



February 2022

Dear Valued 340B Customer

I am writing to inform you that GlaxoSmithKline (GSK) is altering its approach to distributing products purchased at the 340B price. Effective April 1, 2022, GSK will ship products purchased at the 340B price exclusively to locations registered as a 340B covered entity or child site location affiliated with that covered entity. Covered entity contract pharmacies will no longer be eligible recipients for Bill To / Ship To replenishment orders. Federal grantees will remain eligible to place Bill To / Ship To replenishment orders of 340B priced drugs for their contract pharmacies.

To ensure all 340B covered entities can access GSK products at the 340B price, 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. GSK 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](http://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](mailto: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.

Contract pharmacies that are wholly owned by a 340B hospital or have common ownership with a health system, will remain eligible to receive 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](http://www.340besp.com/wholly_owned_application).

In support of a smooth transition to our new distribution model, 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 April 1, 2022 effective date. PHS contracts administered by our wholesalers will no longer support distribution of 340B purchased drugs to 340B contract pharmacies after March 31, 2022.



## Frequently Asked Questions

### **Q: Which products are subject to GSK's policy?**

A: GSK's contract pharmacy policy applies to the following retail products only (ADVAIR™, VENTOLIN™, BREO™, TRELEGY™, ANORO™, INCRUSE™, FLOVENT™, ARNUITY™, and SEREVENT™). Covered entities may access the complete list of NDCs at [What NDCs do we look for? | 340B ESP - Help Center](#).

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

A: No, contract pharmacies that are wholly owned by the covered entity are not subject to GSK's policy and covered entities can ship 340B purchased drugs 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](http://www.340besp.com/wholly_owned_application).

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

A: No, under GSK's policy, if a covered entity has an in-house pharmacy capable of dispensing 340B purchased 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. GSK'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. The only exceptions to the above include Federal grantees, covered entities that submit claims data and contract pharmacies wholly owned by a 340B hospital or that have common ownership with a health system.

### **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](http://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 GSK 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 or to be approved for a wholly owned contract pharmacy exemption. This information is important for GSK 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: GSK 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](mailto: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 April 1, 2022?**

A. For a covered entity's eligible contract pharmacy locations to take effect on April 1, 2022, the entity must designate or submit 340B claims by March 17, 2022. After March 18, 2022, 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 April 1, 2022?**

A. Covered entities can take action to comply with GSK's policy after it goes into effect on April 1, 2022. After March 17, 2022, 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 GSK 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 GSK's policy can do so by registering an account at [www.340Besp.com](http://www.340Besp.com). Users that have registered an account with 340B ESP™ can begin submitting 340B claims for GSK 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: What happens if my organization does not provide 340B claims by the required date?**

A: If a covered entity elects not to submit 340B claims 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.