

April 1, 2024

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 is implementing a policy regarding contract pharmacies' eligibility to receive products at the 340B discount price. Effective **May 1, 2024** SMPA will provide the 340B price for its APTIOM®, GEMTESA®, MYFEMBREE®, and ORGOVYX® brands exclusively to locations registered as a 340B covered entity, as described further below. This policy will be 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 Louisiana or Arkansas provided the covered entities in those states submit 340B claims data within 45-days of dispense for all of their contract pharmacy dispenses resulting in a Bill-to/Ship-to replenishment order at the 340B price.

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.

In order for contract pharmacy designations to take effect by May 1, 2024, 340B covered entities must take action by April 19, 2024.

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 **May 1, 2024**. PHS contracts administered by our wholesalers will no longer support distribution of 340B purchased drugs to 340B contract pharmacies after April 30, 2024.

Best regards,

A handwritten signature in blue ink, appearing to read 'K. Stewart', with a stylized flourish extending to the right.

Kenton Stewart

Senior Vice President, Market Access