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Notice Regarding Vertex's 340B Contract Pharmacy Policy

Dear Covered Entity,

This notice describes updates to Vertex's 340B practice that will become applicable to covered entities as described below. This policy was originally effective July 1, 2024, and applied to our existing Cystic Fibrosis (CF) medicines. Vertex is now updating its policy to add its new CF medicine, ALYFTREK™ (vanzacaftor, tezacaftor, and deutivacaftor). There are no other changes to the policy.

Vertex continues to support the 340B program and access to care for patients in need. However, we also believe it is important to uphold the integrity and intent of the program. Accordingly, effective July 1, 2024, Vertex is implementing a policy regarding contract pharmacies' eligibility to receive our Cystic Fibrosis products purchased at the 340B discount. Under our new policy:

Vertex will no longer facilitate "Bill To/Ship To" replenishment orders for hospital covered entities for contract pharmacies, other than for the exceptions listed below:

- Vertex will permit hospital covered entities under 42 U.S.C. § 256b(a)(4)(L)-(O) to designate a single contract pharmacy location if the covered entity does not have an in-house outpatient pharmacy capable of dispensing 340B-priced covered outpatient drugs to eligible patients. This ensures all covered entities can access Vertex's 340B-priced covered outpatient drugs.
- Vertex, at its sole discretion, is exempting federal grantees under 42 U.S.C. § 256b(a)(4)(A)-(K) from Vertex's 340B Contract Pharmacy Policy. At this time, these covered entities may continue to access 340B-priced medicines through an unlimited number of contract pharmacies.
- At this time, Vertex's 340B Contract Pharmacy Policy does not apply to covered entities in states referenced in Addendum A.

Vertex utilizes the 340B ESP™ platform to support the contract pharmacy designation process for hospital covered entities with no in-house outpatient pharmacy. Covered entities that have not already registered an account with 340B ESP™ should make their contract pharmacy designations by visiting <https://www.340besp.com/designations>. Covered entities that have already registered an account with 340B ESP™ must designate a contract pharmacy by navigating to the Entity Profile tab at <https://www.340besp.com>.

Contract pharmacy designations shall apply to the parent and all child sites, as indicated on the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs Information System (OPAIS) website.



All covered entities may voluntarily submit claims data through 340B ESP™ at <https://www.340besp.com> to support Vertex's 340B Integrity Initiative.

Please refer to the attached FAQ for additional information. If you have further questions regarding this policy or utilization of the 340B ESP™ platform, please contact support@340BESP.com or call 888-398-5520.

Best regards,

Brooke Goobic

Brooke Goobic, Vice President, Market Access

Frequently Asked Questions

1. What covered entities are subject to Vertex's 340B Contract Pharmacy Policy?

Vertex will continue to offer 340B discounts to all covered entities. However, Vertex will no longer facilitate shipments to contract pharmacies of hospital covered entities that have in-house dispensing capabilities. Vertex will facilitate the shipment of 340B-priced covered outpatient drugs to a single contracted pharmacy of the covered entity's choice for hospital covered entities without in-house dispensing capabilities.

Federal grantees and covered entities in certain states are currently exempt from Vertex's 340B Contract Pharmacy Policy.

2. Which products are subject to Vertex's policy?

Vertex's contract pharmacy policy applies to KALYDECO® (ivacaftor), ORKAMBI® (lumacaftor/ivacaftor), SYMDEKO® (tezacaftor/ivacaftor and ivacaftor), TRIKAFTA® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) and ALYFTREK™ (vanzacaftor, tezacaftor, and deutivacaftor)]. The policy does not apply to CASGEVY® because CASGEVY cannot be delivered via a "Bill To/Ship to" arrangement at this time based on CASGEVY's established distribution network. We may reevaluate the applicability of this policy for CASGEVY if there are any changes to CASGEVY's distribution network.

3. Is the 340B ESP™ platform the only way a covered entity without an in-house pharmacy can designate its one contract pharmacy?

Yes. Vertex is utilizing the 340B ESP™ platform to support this designation.

Hospital covered entities that have registered an account with 340B ESP™ can designate a single contract pharmacy by navigating to the Entity Profile tab.

Hospital covered entities that wish to register a new account on the ESP platform can create a new account at <https://www.340besp.com/> and may designate one contract pharmacy by navigating to the Entity Profile tab.

Hospital covered entities that elect not to register an account on the ESP platform can make their one contract pharmacy designation by visiting <https://www.340besp.com/designations>.

- 4. My covered entity does not have an in-house pharmacy that is capable of purchasing and dispensing 340B-priced covered outpatient drugs. How does my covered entity ensure that its chosen contract pharmacy location will be able to access in accordance to the Policy?**

Please allow 10 business days for contract pharmacy designations to take effect. You can make your contract pharmacy designations by visiting <https://www.340besp.com/designations>.

- 5. My covered entity does not have an in-house pharmacy that is capable of purchasing and dispensing 340B-priced covered outpatient drugs and my covered entity has contract pharmacy arrangements with multiple locations. Can my covered entity designate all locations of the same pharmacy?**

No. Vertex's policy allows hospital covered entities (i.e., hospital 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 registered with HRSA.

- 6. My covered entity has a contract pharmacy relationship with a pharmacy that is owned by our health system. Is this pharmacy subject to Vertex's policy?**

If a covered entity has an in-house pharmacy, then under Vertex's policy, the covered entity must use that pharmacy and cannot designate a contract pharmacy, including a wholly owned pharmacy. However, if a covered entity does not have an in-house pharmacy, then a wholly owned pharmacy can be designated as that covered entity's single pharmacy location.

- 7. My covered entity has an in-house pharmacy that is capable of purchasing and dispensing 340B-priced covered outpatient drugs, but my covered entity does not use its in-house pharmacy to dispense 340B-priced covered outpatient drugs. Can my entity designate one contract pharmacy instead?**

No, subject to the exemptions identified in Vertex'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.

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

A contract pharmacy designation can be modified once every twelve (12) months (from the date of first designation). Vertex will facilitate a change sooner if the designated contract pharmacy relationship is terminated before the twelve (12) month period lapses and reflected as terminated in Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPAIS) database. Changes to contract pharmacy designations can be made by visiting www.340besp.com/designations if a contract pharmacy relationship is terminated and/or after twelve (12) months have elapsed.

9. Does Vertex require covered entities to have a HIN registered for the contract pharmacy that they designate?

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 Vertex to manage its process with its distributors.

10. If the contract pharmacy that my covered entity wants to designate does not have a HIN, how does my entity get one?

Vertex 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 or call 888-398-5520. 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.

11. My covered entity would like to voluntarily submit 340B claims for its contract pharmacy. What does our entity need to do to begin submitting 340B claims?

340B covered entities that wish to submit 340B claims under Vertex's policy can do so by registering for an account at www.340BESP.com. Users that have registered an account with 340B ESP™ can begin submitting 340B claims for Vertex by navigating to the Claims Data Submission tab. It is requested that the 340B claims are submitted within 45 days of the dispense date.

12. Will training or support be provided to covered entities on how to use the 340B ESP™ platform?

Covered entities can access information and training at www.340besp.com/FAQs to learn more about 340B ESP™. For assistance, covered entities can access a repository of webinars at www.340besp.com/resources/webinars or call 888-398-5520.

Addendum A

As of July 1st, 2024, Vertex's 340B Contract Pharmacy Policy does not apply to contract pharmacy arrangements with covered entities registered in the OPAIS database and located in Arkansas, Kansas, Louisiana, Maryland, Minnesota, Mississippi, or West Virginia.

As of August 28th, 2024, Vertex's 340B Contract Pharmacy Policy does not apply to contract pharmacy arrangements with covered entities registered in the OPAIS database and located in Missouri.