



February 1, 2023

Dear 340B Covered Entity,

I am writing to inform you that EMD Serono (EMDS) is prospectively modifying its policy regarding distribution of 340B purchases of Rebif® (interferon beta-1a) and GONAL-F® (follitropin alfa for injection) to commercial contract pharmacies. Effective March 1, 2023, EMDS will ship Rebif and Gonal-f purchased at the 340B price exclusively to locations registered as 340B covered entities or to eligible child site locations. Except as permitted below, EMDS will not honor Bill To / Ship To replenishment orders to commercial pharmacies.

Nothing in this policy will prevent covered entities from purchasing Rebif and Gonal-f as desired at the 340B price. Our policy is therefore consistent with the 340B statute's obligation that EMDS offer its products to covered entities at or below the ceiling price. 42 U.S.C. §256b(a)(1).

Only hospital covered entity types will be subject to this new policy. At EMDS's discretion, federal grantees will remain eligible to place Bill To / Ship To replenishment orders of 340B priced Rebif and Gonal-f for their contract pharmacies.

To ensure all 340B covered entities and their patients have access to Rebif and Gonal-f purchased 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 commercial contract pharmacy location to serve this function. EMDS 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](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.

Contract pharmacies that are wholly owned by a 340B hospital or have common ownership with a health system will remain eligible to receive Bill To / Ship To replenishment orders of 340B priced Rebif and Gonal-f. These pharmacies must be registered with HRSA as contract pharmacies of eligible 340B hospitals. 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



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EMD Serono is the Healthcare business of Merck KGaA, Darmstadt, Germany in the U.S. and Canada

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entity is granted an exemption for its wholly or commonly owned contract pharmacy(ies), it may not also designate an independent contract pharmacy.

As noted above, this change in policy impacts only Rebif and Gonal-f; no other EMDS products are impacted by this change.

In support of a smooth transition to our new distribution model for Rebif and Gonal-f, 340B covered entities should work with their contract pharmacy administrators and wholesalers to process any outstanding Bill To / Ship To replenishment orders of these products in advance of the March 1, 2023 effective date.

Best regards,

*Daniel Van Horn*

Daniel Van Horn  
Senior Vice President, Market Access & Patient Solutions



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## Frequently Asked Questions

**Q: Which products are covered under EMD Serono's new contract pharmacy policy?**

A. Rebif® (interferon beta-1a) and GONAL-F® (follitropin alfa for injection). The following NDCs are covered by this policy:

<u>Rebif NDCs</u>	<u>Gonal-f NDCs</u>
44087332201	44087903001
44087334401	44087907001
44087018801	44087900506
44087002203	44087900501
44087004403	44087111501
44087882201	44087111601
	44087111701

**Q: Which covered entities are subject to EMD Serono's new contract pharmacy policy?**

A. All eligible 340B covered entities, with the exception of federal grantees eligible for 340B participation under 42 U.S.C. § 256b(a)(4)(A)-(K), are subject to this new contract pharmacy policy.

**Q. My 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy company. May my entity designate all locations of the same pharmacy company?**

A. If a hospital covered entity does not have in-house dispensing capabilities, only a single contract pharmacy location may be designated via the Designations form on [www.340besp.com/designations](http://www.340besp.com/designations).

**Q. How often may a covered entity change its contract pharmacy location designation?**

A. A covered entity may change its contract pharmacy location designation once every 12 months. A covered entity may change its contract pharmacy location designation within a 12-month period only if the designated contract pharmacy location is terminated as a contract pharmacy of the covered entity from the 340B OPAIS database.

**Q. How would a covered entity change its contract pharmacy location designation?**

A. Changes to a contract pharmacy location designation can be made at [www.340besp.com/designations](http://www.340besp.com/designations).

**Q. How does a covered entity ensure its contract pharmacy designation will be in effect on March 1?**

A. If a hospital covered entity does not have in-house dispensing capabilities, it may complete the form to designate a single contract pharmacy location at [www.340besp.com/designations](http://www.340besp.com/designations). If a hospital covered entity has a wholly owned contract pharmacy, it may complete the Wholly Owned Exemption application at [https://www.340besp.com/wholly\\_owned\\_application](https://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. Affected covered entities are encouraged to submit designations for approval as soon as possible.

**Q. Is EMD Serono requiring that designated contract pharmacies have registered HIN numbers?**

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 location, or to be approved for a wholly owned contract pharmacy exemption. This information is important for EMD Serono to manage its process with its wholesalers.

**Q. If the contract pharmacy location my covered entity wants to designate doesn't have a HIN, how can one be obtained?**

A: EMD Serono will not register a HIN on the pharmacy's behalf. If the pharmacy needs guidance or more information on how to get a HIN assigned, 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.