



**Alkermes, Inc.**  
900 Winter Street, Waltham, MA 02451 USA  
T +1 781 609 6000 F +1 781 890 0524  
www.alkermes.com

## **Notice Regarding Alkermes, Inc.'s Contract Pharmacy Policy Updated Attachment A (August 23, 2024)**

August 23, 2024

Dear Covered Entity Customer,

Alkermes, Inc. is providing this notice to let you know that Alkermes has updated Attachment A to its Contract Pharmacy Policy Notice, which describes voluntary exceptions to the Alkermes Contract Pharmacy Policy for covered entities located in certain states. The remainder of the Alkermes Contract Pharmacy Policy Notice, which is included below, remains unchanged.

### **Contract Pharmacy Policy Notice**

Alkermes, Inc. is providing this notice to announce implementation of its policy governing the eligibility of covered entities to purchase Alkermes' products at the 340B price for shipment to a contract pharmacy, effective July 22, 2024.

Alkermes recognizes the important role of the 340B Program in serving uninsured and low-income patients and remains committed to ensuring that 340B covered entities have access to our products at the 340B price consistent with applicable law. However, Alkermes is concerned that contract pharmacy arrangements are diverting the benefits of the 340B Program from patients to contract pharmacies and contributing to the pervasive lack of transparency within the 340B Program, rendering it difficult to identify inappropriate duplicate discounts and product diversion. In an effort to uphold the integrity of the 340B Program, Alkermes is implementing the following policy governing covered entities' purchases of Alkermes' products at the 340B price for shipment to a contract pharmacy (such policy, the "Contract Pharmacy Policy" or "Policy").

### **CONTRACT PHARMACY POLICY**

Effective July 22, 2024, Alkermes will limit distribution of 340B-priced product to locations registered as a 340B covered entity (including its child sites) for dispensing through such covered entity's in-house pharmacy to its patients consistent with the 340B statute. A 340B covered entity that lacks an in-house pharmacy may designate a single contract pharmacy location for shipment of Alkermes' products purchased at the 340B price. The designated contract pharmacy must be registered as a contract pharmacy location of the 340B covered entity in the Office of Pharmacy Affairs Information System (OPAIS) database. This Policy will be applicable for all Alkermes' products; a list of NDCs for our products is available at <https://www.340besp.com>. For a list of authorized distributors that distribute Alkermes' products at the 340B price, please visit <https://www.alkermes.com/getmedia/47f40518-b6f7-477b-bb22-701a6ea9e3df/Master-Alkermes-ADR.pdf>.

At this time, Alkermes is making voluntary exceptions to its Contract Pharmacy Policy for covered entities located in certain states, as described in Attachment A.

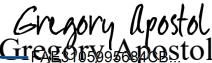


Alkermes is utilizing the 340B ESP™ platform to facilitate contract pharmacy designations. In addition, all 340B covered entities are requested to voluntarily submit claims data for all Alkermes' products purchased under the 340B Program within 45 days after the dispense date via the 340B ESP™ platform to support program integrity and transparency. The platform is available to covered entities at no cost.

340B covered entities that have not already registered an account with 340B ESP™ can register by visiting [www.340bsp.com/designations](http://www.340bsp.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 340B ESP™, please contact [support@340Besp.com](mailto:support@340Besp.com).

We are committed to a smooth implementation of this Policy. If you have any questions about this letter, please contact [support@340Besp.com](mailto:support@340Besp.com).

Sincerely,

Signed by:  
  
Gregory Apostol

Vice President, Head of Market Access



## Frequently Asked Questions<sup>1</sup>

### **Q: Which products are subject to Alkermes' Policy?**

A: Alkermes' Contract Pharmacy Policy applies to all Alkermes' products. A list of NDCs for our products is available at <https://www.340besp.com>.

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

A: Yes. Contract pharmacies that are wholly owned by the 340B covered entity or that have common ownership with a 340B covered entity are not separately eligible to receive shipments of Alkermes' products on a bill to/ship to basis at the 340B price. However, a 340B covered entity that does not have an in-house pharmacy may designate a single contract pharmacy location regardless of ownership interest. This means that a 340B covered entity may select a wholly-owned contract pharmacy as its single contract pharmacy location.

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

A: No. Under Alkermes' Policy, if a 340B covered entity has an in-house pharmacy capable of dispensing products purchased at the 340B price 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 pharmacy locations). Can my entity designate all locations of the same pharmacy?**

A: No. Alkermes' Policy allows 340B covered entities to designate a single contract pharmacy location only. Contract pharmacy locations are registered individually on the HRSA database and 340B covered entities are permitted to designate only a single contract pharmacy location that corresponds to a single contract pharmacy registered with HRSA.

### **Q: Can child sites also designate a single contract pharmacy?**

A: No. All child sites must utilize the parent site's contract pharmacy designation.

### **Q: How often can my covered entity change its contract pharmacy designation?**

A: 340B 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 is terminated from the OPAIS database.

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<sup>1</sup> While the voluntary exceptions to the Alkermes, Inc. Contract Pharmacy Policy described in Attachment A are not reflected in these FAQs, the exceptions remain applicable to 340B covered entities located in the states identified in Attachment A.



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

A: Changes to the single contract pharmacy designation 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. 340B 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 is terminated from the OPAIS database.

**Q: Is Alkermes 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 340B covered entity to designate it as its single contract pharmacy location.

**Q: If the contract pharmacy my covered entity wants to designate does not have a HIN, how does my entity get one?**

A: Alkermes will not register a HIN on your behalf; however, if you need guidance or more information on how to get a HIN assigned to the contract pharmacy your entity would like to designate, 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 designation of a single contract pharmacy location takes effect on July 22, 2024?**

A: For a 340B covered entity's eligible contract pharmacy location to take effect on July 22, 2024, the entity must designate that location via [www.340Besp.com/designations](http://www.340Besp.com/designations) by June 21, 2024. After June 21, 2024, the designation of an eligible contract pharmacy may not take effect until up to 10 business days following July 22, 2024 or 10 business days following the designation, whichever is later.

**Q: How long does it take for my covered entity's designation of its single contract pharmacy location to take effect after June 21, 2024?**

A: If a 340B covered entity designates an eligible contract pharmacy location by June 21, 2024, that designation will take effect on July 22, 2024. After June 21, 2024, the designation of an eligible contract pharmacy may not take effect until up to 10 business days following July 22, 2024 or 10 business days following the designation, whichever is later.

**Q: My covered entity would like to submit 340B claims data for Alkermes' product purchase under the 340B program. What does my entity need to do to begin submitting 340B claims data?**

A: 340B covered entities that wish to submit 340B claims data 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 data for Alkermes' products by navigating to the Claims Data Submission tab.

**Q: My covered entity is a federal grantee that dispenses product through our pharmacy, which is located at a different address and listed as a shipping address in the OPAIS database. Under Alkermes' Policy, is our pharmacy considered an in-house pharmacy eligible to receive Alkermes' products purchased at the 340B price?**

A: Yes, a pharmacy that is part of a federally qualified health center (FQHC) or other federal grantee (collectively "Grantee") and is listed in the OPAIS database as a shipping address of the covered entity is considered an in-house pharmacy of the covered entity and eligible to receive Alkermes' products purchased at the 340B price. Accordingly, Alkermes will provide its products at the 340B price to a Grantee that purchases product to be shipped to the Grantee-owned pharmacy provided the pharmacy's address is identified as a shipping address of the Grantee in the OPAIS database.



**Attachment A – Voluntary Policy Exceptions  
(as of August 23, 2024)**

Alkermes is making the voluntary exceptions set forth below to its Contract Pharmacy Policy.

Effective July 22, 2024 (the effective date of the Contract Pharmacy Policy):

- **Arkansas:** 340B covered entities located within Arkansas may direct shipment of Alkermes' products purchased at the 340B price to contract pharmacies located in Arkansas that are registered as a contract pharmacy location of the Arkansas 340B covered entity in the OPAIS database.
- **Louisiana:** 340B covered entities located within Louisiana may direct shipment of Alkermes' products purchased at the 340B price to contract pharmacies located in Louisiana that are registered as a contract pharmacy location of the Louisiana 340B covered entity in the OPAIS database.
- **West Virginia:** 340B covered entities located within West Virginia may direct shipment of Alkermes' products purchased at the 340B price to any contract pharmacy registered as a contract pharmacy location of the West Virginia covered entity in the OPAIS database.
- **Mississippi:** 340B covered entities located within Mississippi may direct shipment of Alkermes' products purchased at the 340B price to contract pharmacies located in Mississippi that are registered as a contract pharmacy location of the Mississippi covered entity in the OPAIS database.
- **Maryland:** 340B covered entities located within Maryland may direct shipment of Alkermes' products purchased at the 340B price to contract pharmacies located in Maryland that are registered as a contract pharmacy location of the Maryland covered entity in the OPAIS database.
- **Kansas:** 340B covered entities located within Kansas may direct shipment of Alkermes' products purchased at the 340B price to contract pharmacies located in Kansas that are registered as a contract pharmacy location of the Kansas covered entity in the OPAIS database.

Effective August 1, 2024:

- **Minnesota:** 340B covered entities located within Minnesota may direct shipment of Alkermes' products purchased at the 340B price to contract pharmacies located in Minnesota that are registered as a contract pharmacy location of the Minnesota covered entity in the OPAIS database.



Effective August 28, 2024:

- **Missouri:** 340B covered entities located within Missouri may direct shipment of Alkermes' products purchased at the 340B price to any contract pharmacy registered as a contract pharmacy location of the Missouri covered entity in the OPAIS database.