September 23, 2026

NOTICE TO 340B COVERED ENTITIES REGARDING MERCK'S 340B IN-HOUSE PHARMACY CLAIMS DATA POLICY

Dear 340B Covered Entity:

Merck Sharp & Dohme LLC ("Merck") is committed to the mission of the 340B Drug Pricing Program ("340B Program") and ensuring that eligible patients continue to benefit from discounted drug pricing. Merck is equally committed to helping ensure the 340B Program's integrity, including preventing Medicaid-340B duplicate discounts prohibited by the 340B statute.

This notice is to inform you of Merck's 340B In-House Pharmacy Claims Data Policy ("In-House Pharmacy Claims Data Policy" or "Policy"), which is part of Merck's broader 340B Program integrity initiative. This Policy is ***separate from and in addition to*** Merck's existing 340B contract pharmacy policy. The two policies operate independently, and compliance with one does not satisfy the requirements of the other.

Consistent with decisions by the Third Circuit in *Sanofi* and the D.C. Circuit in *Novartis*, which have upheld the ability of manufacturers to impose conditions on their offers to sell covered outpatient drugs at the 340B price, Merck is updating the terms of its offer to sell certain covered outpatient drugs at the 340B price to require submission of claims-level data for units dispensed through a covered entity's in-house pharmacy locations.

Merck has maintained a strong commitment to the 340B Program since its inception. Under Merck's 340B Program integrity initiative, of which this Policy is a part, we will continue to offer all covered entities our 340B covered outpatient drugs at or below the 340B ceiling price consistent with the 340B statute. We also will continue to work with all stakeholders to improve program integrity and will continue this commitment to the 340B Program through this In-House Pharmacy Claims Data Policy.

Merck's vendor, Second Sight Solutions (see www.340BESP.com), administers this Policy through the 340B ESP™ platform. The terms of the Policy are set forth below, together with **Table 1** (applicable Merck products) and **Attachment A** (state exemptions). Frequently asked questions follow. For questions regarding this Policy, please contact Merck at 340bdata@merck.com.

TERMS OF MERCK'S 340B IN-HOUSE PHARMACY CLAIMS DATA POLICY

Scope and Applicability

Effective **October 1, 2026**, Merck will require all hospital and CH covered entities to submit claims-level data (pharmacy and medical claims) for all 340B dispenses made by or through such covered entity's in-house pharmacy(ies) for the Merck covered outpatient drugs listed in **Table 1** of this Policy.

All federal grantee covered entities (apart from CH grantee entities) continue to be exempt from this Policy.

Covered entities located in the states listed in **Attachment A** are exempt from this Policy.

Definition of In-House Pharmacy

For purposes of this Policy, an "in-house pharmacy" is a pharmacy that is: (i) 100% owned by the covered entity, (ii) capable of purchasing and dispensing Merck 340B covered outpatient drugs, (iii) licensed or authorized by the appropriate state regulatory body to dispense prescription medications, and (iv) not listed on HRSA's Office of Pharmacy Affairs Information System ("OPAIS") database as a contract pharmacy for the covered entity.

Claims Data Submission Requirements

Covered entities subject to this Policy must submit claims-level data for all 340B dispenses of the products listed in Table 1 that are dispensed through the covered entity's in-house pharmacy(ies). Claims-level data includes both pharmacy claims and medical claims data.

Claims data must be submitted through the 340B ESP™ platform within **forty-five (45) days** of the date of 340B dispense. Failure to provide timely, complete, and accurate claims-level data in accordance with the timeline set forth in this Policy may affect a covered entity’s eligibility for 340B pricing for the products listed in Table 1 under this Policy. Merck reserves the right to suspend or modify access to 340B pricing for covered entities that do not comply with the data submission requirements set forth herein, upon reasonable notice.

Relationship to Contract Pharmacy Policy

This In-House Pharmacy Claims Data Policy is separate from Merck's 340B contract pharmacy policy. The contract pharmacy policy governs access to 340B pricing for drugs dispensed through contract pharmacies. This Policy governs the submission of claims-level data for drugs dispensed through a covered entity's in-house pharmacy(ies). Compliance with both policies is required to the extent each is applicable to a covered entity's operations.

Modifications to this Policy

Merck reserves the right to modify, update, or amend this Policy at any time. Covered entities will be notified of any material changes to this Policy through the 340B ESP™ platform or other appropriate means.

TABLE 1

Applicable Merck Products Subject to the In-House Pharmacy Claims Data Policy

Product Name
BELSOMRA®
JANUVIA®
JANUMET®
JANUMET® XR
LIPFENDRA®
STEGLATRO®
STEGLUJAN®
SEGLUROMET®
VERQUVO™

Note: This Policy applies only to the products listed above. Merck reserves the right to add or remove products from this list upon notice to covered entities.

ATTACHMENT A

State Exemptions from Merck's In-House Pharmacy Claims Data Policy

Covered entities located in the following states are exempt from Merck's In-House Pharmacy Claims Data Policy:

Arkansas
Colorado
Illinois
Louisiana
Maine
Nebraska
New Mexico*
Oregon
Rhode Island
South Dakota
Tennessee
Utah
Vermont
Washington

* New Mexico exemption applies only to Federally Qualified Health Centers (FQHCs) and FQHC look-alikes.

Merck reserves the right to add or remove states from this list at our discretion.

FREQUENTLY ASKED QUESTIONS

Merck's 340B In-House Pharmacy Claims Data Policy

Q: What is Merck's In-House Pharmacy Claims Data Policy?

A: Merck's In-House Pharmacy Claims Data Policy requires hospital and CH covered entities to submit claims-level data (pharmacy and medical claims) for all 340B dispenses of applicable Merck products that are dispensed through the covered entity's in-house pharmacy(ies). This Policy is part of Merck's broader 340B Program integrity initiative and is administered through the 340B ESP™ platform.

Q: Which covered entity types does this Policy apply to?

A: This Policy applies to hospital and CH covered entities. All federal grantee covered entities (apart from CH grantee entities) continue to be exempt from this Policy.

Q: What is an "in-house pharmacy" under this Policy?

A: An in-house pharmacy is a pharmacy that is: (i) 100% owned by the covered entity, (ii) capable of purchasing and dispensing Merck 340B covered outpatient drugs, (iii) licensed or authorized by the appropriate state regulatory body to dispense prescription medications, and (iv) not listed on HRSA's OPAIS database as a contract pharmacy for the covered entity.

Q: What Claims Level Data must be submitted?

A: Covered entities must submit both pharmacy claims and medical claims data for all 340B dispenses of the products listed in Table 1 that are dispensed through in-house pharmacies. Claims-level data should include sufficient information to identify the 340B transaction, including but not limited to the National Drug Code (NDC), quantity dispensed, date of dispense, and the applicable covered entity identifier.

Q: How often must claims data be submitted?

A: Claims data must be submitted through the 340B ESP™ platform within forty-five (45) days of the date of 340B dispense. Merck encourages covered entities to submit data on a rolling basis rather than waiting until the 45-day deadline.

Q: What happens if a covered entity fails to submit data within 45 days?

A: Failure to provide timely, complete, and accurate claims-level data in accordance with the timeline set forth in this Policy may affect a covered entity’s access to 340B pricing for the products listed in Table 1 under this Policy. Merck reserves the right to suspend or modify access to 340B pricing for covered entities that do not comply with the data submission requirements set forth herein, upon reasonable notice.

Q: Does this Policy apply to all Merck products?

A: No. This Policy applies only to the Merck covered outpatient drugs listed in Table 1 of the Policy. Not all Merck products are subject to this Policy.

Q: How is this Policy different from Merck's contract pharmacy policy?

A: Merck's contract pharmacy policy governs access to 340B pricing for drugs dispensed through contract pharmacies (i.e., pharmacies not owned by the covered entity that dispense 340B drugs on behalf of the covered entity pursuant to a contract pharmacy arrangement). This In-House Pharmacy Claims Data Policy separately addresses the submission of claims-level data for drugs dispensed through a covered entity's own in-house pharmacy(ies). The two policies are independent, and compliance with one does not satisfy the requirements of the other.

Q: Does this Policy apply to federal grantee covered entities?

A: All federal grantee covered entities (apart from CH grantee entities) continue to be exempt from this Policy. CH grantee entities are subject to this Policy.

Q: How do I register for 340B ESP™?

A: To register for the 340B ESP™ platform, visit www.340BESP.com. For questions about registration or the submission process, please contact Merck at 340bdata@merck.com.

Q: Are covered entities in all states subject to this Policy?

A: No. Covered entities located in the states listed in Attachment A are exempt from this Policy. Merck reserves the right to add or remove states from this list at our discretion.

Q: Does Merck require both pharmacy and medical claims data?

A: Yes. Covered entities must submit both pharmacy claims data and medical claims data for 340B dispenses of applicable products through in-house pharmacies. Both types of claims data are necessary to help identify duplicate discounts and to ensure comprehensive program integrity.