



March 20, 2025

**NOTICE TO 340B COVERED ENTITIES NOT IN ARKANSAS, LOUISIANA, MARYLAND, MINNESOTA,
MISSISSIPPI, MISSOURI AND WEST VIRGINIA
REGARDING UPDATED MERCK 340B PROGRAM INTEGRITY INITIATIVE**

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**NOTICE TO 340B COVERED ENTITIES IN ARKANSAS, LOUISIANA, MARYLAND, MINNESOTA,
MISSISSIPPI, MISSOURI AND WEST VIRGINIA
REGARDING UPDATED MERCK 340B PROGRAM INTEGRITY INITIATIVE**

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NOTICE TO 340B COVERED ENTITIES IN SOUTH DAKOTA (effective 7/1/2025)

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NOTICE TO 340B COVERED ENTITIES REGARDING UPDATED MERCK 340B PROGRAM INTEGRITY INITIATIVE

March 20, 2025

Dear 340B Covered Entity,

I am writing to inform you of an update to the 340B Program integrity initiative that Merck has implemented in order to help ensure compliance with the 340B Program requirements. Effective **March 31, 2025**, Merck will implement the changes outlined below related to its contract pharmacy policy under the 340B Program integrity initiative. Merck continues to strongly support the mission of the 340B Program and is committed to maintaining and strengthening its foundations. We also are committed to continuing to offer 340B discounts to all covered entities on all of Merck's covered outpatient drugs. The following policy supersedes any previous policy or exemptions, effective March 31, 2025.

What is changing?

- Under Merck's updated policy, for the products listed in Table 1, a hospital or Consolidated Health Center Program (CH) covered entity without an in-house pharmacy may designate a single contract pharmacy location to receive 340B-priced drugs only when the following conditions are satisfied: 1) the covered entity submits 340B claims data for claims originating from the designated contract pharmacy through the 340B ESP platform, and 2) the designated contract pharmacy is located within 40 miles of the covered entity parent site. A hospital or CH covered entity with an in-house pharmacy is not eligible to designate a contract pharmacy.
 - If a hospital or CH covered entity lacks an in-house outpatient pharmacy and is unable to identify an eligible contract pharmacy within 40 miles, Merck's vendor, Second Sight Solutions (see www.340BESP.com), will work with the covered entity to identify an available option for a contract pharmacy that is able to dispense covered outpatient drugs to the entity's patients.
 - A wholly-owned contract pharmacy may be designated as the single contract pharmacy for a hospital or CH covered entity that lacks its own in-house outpatient pharmacy, if it is within 40 miles of the covered entity's parent site or if Merck otherwise agrees to treat the wholly-owned contract pharmacy as the covered entity's single designated contract pharmacy, and the covered entity submits 340B claims data for claims originating from the designated contract pharmacy through the 340B ESP platform.
 - The designated contract pharmacy must be registered as a contract pharmacy on the HRSA OPAIS database. To ensure transparency and program integrity at designated contract pharmacies, all dispensing to 340B-eligible patients must occur at the designated contract pharmacy location, and 340B drugs will be shipped directly to that location either by Merck or an authorized distributor.
- Effective March 31, 2025, this version of our 340B integrity initiative (as described on pages 2–5 of this document) will apply to hospital and CH covered entities in Kansas, and the version of our 340B integrity initiative that is described starting on page 6 of this document will apply to hospital and CH covered entities in West Virginia.
- Merck has updated the FAQs applicable to our policy.

What is not changing?

For the Merck products listed in Table 1 below, the following policy continues to apply:

- An entity enrolled in the 340B Program as a hospital or CH covered entity that has its own in-house outpatient pharmacy capable of dispensing the 340B-discounted Merck products listed in Table 1 below **is not eligible** to have 340B-discounted Merck products delivered to contract pharmacies. These 340B purchased products will **only** be shipped/delivered to the in-house outpatient pharmacy registered on the HRSA OPAIS database.
- All federal grantee covered entities (apart from CH grantee entities) continue to be exempt from this policy. Merck's policy continues to apply only to hospital and CH covered entities.

| Table 1. Applicable Merck covered outpatient drug products |
|--|
| BELSOMRA® (suvorexant) |
| JANUVIA® (sitagliptin) |
| JANUMET® (sitagliptin and metformin hydrochloride) |
| JANUMET® XR (sitagliptin and metformin hydrochloride extended release) |
| STEGLATRO® (ertugliflozin) |
| STEGLUJAN® (ertugliflozin and sitagliptin) |
| SEGLUROMET® (ertugliflozin and metformin) |
| VERQUVO™ (vericiguat) |

For WINREVAIR™ (sotatercept-csrk), the following policy continues to apply:

- WINREVAIR is available through a limited specialty pharmacy network. Effective April 12, 2024, a hospital or CH covered entity is eligible to access WINREVAIR by designating a single specialty pharmacy location through Merck’s vendor, Second Sight Solutions (see www.340BESP.com). The designated specialty pharmacy must be part of Merck’s limited network of specialty pharmacies for that product. This specialty pharmacy location for WINREVAIR is in addition to a single contract pharmacy designation for the products listed in Table 1 above if the hospital or CH covered entity lacks its own in-house outpatient pharmacy.
- All federal grantee covered entities (apart from CH grantee entities) are exempt from Merck’s 340B Program integrity initiative and will be eligible to access WINREVAIR through Merck’s limited network of specialty pharmacies for that product.

Merck remains concerned with the lack of transparency and heightened risks of statutory noncompliance that arise from contract pharmacy arrangements, and we believe substantial governance and oversight are needed to ensure that the 340B Program is viable for safety net providers and the vulnerable patients these entities serve. The changes outlined above are part of Merck’s consistent commitment to help ensure the 340B Program’s integrity, including preventing Medicaid-340B duplicate discounts prohibited by the statute. As Merck has noted in prior communications about this initiative, we are particularly concerned about duplicate discounts and other statutory violations in the context of contract pharmacy transactions, as multiple government reports have likewise recognized. In *Sanofi Aventis U.S. LLC v. U.S. Department of Health & Human Services*, the U.S. Court of Appeals for the Third Circuit reviewed the 340B statute and concluded that “drug makers’ delivery conditions” regarding contract pharmacies comply with the 340B statute if a covered entity “can still use the Section 340B program” and buy and dispense “discounted drugs by having them delivered to an in-house or contract pharmacy.” The court also explained that “Section 340B does not require delivery to an unlimited number of contract pharmacies.” Similarly, in *Novartis Pharmaceuticals Corporation v. Johnson*, the U.S. Court of Appeals for the D.C. Circuit reviewed the 340B statute and concluded that “section 340B does not categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities” and that the contract pharmacy policies of the two plaintiff manufacturers “do not violate section 340B.” Each version of Merck’s contract pharmacy policy, including the version described in this letter, is consistent with the Third Circuit’s decision in *Sanofi* and with the D.C. Circuit’s decision in *Novartis*.

Additionally, in September 2024, the U.S. District Court for the District of Columbia entered a consent judgment in Merck’s favor against the U.S. Department of Health and Human Services (HHS), the HHS Secretary, HRSA, and the HRSA Administrator, regarding Merck’s 340B Program integrity initiative. That judgment declares that the Merck policy for which HRSA issued a “violation letter” to Merck in May 2022 “does not violate Section 340B on its face,” and that section 340B “does not categorically prohibit Merck from imposing conditions on the distribution of covered drugs to covered entities.” Final Judgment, ECF No. 21 at 1, *Merck Sharp & Dohme LLC v. HHS*, No. 22-cv-01986 (D.D.C. Sept. 17, 2024).

Merck has maintained a strong commitment to the 340B Program since its inception. Under the updated Merck 340B Program integrity initiative, 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 these updates to our initiative.

If you have any questions about this initiative, please contact Merck at 340bdata@merck.com. Additionally, information about 340B ESP™ is available at www.340BESP.com.

FREQUENTLY ASKED QUESTIONS (Updated March 31, 2025)

Q: (New) What is changing with respect to Merck's 340B Program integrity initiative beginning March 31, 2025?

A: Effective March 31, 2025, for the products listed in Table 1, any hospital or CH covered entity that lacks its own in-house outpatient pharmacy may designate a single contract pharmacy location of its choice provided that the single contract pharmacy is located within 40 miles of the covered entity parent site, the covered entity submits 340B claims data for the designated contract pharmacy, and the designated contract pharmacy is registered on the HRSA OPAIS database. (If a hospital or CH covered entity lacks an in-house outpatient pharmacy and is unable to identify an eligible contract pharmacy within 40 miles, Merck's vendor, Second Sight Solutions (see www.340BESP.com), will work with the covered entity to identify an available option for a contract pharmacy that is able to dispense covered outpatient drugs to the entity's patients.)

What is not changing under our policy is that an entity enrolled in the 340B Program as a hospital or CH covered entity that has its own in-house outpatient pharmacy capable of dispensing the 340B-discounted Merck products listed in Table 1 below **is not eligible** to have 340B-discounted Merck products delivered to contract pharmacies. These 340B purchased products will **only** be shipped/delivered to the in-house outpatient pharmacy registered on the HRSA OPAIS database. The policy also continues to apply only to hospital and CH covered entities.

Q: For the Merck products listed in Table 1 of Merck's policy: If a hospital or CH covered entity lacks an in-house outpatient pharmacy, how does it designate a single contract pharmacy location of its choice that is within 40 miles of the entity's parent site?

A: Designations of a single contract pharmacy location can be made through 340B ESP™ (see www.340BESP.com), and 340B ESP™ will provide a list of pharmacy locations that are within 40 miles of the covered entity's parent site. 340B covered entities that haven't already registered an account with 340B ESP™ can make their designations by visiting www.340besp.com/designations.

This designation will be made for the parent 340B ID and will apply to any child sites. Please note that a contract pharmacy must have an assigned HIN for the wholesaler to process 340B transactions.

Q: For WINREVAIR, is the product available to be shipped/delivered to an in-house outpatient pharmacy?

A: No, WINREVAIR is only available through a limited specialty pharmacy network.

Q: For WINREVAIR, which specialty pharmacies are part of Merck's limited specialty pharmacy network?

A: WINREVAIR is available through two specialty pharmacies, Accredo and CVS Specialty pharmacies. There are no restrictions on the distance of a designated specialty pharmacy location from the covered entity's parent site.

Q: Where can I find information about 340B ESP™?

A: Information about 340B ESP™ is available at www.340BESP.com.

Q: What is involved in the 340B ESP™ process?

A: If a covered entity wishes to register, getting started with 340B ESP™ involves the following: Go to www.340BESP.com to register your account. Upon initial registration you will be prompted with an onboarding tutorial that will walk you through the account set up process step by step. This process takes ~15 minutes.

Additional information about 340B ESP™ is also available at www.340BESP.com/FAQs or by calling 340B ESP™ at 888-398-5520.

Q: For the Merck products listed in Table 1 of Merck's policy, what should a hospital or CH covered entity do if it lacks an in-house outpatient pharmacy and cannot identify a single contract pharmacy location that is located within 40 miles of the entity's parent site?

A: If a hospital or CH covered entity that lacks an in-house outpatient pharmacy is unable to identify an eligible contract pharmacy within 40 miles of the covered entity's parent site, the entity should contact Second Sight Solutions (see www.340BESP.com), who will work with the covered entity to identify an available option for a contract pharmacy that is able to dispense covered outpatient drugs to the entity's patients.

Q: (Updated FAQ) Does Merck's updated policy apply to contract pharmacies that are wholly-owned by a 340B hospital or CH covered entity or are under common ownership with a 340B health system?

A: Yes, Merck's 340B Program integrity initiative applies to contract pharmacies that are wholly-owned by a 340B hospital or CH covered entity or are under common ownership with a 340B health system or CH covered entity. Any contract pharmacy location registered on the HRSA OPAIS database, regardless of ownership interest, will be treated as a contract pharmacy. For the Merck products listed in Table 1, a wholly-owned contract pharmacy may be designated as the single contract pharmacy for a hospital or

CH covered entity that lacks its own in-house outpatient pharmacy, if it is within 40 miles of the covered entity's parent site or if Merck otherwise agrees to treat the wholly-owned contract pharmacy as the covered entity's single designated contract pharmacy, and the covered entity submits 340B claims data for claims originating from the designated contract pharmacy through the 340B ESP platform. (If a hospital or CH covered entity lacks an in-house outpatient pharmacy and is unable to identify an eligible contract pharmacy within 40 miles, Merck's vendor, Second Sight Solutions (see www.340BESP.com), will work with the covered entity to identify an available option for a contract pharmacy that is able to dispense covered outpatient drugs to the entity's patients.)

Q: (New) May a covered entity designate a centralized pharmacy replenishment facility as its single contract pharmacy location?

A: No. Centralized pharmacy replenishment facilities or "central-fill pharmacies" are not eligible to be designated as a single contract pharmacy location for a hospital or CH covered entity.

Q: (New) What is an "in-house outpatient pharmacy"?

A: An "in-house outpatient pharmacy" is a pharmacy that is 100% owned by the covered entity, is capable of dispensing the applicable Merck 340B covered outpatient drugs, is listed as a valid address for the hospital or CH covered entity in HRSA's OPAIS covered entity database, and is not listed on OPAIS as a registered contract pharmacy for the hospital or CH covered entity. If a hospital or CH covered entity has an "in-house outpatient pharmacy", the hospital and CH covered entity may use that pharmacy to receive delivery of applicable Merck 340B-priced products and is not eligible to make a single contract pharmacy designation under this policy.

Q: (New) Does Merck permit an entity to tally dispensing activity from non-designated contract pharmacy locations and then, based on that tallying, place subsequent orders to be shipped to a different, single designated contract pharmacy or entity-owned location?

A: No. Contract pharmacy designations are specific to a location registered individually on the HRSA database by name and address (i.e., physical location), and 340B dispensing activity must occur at this location in order for the location to receive delivery of Merck's 340B-priced covered outpatient drugs.

Q: (New) Does Merck permit an entity to designate a single contract pharmacy "replenishment" location, include dispensing activity from several other non-designated contract pharmacy locations of the same organization, and then create replenishment orders based on all the dispensing activity to a single replenishment location?

A: No. Contract pharmacy designations are specific to a location registered individually on the HRSA database by name and address (i.e., physical location). To ensure transparency and program integrity, all dispensing to 340B-eligible patients must occur at the properly designated contract pharmacy location, and 340B drugs will be shipped directly to that location either by Merck or an authorized distributor.

Q: Does Merck's 340B Program integrity initiative apply to all of Merck's products?

A: Merck's 340B Program integrity initiative continues to apply only to the Merck products in Table 1 and WINREVAIR™ (sotatercept-csrk). See the 340B ESP website at www.340BESP.com for the list of NDCs applicable to the Merck 340B Program integrity initiative. As this list may be updated from time to time by Merck, please visit the 340B ESP website for the current list of applicable NDCs.

Q: How can a 340B covered entity change its contract pharmacy and/or specialty pharmacy designation?

A: Changes to the single contract pharmacy can 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. Covered entities may change their contract pharmacy and/or specialty pharmacy designations 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: (Updated) Is there a limitation on how far back replenishment orders can be placed and still receive 340B pricing?

A: Contract pharmacy replenishment orders for those hospital and CH covered entities registered with 340B ESP™ will be honored for claims submitted within forty-five (45) days of the dispense date. Please allow for ten (10) business days for the single contract pharmacy or specialty pharmacy designation to take effect after registering with 340B ESP™.

If you have additional questions about the Merck Program, please contact Merck directly at our Merck National Service Center by calling 1-800-672-6372.

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NOTICE TO 340B COVERED ENTITIES REGARDING AN UPDATE TO THE MERCK 340B PROGRAM INTEGRITY INITIATIVE FOR THE FOLLOWING STATES:

- **ARKANSAS**
- **LOUISIANA**
- **MARYLAND**
- **MINNESOTA**
- **MISSISSIPPI**
- **MISSOURI**
- **WEST VIRGINIA**

March 20, 2025

Dear 340B Covered Entities,

I am writing to inform you of an update to the 340B Program integrity initiative that Merck has implemented in order to help ensure compliance with the 340B Program requirements. Effective **March 31, 2025**, Merck will implement the changes outlined below related to its contract pharmacy policy under the 340B Program integrity initiative. Merck continues to strongly support the mission of the 340B Program and is committed to maintaining and strengthening its foundations. We also are committed to continuing to offer 340B discounts to all covered entities on all of Merck's covered outpatient drugs.

What is changing?

- Under Merck's updated policy, for the products listed in Table 1, Merck will voluntarily honor 340B discounts and chargebacks for contract pharmacy transactions for hospital and CH covered entities, including multiple contract pharmacy arrangements, provided the hospital or CH Covered entity registers and submits 340B claims data for transactions originating from all eligible contract pharmacies through Merck's vendor, Second Sight Solutions (see www.340BESP.com). If the hospital or CH covered entity registers and submits 340B claims data for transactions originating from all eligible contract pharmacies, Merck will voluntarily honor 340B discounts and chargebacks for all eligible contract pharmacy transactions once the registration and 340B claims data have been processed. Under this updated policy, Merck will no longer permit a hospital or CH covered entity that lacks its own in-house outpatient pharmacy to designate a single contract pharmacy location if the hospital or CH covered entity chooses not to provide 340B claims data for claims originating from its contract pharmacies to Merck's vendor, Second Sight Solutions.
- Effective March 31, 2025, the version of our 340B integrity initiative (as described on pages 2–5 of this document) will apply to hospital and CH covered entities in Kansas), and this version of our 340B integrity initiative that is described starting on page 6 of this document will apply to hospital and CH covered entities in West Virginia.
- Merck has updated the FAQs applicable to our policy.

What is not changing?

For the Merck products listed in Table 1 below, the following policy continues to apply and is extended to West Virginia as set forth below:

- For hospital and CH covered entities placing orders on or after:
 - July 31, 2023 for ARKANSAS AND LOUISIANA
 - July 1, 2024 for MARYLAND AND MISSISSIPPI
 - August 1, 2024 for MINNESOTA
 - August 28, 2024 for MISSOURI
 - March 31, 2025 for WEST VIRGINIA
- This policy continues to apply only to Merck's covered outpatient drugs that are predominantly dispensed through retail, specialty, and outpatient pharmacies. The 340B ESP website at www.340BESP.com provides a list of NDCs applicable to the Merck 340B Program integrity initiative.
- All federal grantee covered entities (apart from CH grantee entities) continue to be exempt from this policy. Merck's policy

continues to apply only to hospital and CH covered entities.

| Table 1. Applicable Merck covered outpatient drug products |
|--|
| BELSOMRA® (suvorexant) |
| JANUVIA® (sitagliptin) |
| JANUMET® (sitagliptin and metformin hydrochloride) |
| JANUMET® XR (sitagliptin and metformin hydrochloride extended release) |
| STEGLATRO® (ertugliflozin) |
| STEGLUJAN® (ertugliflozin and sitagliptin) |
| SEGLUROMET® (ertugliflozin and metformin) |
| VERQUVO™ (vericiguat) |

For WINREVAIR™ (sotatercept-csrk), the following policy continues to apply and is extended to West Virginia as set forth below:

- For hospital and CH covered entities, WINREVAIR is available through a limited specialty pharmacy network. For orders placed on or after:
 - April 12, 2024 for ARKANSAS AND LOUISIANA
 - July 1, 2024 for MARYLAND AND MISSISSIPPI
 - August 1, 2024 for MINNESOTA
 - August 28, 2024 for MISSOURI
 - March 31, 2025 for WEST VIRGINIA
- Merck will voluntarily honor 340B discounts and chargebacks for specialty pharmacy transactions for WINREVAIR in Merck’s limited pharmacy network for hospital and CH covered entities, provided the hospital or CH covered entity registers and submits 340B claims data for all claims of WINREVAIR originating from all specialty pharmacies in Merck’s limited specialty pharmacy network through Merck’s vendor, Second Sight Solutions (see www.340BESP.com). If a hospital or CH covered entity chooses not to provide 340B claims data for WINREVAIR originating from all specialty pharmacies in Merck’s limited specialty pharmacy network, a single specialty pharmacy location of its choice (in Merck’s limited pharmacy network) may be designated through Merck’s vendor, Second Sight Solutions (see www.340BESP.com).

Merck remains concerned with the lack of transparency and heightened risks of statutory noncompliance that arise from contract pharmacy arrangements, and we believe substantial governance and oversight are needed to ensure that the 340B Program is viable for safety net providers and the vulnerable patients these entities serve. The changes outlined above are part of Merck’s consistent commitment to help ensure the 340B Program’s integrity, including preventing Medicaid-340B duplicate discounts prohibited by the statute. As Merck has noted in prior communications about this initiative, we are particularly concerned about duplicate discounts and other statutory violations in the context of contract pharmacy transactions, as multiple government reports have likewise recognized. In *Sanofi Aventis U.S. LLC v. U.S. Department of Health & Human Services*, the U.S. Court of Appeals for the Third Circuit reviewed the 340B statute and concluded that “drug makers’ delivery conditions” regarding contract pharmacies comply with the 340B statute if a covered entity “can still use the Section 340B program” and buy and dispense “discounted drugs by having them delivered to an in-house or contract pharmacy.” The court also explained that “Section 340B does not require delivery to an unlimited number of contract pharmacies.” Similarly, in *Novartis Pharmaceuticals Corporation v. Johnson*, the U.S. Court of Appeals for the D.C. Circuit reviewed the 340B statute and concluded that “section 340B does not categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities” and that the contract pharmacy policies of the two plaintiff manufacturers “do not violate section 340B.” Each version of Merck’s contract pharmacy policy, including the version described in this letter, is consistent with the Third Circuit’s decision in *Sanofi* and with the D.C. Circuit’s decision in *Novartis*.

Additionally, in September 2024, the U.S. District Court for the District of Columbia entered a consent judgment in Merck’s favor against the U.S. Department of Health and Human Services (HHS), the HHS Secretary, HRSA, and the HRSA Administrator, regarding Merck’s 340B Program integrity initiative. That judgment declares that the Merck policy for which HRSA issued a “violation letter” to Merck in May 2022 “does not violate Section 340B on its face,” and that section 340B “does not categorically prohibit Merck from imposing conditions on the distribution of covered drugs to covered entities.” Final Judgment, ECF No. 21 at 1, *Merck Sharp & Dohme LLC v. HHS*, No. 22-cv-01986 (D.D.C. Sept. 17, 2024).

Merck has maintained a strong commitment to the 340B Program since its inception. Under the updated Merck 340B Program integrity initiative, 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 these updates to our initiative.

If you have any questions about this initiative, please contact Merck at 340bdata@merck.com. Additionally, information about 340B ESP™ is available at www.340BESP.com.

FREQUENTLY ASKED QUESTIONS (Updated March 31, 2025) REGARDING THE UPDATE TO THE MERCK 340B PROGRAM INTEGRITY INITIATIVE FOR THE FOLLOWING STATES:

- **ARKANSAS**
- **LOUISIANA**
- **MARYLAND**
- **MINNESOTA**
- **MISSISSIPPI**
- **MISSOURI**
- **WEST VIRGINIA**

Q: What is Merck's policy for WINREVAIR™ (sotatercept-csrk) with respect to Merck's 340B Program integrity initiative?

A: For WINREVAIR™ (sotatercept-csrk), the following policy continues to apply and is extended to:

For hospital and CH covered entities, WINREVAIR is available through a limited specialty pharmacy network. For orders placed on or after:

- April 12, 2024 for ARKANSAS AND LOUISIANA
 - July 1, 2024 for MARYLAND AND MISSISSIPPI
 - August 1, 2024 for MINNESOTA
 - August 28, 2024 for MISSOURI
 - March 31, 2025 for WEST VIRGINIA
- WINREVAIR is available through a limited specialty pharmacy network. For WINREVAIR, Merck will voluntarily honor 340B discounts and chargebacks for specialty pharmacy transactions in Merck's limited pharmacy network for hospital and CH covered entities, provided the hospital or CH covered entity registers and submits 340B claims data for all claims of WINREVAIR originating from their specialty pharmacies through Merck's vendor, Second Sight Solutions (see www.340BESP.com).
 - If a hospital or CH covered entity chooses not to provide 340B claims data for WINREVAIR originating from all specialty pharmacies in Merck's limited pharmacy network, a single specialty pharmacy location of its choice (in Merck's limited pharmacy network) may be designated through Merck's vendor, Second Sight Solutions (see www.340BESP.com).
 - All federal grantee covered entities (apart from CH grantee entities) are exempt from Merck's 340B Program integrity initiative and will be eligible to access the 340B-discounted price of WINREVAIR through Merck's limited network of specialty pharmacies for that product.

Q: Who should I contact if I have questions about the updates to Merck's policy for these states?

A: Please contact Merck directly at our Merck National Service Center by calling 1-800-672-6372 or contact Merck's vendor, Second Sight Solutions (see www.340BESP.com), and we will work with you to address your questions.

Q: For WINREVAIR, is the product available to be shipped/delivered to an in-house outpatient pharmacy?

A: No, WINREVAIR is only available through a limited specialty pharmacy network.

Q: For WINREVAIR, which specialty pharmacies are part of Merck limited specialty pharmacy network?

A: WINREVAIR is available through two specialty pharmacies, Accredo and CVS Specialty pharmacies. There are no restrictions on the distance of a designated specialty pharmacy location from the covered entity's parent site.

Q: Where can I find information about 340B ESP™?

A: Information about 340B ESP™ is available at www.340BESP.com.

Q What is involved in the 340B ESP™ process?

A: If a covered entity wishes to register, getting started with 340B ESP™ involves the following: Go to www.340BESP.com to register your account. Upon initial registration you will be prompted with an onboarding tutorial that will walk you through the account set up process step by step. This process takes ~15 minutes.

Additional information about 340B ESP™ is also available at www.340BESP.com/FAQs or by calling 340B ESP™ at 888-398-5520.

Q: Does Merck's updated policy apply to contract pharmacies that are wholly owned by a 340B hospital or CH covered entity or are under common ownership with a health system or CH covered entity?

A: Yes, with respect to all states, Merck's 340B Program integrity initiative will apply to contract pharmacies that are wholly owned by a 340B hospital or CH covered entity, or are under common ownership with a health system or CH covered entity. Any contract pharmacy location registered on the HRSA OPAIS database, regardless of ownership interest, will be treated as a contract pharmacy.

Q: (New) Does Merck require the submission of limited 340B claims data originating from contract pharmacies for the Merck Products in Table 1, including those hospital and CH covered entities that lack an in-house outpatient pharmacy?

A: Yes. Merck will voluntarily honor 340B discounts and chargebacks for contract pharmacy transactions for hospital and CH covered entities, including multiple contract pharmacy arrangements, provided the hospital or CH covered entity registers and submits 340B claims data for transactions originating from all eligible contract pharmacies through Merck's vendor, Second Sight Solutions (see www.340BESP.com). If the hospital or CH covered entity registers and submits 340B claims data for transactions originating from all eligible contract pharmacies, Merck will voluntarily honor 340B discounts and chargebacks for all eligible contract pharmacy transactions once the registration and 340B claims data have been processed. Under this updated policy, effective **March 31, 2025**, Merck will no longer permit a hospital or CH covered entity that lacks its own in-house outpatient pharmacy to designate a single contract pharmacy location if the hospital or CH covered entity chooses not to provide 340B claims data for claims originating from its contract pharmacies to Merck's vendor, Second Sight Solutions.

Q: Why has Merck changed its policy applicable for the states listed above but not for other states?

A: The states listed above have passed state-specific statutes that relate to the 340B Program. Those statutes have been challenged in litigation and may be invalidated by the courts. While litigation plays out over those issues, Merck has amended its policy as to the states listed above.

Q: Does Merck's 340B Program integrity initiative apply to all of Merck's products?

A: In all states, Merck's 340B Program integrity initiative continues to apply only to the Merck products in Table 1 and WINREVAIR™ (sotatercept-csrk). Physician-administered drugs continue to be outside the scope of Merck's 340B Program integrity initiative. See the 340B ESP website at www.340BESP.com for the list of NDCs applicable to the Merck 340B Program integrity initiative. As this list may be updated from time to time by Merck, please visit the 340B ESP website for the current list of applicable NDCs.

Q: How can a 340B covered entity change its specialty pharmacy contract pharmacy designation for WINREVAIR™ (sotatercept-csrk)?

A: Changes to the single specialty pharmacy can 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. 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: (Updated) Is there a limitation on how far back replenishment orders can be placed and still receive 340B pricing?

A: Contract pharmacy replenishment orders for those hospital and CH covered entities registered with 340B ESP™ will be honored for claims submitted within forty-five (45) days of the dispense date. Please allow for ten (10) business days for the specialty pharmacy designation to take effect after registering with 340B ESP™.

If you have additional questions about the Merck Program, please contact Merck directly at our Merck National Service Center by calling 1-800-672-6372.

NOTICE TO 340B COVERED ENTITIES IN SOUTH DAKOTA

March 20, 2025

Dear 340B Covered Entity,

Effective July 1, 2025, contract pharmacy arrangements between 340B covered entities located in South Dakota and their contract pharmacies are exempt from Merck's 340B Program integrity initiative. Prior to July 1, 2025, 340B covered entities located in South Dakota shall be subject to Merck's 340B Program integrity initiative as described on pages 2–5 of this document. In all other states, Merck will continue to apply the policy as announced to covered entities dated March 20, 2025.

WINREVAIR™ (sotatercept-csrk) will continue to be available through a limited specialty pharmacy network. Merck will voluntarily honor 340B discounts and chargebacks for specialty pharmacy transactions in Merck's limited pharmacy network.

We continue to reserve the right to further update our policy at our discretion. If you have any questions about this change to the initiative, please contact Merck at 340bdata@merck.com.