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Dear 340B Covered Entities:

I am writing to inform you that Sobi, which currently operates and will continue to operate in a limited distribution model, is altering its approach to distributing products purchased at the 340B price. Effective July 1, 2024, Sobi 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.

To ensure all 340B covered entities can access Sobi's 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 within 40 miles of the covered entity parent site. Sobi 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. 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.

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 effective date of this notice. PHS contracts administered by our wholesalers will no longer support the distribution of 340B purchased drugs to 340B contract pharmacies after June 30, 2024. Sobi's 340B contract pharmacy limitations do not apply where prohibited by state law. This exception notwithstanding, Sobi will continue to operate under a limited distribution model, which allows only IDN-owned pharmacies to serve as contract pharmacy locations eligible to receive and dispense 340B-priced, in-scope products.

Best regards,

Steven Pieri

Steven Pieri, Vice President, Head of Market Access

Frequently Asked Questions

Q: Which products are subject to Sobi's policy?

A: Sobi's contract pharmacy policy applies to all NDCs of Doptelet, Kineret, and Vonjo.

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

A: Any covered entity may elect to designate a contract pharmacy location registered on the HRSA OPAIS database located within 40 miles of the covered entity parent site, regardless of ownership interest, as its single contract pharmacy location.

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

A: No, under Sobi'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. Sobi's policy allows qualifying 340B covered entities (i.e., covered entities without an in-house pharmacy) to designate a single contract pharmacy location within 40 miles of the covered entity parent site. 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.

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. Users that have registered an account with 340B ESP™ can navigate to the Entity Profile tab to make their contract pharmacy designation.

Q. Is Sobi 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. This information is important for Sobi 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: Sobi 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. 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 July 1, 2024?

A. For a covered entity's eligible contract pharmacy locations to take effect on July 1, 2024, the entity must designate by **June 21, 2024**. After July 1, 2024, 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 July 1, 2024?

A. Covered entities can take action to comply with Sobi's policy after it goes into effect on July 1, 2024. After July 1, 2024, please allow 10 business days for the eligible contract pharmacy locations to take effect.

Q: My entity is located in a state that has passed legislation prohibiting 340B contracting restrictions. Does Sobi's 340B contract pharmacy policy still apply to us?

A: Sobi's 340B contract pharmacy policy does not apply in any state where prohibited by law; at the time of this document's publication this includes Arkansas, Colorado, Hawaii, Kansas, Louisiana, Maryland, Minnesota, Mississippi, Missouri, Nebraska, North Dakota, South Dakota, Utah, Vermont and West Virginia. Sobi continues to operate under a limited distribution model under which only IDN-owned pharmacies may be utilized as contract pharmacy locations to receive and dispense in-scope products purchased at the 340B price.