



August 30, 2024

**Notice to 340B Covered Entities – Update to EMD Serono’s 340B Contract Pharmacy Policy, Effective October 1, 2024**

Dear 340B Covered Entity,

Effective October 1, 2024, EMD Serono (“EMDS”) will revise its 340B Contract Pharmacy Policy to (1) eliminate the exception for shipments to pharmacies that are wholly owned by a covered entity, (2) require that any contract pharmacy permissible under the Policy meet geographic proximity standards relative to the covered entity, and (3) apply the Policy to all covered entity types other than Ryan White Clinics purchasing Serostim® (somatropin).

Nothing in this updated policy will prevent covered entities from purchasing as many units of EMDS covered outpatient drugs as desired at the 340B price for delivery to their in-house 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 (as recently held by the Third and D.C. Circuit Courts of Appeal).

To ensure that all 340B covered entities and their patients have access to EMD Serono products at the 340B price, any 340B covered entity, including a federal grantee, that does not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single commercial contract pharmacy to dispense these products to the covered entity’s patients. The designated pharmacy must be registered on the HRSA OPAIS database as a contract pharmacy located within a forty (40) mile radius of the covered entity site and cannot be a central fill pharmacy. 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](http://www.340besp.com/designations). Users that have registered an account with 340B ESP™ may designate a contract pharmacy by navigating to the Entity Profile tab.

Covered entities that wish to purchase Serostim may designate one additional contract pharmacy location within 40 miles of the covered entity site in EMDS’s secured distribution network (the “SDN”), for the purpose of dispensing Serostim only. Alternatively, if the desired contract



EMD Serono

[emdserono.com](http://emdserono.com)

200 Pier 4 Boulevard, Suite 300  
Boston, Massachusetts 02210  
Tel.: 800-283-8088

1 of 7

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



pharmacy is not in the SDN, the contract pharmacy may apply to EMD Serono for entry into the SDN. Ryan White Clinics purchasing Serostim will remain eligible to place “Bill To / Ship To” replenishment orders of 340B priced Serostim for delivery to all of their contract pharmacies that are in the SDN.

Contract pharmacies that are wholly owned by a 340B covered entity or are under common ownership with a health system (and are not located within the covered entity) will no longer remain eligible to receive “Bill To / Ship To” replenishment orders of 340B priced EMDS covered outpatient drugs. A covered entity may instead elect to designate a wholly owned contract pharmacy as its single contract pharmacy location to dispense EMDS products purchased at the 340B price provided the covered entity does not have an in-house pharmacy, and the wholly-owned pharmacy is registered on the HRSA OPAIS database as a contract pharmacy located within a forty (40) mile radius of the covered entity location, and is not a central fill pharmacy. Designations can be made at [www.340besp.com/designations](http://www.340besp.com/designations).

All covered entities, including those that have already registered and designated a contract pharmacy, will need to designate a contract pharmacy that is compliant with this policy update by September 20, 2024.

This change in policy extends to all EMDS marketed products.

In support of a smooth transition to our updated 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, 2024 effective date.

Best regards,

*Daniel Van Horn*

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



EMD Serono

[emdserono.com](http://emdserono.com)

200 Pier 4 Boulevard, Suite 300  
Boston, Massachusetts 02210  
Tel.: 800-283-8088

2 of 7

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

### **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. The Policy applies to all covered entity types other than Ryan White Clinics purchasing Serostim® (somatropin).

**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. No. If a covered entity does not have in-house dispensing capabilities, only a single contract pharmacy location registered on the HRSA OPAIS database as being within 40 miles of the covered entity location and that is not a central fill pharmacy may be designated via the Designations form on [www.340besp.com/designations](http://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](http://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 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). Affected covered entities are encouraged to submit designations for approval as soon as possible. All covered entities, other than Ryan White Clinics, including those that have already registered and designated a contract pharmacy, will need to designate a contract pharmacy that is compliant with this policy update by September 20, 2024. 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. 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 cannot 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.

**Q: I have already registered and designated a single contract pharmacy location and am purchasing EMD Serono marketed products for delivery to this contract pharmacy. Will I have to re-designate a contract pharmacy location on or before October 1, 2024?**

A: Yes. Entities that currently comply with the EMDS policy will need to re-designate a contract pharmacy compliant with the updated policy by September 20, 2024 to continue to utilize that contract pharmacy.

**Q: I have already been granted a Wholly Owned exemption and am purchasing EMD Serono marketed products for delivery to this pharmacy. Will I have to re-designate or re-apply for a Wholly Owned Exemption on or before October 1, 2024?**

A: Effective October 1, 2024, contract pharmacies that are wholly owned by a 340B hospital or have common ownership with a health system will no longer be eligible to receive "Bill To / Ship To" replenishment orders of 340B priced EMDS products. A covered entity that does not have an in-house pharmacy may designate a wholly owned contract pharmacy that is located within a forty (40) mile radius of the covered entity location and that is not a central fill pharmacy as its single contract pharmacy designation. Designations can be made at [www.340besp.com/designations](http://www.340besp.com/designations).

**Q: My covered entity does not have any contract pharmacies that are located within 40 miles. Am I still able to designate a contract pharmacy?**

A: Under EMD Serono's Contract Pharmacy Policy update effective October 1, 2024, all designated contract pharmacies must be located within 40 miles of the covered entity site. EMD Serono will allow, however, the use of a contract pharmacy beyond the 40-mile radius if a covered entity demonstrates that (1) it lacks an in-house pharmacy capable of purchasing and dispensing EMD Serono covered outpatient drugs, and (2) there is no contract pharmacy capable of purchasing and dispensing EMD Serono covered outpatient drugs within a 40-mile radius of the covered entity's parent site as listed on the HRSA database. If you meet these conditions, please reach out to [support@340besp.com](mailto:support@340besp.com) for assistance.

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

A: No. EMD Serono's policy does not apply to 340B purchases of Saizen because EMD Serono 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 purchase Serostim for delivery to any contract pharmacy?**

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

**Q: I would like to select a contract pharmacy in the Serostim secured distribution network to which 340B purchases of Serostim can be delivered. Is this pharmacy required to be within 40 miles of my covered entity site?**

A: Subject to the exception noted above, all designated contract pharmacies must be located within 40 miles of the covered entity's location and must not be a central fill pharmacy.

**Q: My covered entity is a Ryan White Clinic, am I required to designate a single contract pharmacy in the Serostim secured distribution network to purchase at the 340B price?**

A: No. At this time, Ryan White Clinics are exempt from EMD Serono's Contract Pharmacy Policy for purchases of Serostim *only*.

**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 can be found at [www.340besp.com/designations](http://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 purchase Serostim may designate an additional contract pharmacy location in EMD Serono's secured distribution network for the purpose of dispensing Serostim (provided that this pharmacy is within a forty (40) mile radius of the covered entity and is not a central fill pharmacy). For example, if a covered entity's in-house pharmacy cannot dispense Serostim but it can dispense other EMD Serono marketed products, this covered entity may designate a single contract pharmacy that is part of EMD Serono's secured distribution network. 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 Serostim for delivery to this contract pharmacy. Will I have to re-designate a contract pharmacy location on or before October 1, 2024 to purchase Serostim at the 340B price?**

A: Yes. With this updated policy, covered entities will need to re-designate a contract pharmacy compliant with the updated policy by September 20, 2024 to continue to deliver Serostim purchased at the 340B price to their contract pharmacy. 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.

**EMD Serono, Inc.**

**NDC 11s Subject to EMDS's 340B Contract Pharmacy Restriction Policy as of 10.1.24**

NDC 11	Product Description	
44087903001	GONAL-F 450 IU (33 MCG) (1) - USA	
44087907001	GONAL-F 1050 IU	
44087900506	GONAL-F 75 IU VIAL (5.5 MCG) (10)-USA	
44087900501	GONAL-F 75 IU VIAL (5.5MCG) (1) - USA	
44087111501	GONAL-F REDIJECT 300 IU	
44087111601	GONAL-F REDIJECT 450 IU	
44087111701	GONAL-F REDIJECT 900 IU	
44087332201	REBIF REBIDOSE 22 (12) - USA	
44087334401	REBIF REBIDOSE 44 (12) - USA	
44087018801	REBIF REBIDOSE TITR (12) - USA	
44087002203	REBIF SYR 22 MCG (6 MIU) STR.PK (12)	
44087004403	REBIF SYR RNS 44 MCG (12 MIU) (12)	
44087882201	REBIF TITRA. PCK (6X22+6X8.8) (12)-USA	
44087400000	Mavenclad (cladribine) 10 mg per Tablet (10)	
44087400004	Mavenclad (cladribine) 10 mg per Tablet (4)	
44087400005	Mavenclad (cladribine) 10 mg per Tablet (5)	
44087400006	Mavenclad (cladribine) 10 mg per Tablet (6)	
44087400007	Mavenclad (cladribine) 10 mg per Tablet (7)	
44087400008	Mavenclad (cladribine) 10 mg per Tablet (8)	
44087400009	Mavenclad (cladribine) 10 mg per Tablet (9)	
44087122501	CETROTIDE VIAL 0.25 MG (1) - USA	
44087115001	OVIDREL SYR 250 MCG (1) - USA	
44087000407	SEROSTIM VIAL 4 MG (7) - USA	*see policy exception for Ryan White clinics
44087000507	SEROSTIM VIAL 5 MG (7) - USA	*see policy exception for Ryan White clinics
44087000607	SEROSTIM VIAL 6 MG (7) - USA	*see policy exception for Ryan White clinics
44087353501	BAVENCIO (avelumab) VIAL 200 MG/10 ML(1)-USA	
44087500003	Tepmetko (tepotinib) 225mg per tablet (30)	
44087500006	Tepmetko (tepotinib) 225mg per tablet (60)	