

August 28, 2024 Update

Dear 340B Covered Entity,

Sumitomo Pharma America, Inc. (SMPA) supports the 340B program and its mission of supporting safety net hospitals and clinics that treat financially vulnerable patients. In an effort to uphold the integrity of the 340B program and address the risk of duplicate discounts and diversion, SMPA has implemented a policy regarding contract pharmacies' eligibility to receive products at the 340B discount price. SMPA provides the 340B price for its APTIOM<sup>®</sup>, GEMTESA<sup>®</sup>, MYFEMBREE<sup>®</sup>, and ORGOVYX<sup>®</sup> brands exclusively to locations registered as a 340B covered entity, as described further below. This policy is applicable for all APTIOM, GEMTESA, MYFEMBREE, and ORGOVYX NDCs, and a list of applicable NDCs is available at <https://www.340besp.com>.

### **Policy for APTIOM, GEMTESA, and MYFEMBREE**

To ensure all 340B covered entities can continue to access APTIOM, GEMTESA, and MYFEMBREE at the 340B price, any covered entity that does not have an in-house pharmacy capable of dispensing product purchased at the 340B price may designate a single contract pharmacy location within 40 miles of the parent site location.

SMPA will allow the use of a contract pharmacy beyond the 40-mile radius if a covered entity shows that (1) it lacks an in-house pharmacy capable of purchasing and dispensing SMPA's drugs and (2) there is no contract pharmacy capable of purchasing and dispensing SMPA's drugs within a 40-mile radius of the covered entity's parent site as listed on the HRSA database, provided that the contract pharmacy selected is not a centralized pharmacy replenishment facility or "central-fill pharmacy".

### **Policy for ORGOVYX**

To ensure all 340B covered entities can continue to access ORGOVYX at the 340B price:

- Any covered entity that does not have an in-house pharmacy capable of dispensing specialty products may also designate one (1) specialty pharmacy from within SMPA's ORGOVYX limited distribution network.

- Wholly owned exemption: contract pharmacies registered in the HRSA OPAIS database that are wholly owned by a 340B hospital or have common ownership with a health system may remain eligible to receive Bill-to/Ship-to replenishment orders at the 340B price. To apply for a wholly owned contract pharmacy exemption, please visit [www.340besp.com/wholly\\_owned\\_application](http://www.340besp.com/wholly_owned_application). If a hospital covered entity is granted an exemption for its wholly or commonly owned contract pharmacy(ies), it may not also designate an independent contract pharmacy.

The policies above apply to all covered entities, including federal grantees. The policies do not apply to covered entities located in certain states as described in Appendix A.

SMPA encourages 340B covered entities designating a single contract pharmacy to voluntarily submit limited claims data for their single contract pharmacy transactions for purposes of 340B program integrity and transparency.

SMPA is utilizing the 340B ESP™ platform to support both the facilitation of the contract pharmacy designations and the collection of the 340B claims data. 340B covered entities that 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 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.

Best regards,



Kenton Stewart

Senior Vice President, Market Access

**APPENDIX A**  
**STATE POLICIES**

<b>State</b>	<b>Notice</b>	<b>Effective Date</b>
Arkansas	SMPA's 340B policies do not apply to covered entities located in Arkansas provided the covered entity submits 340B claims data within 45-days of dispense for all of its contract pharmacy dispenses resulting in a bill-to/ship-to replenishment order at the 340B price.	May 1, 2024
Louisiana	SMPA's 340B policies do not apply to covered entities located in Louisiana provided the covered entity submits 340B claims data within 45-days of dispense for all of its contract pharmacy dispenses resulting in a bill-to/ship-to replenishment order at the 340B price.	May 1, 2024
Kansas	SMPA's 340B policies do not apply to covered entities located in Kansas provided the covered entity submits 340B claims data within 45-days of dispense for all of its contract pharmacy dispenses resulting in a bill-to/ship-to replenishment order at the 340B price.	July 1, 2024
Maryland	SMPA's 340B policies do not apply to covered entities located in Maryland provided the covered entity submits 340B claims data within 45-days of dispense for all of its contract pharmacy dispenses resulting in a bill-to/ship-to replenishment order at the 340B price.	July 1, 2024
Minnesota	SMPA's 340B policies do not apply to covered entities located in Minnesota provided the covered entity submits 340B claims data within 45-days of dispense for all of its contract pharmacy dispenses resulting in a bill-to/ship-to replenishment order at the 340B price.	July 1, 2024
Mississippi	SMPA's 340B policies do not apply to covered entities located in Mississippi provided the covered entity submits 340B claims data within 45-days of dispense for all of its contract pharmacy dispenses resulting in a bill-to/ship-to replenishment order at the 340B price.	July 1, 2024
Missouri	SMPA's 340B policies do not apply to covered entities located in Missouri provided the covered entity submits 340B claims data within 45-days of dispense for all of its	August 28, 2024

	contract pharmacy dispenses resulting in a bill-to/ship-to replenishment order at the 340B price.	
West Virginia	SMPA's 340B policies do not apply to covered entities located in West Virginia.	June 6, 2024