submit claims data by February 14, 2023. After February 15, 2023, please allow 10 business days for the eligible contract pharmacy locations to take effect.

Q. How long does it take for my covered entity's eligible contract pharmacy locations to take effect after March 1, 2023?

A. Covered entities can take action to comply with Bayer's policy after it goes into effect on March 1, 2023. After February 14, 2023, please allow 10 business days for the eligible contract pharmacy locations to take effect.

Q: My covered entity would like to submit 340B claims for its contract pharmacies and continue purchasing Bayer 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 Bayer's policy can do so by registering an account at www.340Besp.com. Users that have registered an account with 340B ESP™ can begin submitting 340B claims for Bayer by navigating to the Claims Data Submission tab. 340B claims must be submitted within 45 days of the date of dispense in order for the contract pharmacy to remain eligible to receive 340B purchased drugs.

Q: How many days from the date of a drug's dispense does my covered entity have to submit the corresponding claims data?

A: Covered Entities electing to comply with Bayer's updated contract pharmacy policy must submit claims data within 45 days of the eligible claim's date of service. If a claim is submitted more than 45 days after the claim's date of service, the applicable drug dispense will not be eligible for 340B pricing. Where a particular drug requires longer than 45 days to trigger a replenishment order, the covered entity will still receive 340B pricing on the applicable drug dispense if the corresponding claims data is submitted within 45 days of the eligible claim's date of service.

Q: What happens if my organization does not provide 340B claims by the required date?

A: If a covered entity elects not to submit claims data for its contract pharmacies, the covered entity will have the option to select a single contract pharmacy if it doesn't have an in-house pharmacy capable of dispensing 340B purchased products OR may apply for a wholly owned contract pharmacy exemption to continue using its wholly owned contract pharmacies.