



September 1, 2023

Notice to 340B Covered Entities – Update to EMD Serono’s 340B Contract Pharmacy Policy, Effective October 1, 2023

Dear 340B Covered Entity,

Effective October 1, 2023, EMD Serono (“EMDS”) will revise its 340B Contract Pharmacy Policy to apply to *all* EMDS marketed products. Currently, only Rebif® (interferon beta-1a) and GONAL-F® (follitropin alfa for injection) are subject to this Policy. As of October 1, 2023, EMDS will ship all EMDS marketed products 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 for any of its products.

Nothing in this updated policy will prevent covered entities from purchasing as many units of EMDS products as desired at the 340B price for delivery to their locations. Our updated 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).

As before, only hospital covered entity types are subject to this Contract Pharmacy Policy. At EMDS’s discretion, federal grantees will remain eligible to place Bill To / Ship To replenishment orders of 340B priced EMDS products for their contract pharmacies.

To ensure that all 340B covered entities and their patients have access to EMD Serono products 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 will continue to utilize the 340B ESP™ platform to support this designation. 340B covered entities that do not have an in-house pharmacy and have not 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™ and have not already designated a single commercial contract pharmacy location may designate a contract pharmacy by navigating to the Entity Profile tab.

With respect to Serostim®, covered entities that wish to dispense Serostim may designate one additional contract pharmacy location in EMDS’s secured distribution network (the “SDN”), for the



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purpose of dispensing Serostim only. Alternatively, if the desired contract pharmacy is not in the SDN, the contract pharmacy may apply to EMD Serono for entry into the SDN.

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 EMDS products. 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. 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, except with respect to 340B purchases of Serostim.

As noted above, this change in policy extends to all EMDS marketed products.

In support of a smooth transition to our new distribution model for all EMDS marketed products, 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 October 1, 2023 effective date.

Best regards,

Daniel Van Horn

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Frequently Asked Questions

Q: Which products are covered under EMD Serono’s updated contract pharmacy policy?

A. All EMD Serono marketed products. The following NDCs are covered by this policy:

NDCs							
Serostim®	Rebif®	Gonal-f®	Tepmetko®	Bavencio®	Mavenclad®	Cetrotide®	Ovidrel®
44087000407	44087332201	44087907001	44087500003	44087353501	44087400000	44087122501	44087115001
44087000507	44087334401	44087903001	44087500006		44087400004		
44087000607	44087018801	44087111501			44087400005		
	44087002203	44087111601			44087400006		
	44087004403	44087111701			44087400007		
	44087882201	44087900501			44087400008		
		44087900506			44087400009		

Q: Which covered entities are subject to EMD Serono’s updated 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. May my entity designate all locations of the same pharmacy?

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. Please see below for questions regarding contract pharmacy locations for Serostim.

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 (from the date of first designation). 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. Please see below for questions regarding contract pharmacy locations for Serostim.

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

A. Covered entities can elect a single contract pharmacy location every twelve (12) months (from the date of first designation). Changes to a contract pharmacy location designation can be made at www.340besp.com/designations. Please see below for questions regarding contract pharmacy locations for Serostim.

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

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. 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. 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, except with respect to 340B purchases of Serostim. Affected covered entities are encouraged to submit designations for approval as soon as possible, if they have not already done so. Please see below for questions regarding contract pharmacy locations for Serostim.

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. 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: I have already registered and designated a single contract pharmacy location and am purchasing Rebif and Gonal-F through this contract pharmacy. Will I have to re-designate or re-apply for a contract pharmacy location on or before October 1, 2023?

A: Entities that have already taken action to comply with the EMDS policy by registering and designating a contract pharmacy location will not need to re-designate a contract pharmacy to purchase all EMDS products at the 340B price, except with respect to 340B purchases of Serostim. Please see below for questions regarding contract pharmacy locations for Serostim.

Q: I have already been granted a Wholly Owned exemption and am purchasing Rebif and Gonal-F through this pharmacy. Will I have to re-designate or re-apply for a Wholly Owned Exemption on or before October 1, 2023?

A: Entities that have already taken action to comply with the EMDS policy by being approved for a Wholly Owned exemption will not need to re-apply for Wholly Owned Exemptions to purchase all EMDS marketed products at the 340B price. Please see below for questions regarding contract pharmacy locations for Serostim.

Q: Does EMD Serono's updated contract pharmacy policy apply to 340B purchases of Saizen®?

A: No, EMDS's updated contract pharmacy policy does not apply to 340B purchases of Saizen. EMDS discontinued the manufacture, sale and distribution of Saizen as of December 31, 2022. Covered entities may still purchase remaining inventory of Saizen from wholesalers. All 340B covered entities will remain eligible to place bill to/ship to replenishment orders of 340B priced Saizen for their contract pharmacies.

Policy Changes Related to Serostim

Q: Can a covered entity dispense Serostim to any contract pharmacy?

A: No, EMD Serono only distributes Serostim through a secured distribution network of pharmacies.

Q: How will a covered entity know if a contract pharmacy is within the secured distribution pharmacy network for Serostim?

A: The secured distribution network pharmacy locations that may serve as 340B contract pharmacies to dispense Serostim can be found at www.340besp.com/designations during the designation process. Alternatively, if the desired contract pharmacy is not in the secured distribution network, the contract pharmacy may apply to EMD Serono for entry into the secured distribution network.

Q: Our 340B covered entity pharmacy is not currently included in the Serostim secured distribution network. Does this change mean that our 340B covered entity pharmacy is now approved to dispense Serostim?

A: No. This change has no effect on which pharmacies are included in the Serostim secured distribution network. Covered entities that wish to dispense Serostim may designate an additional contract pharmacy location in EMDS's secured distribution network, for the purposes of dispensing Serostim only. For example, if a covered entity cannot dispense Serostim at its in-house pharmacy but can dispense other EMDS marketed products, this covered entity may designate a single contract pharmacy that is part of EMDS' secured distribution network to dispense Serostim. Alternatively, if the selected contract pharmacy is not in the secured distribution network, the contract pharmacy may apply to EMD Serono for entry into the secured distribution network.

Q: I have already registered and designated a contract pharmacy location and am purchasing Rebif and Gonal-F through this contract pharmacy. Will I have to re-designate a contract pharmacy location on or before October 1, 2023 to purchase Serostim at the 340B price?

A: Yes. Covered entities that wish to dispense Serostim may designate an additional contract pharmacy location in EMDS's secured distribution network, for the purposes of dispensing Serostim only. Alternatively, if the desired contract pharmacy is not in the secured distribution network, the contract pharmacy may apply to EMD Serono for entry into the secured distribution network.

Q: I have already been granted a Wholly Owned exemption and am purchasing Rebif and Gonal-F through this pharmacy(ies). Will I have to re-apply for a Wholly Owned Exemption on or before October 1, 2023 to purchase Serostim at the 340B price?

A: No, entities that have already taken action to comply with the EMDS policy by being approved for a Wholly Owned exemption will not need to re-apply for Wholly Owned Exemptions. However, if the covered entity wishes to purchase Serostim at the 340B price and the Wholly-Owned pharmacies are not within EMDS's secured distribution network for Serostim, the covered entity may designate an additional contract pharmacy location in EMDS's secured distribution network, for the purposes of dispensing Serostim only. Alternatively, if the Wholly-Owned pharmacy is not in the secured distribution network, the Wholly-Owned pharmacy may apply to EMD Serono for entry into the secured distribution network.