



August 1, 2024

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

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

April 12, 2024

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 April 12, 2024, Merck is updating the list of products included in our 340B Program integrity initiative to include WINREVAIR™ (sotatercept-csrk). 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?

- WINREVAIR is available through a limited specialty pharmacy network. Effective April 12, 2024, a hospital or Consolidated Health Center Program (CH) covered entity will be 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 below 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.

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 **are 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.
- Merck will allow a hospital or CH covered entity that lacks its own in-house outpatient pharmacy to 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 and 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.
 - Merck no longer requires the submission of limited 340B claims data for claims originating from contract pharmacies. Merck encourages 340B covered entities designating a single contract pharmacy to voluntarily submit limited claims data for their single contract pharmacy transactions for purposes of 340B Program integrity and transparency.
- The 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 health system or CH covered entity.
 - 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.
- Merck's policy continues to apply only to hospital and CH covered entities.
- All federal grantee covered entities (apart from CH grantee entities) continue to be exempt from this policy.

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)

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". Each version of Merck's contract pharmacy policy, including the version described in this letter, is consistent with the court's decision in *Sanofi*.

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 April 12, 2024)

Q: What is changing with respect to Merck's 340B Program integrity initiative beginning April 12, 2024

A: Effective April 12, 2024, Merck is updating the list of products included in our 340B Program integrity initiative to include WINREVAIR™. WINREVAIR is available through a limited specialty pharmacy network. Effective April 12, 2024, a hospital or Consolidated Health Center Program (CH) covered entity will be eligible to access WINREVAIR by designating a single specialty contract 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 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.

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 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: 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 or CH covered entity?

A: Yes, this update to 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 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.

Q: Does Merck require the submission of limited 340B claims data for claims originating from contract pharmacies?

A: No. Merck encourages 340B covered entities designating a single contract pharmacy to voluntarily submit limited claims data for their single contract pharmacy transactions for purposes of 340B Program integrity and transparency.

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 Merck's covered outpatient drugs that are predominantly dispensed through retail, specialty, and outpatient pharmacies. 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 OP AIS database.

Q: Is there a limitation on how far back replenishment orders can be placed and still receive 340B pricing, once eligibility for the single contract pharmacy or specialty pharmacy designation has been processed by our wholesaler?

A: Contract pharmacy replenishment orders for those covered entities registered with 340B ESP™ will be honored for dispenses within the prior forty-five (45) days. 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**
- **KANSAS**
- **LOUISIANA**
- **MARYLAND**
- **MINNESOTA**
- **MISSISSIPPI**
- **MISSOURI**

August 1, 2024

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 July 1, 2024, Merck updated the states listed above to include Kansas, Maryland, and Mississippi. Merck is also updating the list of states above to include Minnesota effective August 1, 2024 and Missouri effective August 28, 2024. Except for the list of states above, Merck's policy continues to apply. 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.

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

- WINREVAIR is available through a limited specialty pharmacy network. Effective April 12, 2024 for ARKANSAS and LOUISIANA, July 1, 2024 for MARYLAND, MISSISSIPPI AND KANSAS, August 1, 2024 for Minnesota and August 28, 2024 for Missouri, 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). This specialty pharmacy location for WINREVAIR is in addition to a single contract pharmacy designation for the products listed in Table 1 below 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 the 340B-discounted price of WINREVAIR through Merck's limited network of specialty pharmacies for that product.

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

- For orders placed on or after:
 - July 31, 2023 for ARKANSAS AND LOUISIANA ,
 - July 1, 2024 for KANSAS, MARYLAND AND MISSISSIPPI
 - August 1, 2024 for MINNESOTA
 - August 28, 2024 for MISSOURI

Merck will voluntarily honor 340B discounts and chargebacks for contract pharmacy transactions for hospital and CH covered entities, provided the hospital or CH covered entity registers and submits 340B claims data for all claims originating from their contract 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 originating from all eligible contract pharmacies and lacks its own in-house outpatient pharmacy, a single contract pharmacy location of its choice may be designated through Merck's vendor, Second Sight Solutions (see www.340BESP.com), provided that the single contract pharmacy is located within 40 miles of the covered entity parent site and registered on the HRSA 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.

- This policy also 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.
- Additionally, this policy continues to 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 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.
- Merck's policy continues to apply only to hospital and CH covered entities.
- All federal grantee covered entities (apart from CH grantee entities) continue to be exempt from this policy.

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)

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". Each version of Merck's contract pharmacy policy, including the version described in this letter, is consistent with the court's decision in *Sanofi*.

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 August 1, 2024) REGARDING THE UPDATE TO THE MERCK 340B PROGRAM INTEGRITY INITIATIVE FOR THE FOLLOWING STATES:

- **ARKANSAS**
- **KANSAS**
- **LOUISIANA**
- **MARYLAND**
- **MINNESOTA**
- **MISSISSIPPI**
- **MISSOURI**

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

A: Effective April 12, 2024 for ARKANSAS and LOUISIANA, July 1, 2024 for KANSAS, MARYLAND, and MISSISSIPPI, and August 1, 2024 for MINNESOTA and August 28, 2024 for MISSOURI Merck will apply the following policy for WINREVAIR :

- 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). This specialty pharmacy location for WINREVAIR is in addition to a single contract pharmacy designation for the products listed in Table 1 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 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: 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 have not 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: 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: 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: Is Merck still requiring the submission of limited 340B claims originating from contract pharmacies for the Merck Products in Table 1?

A: For orders placed on or after 1) July 31, 2023 for ARKANSAS AND LOUISIANA, 2) July 1, 2024 for KANSAS, MARYLAND AND MISSISSIPPI, 3) August 1, 2024 for MINNESOTA and 4) August 28, 2024 for MISSOURI by an entity enrolled in the 340B Program as a hospital or as a Consolidated Health Center Program (CH) covered entity, Merck will voluntarily honor 340B discounts and chargebacks for contract pharmacy transactions, including multiple contract pharmacy arrangements, provided the hospital and CH Covered entity registers and submits 340B claims data originating from all eligible contract pharmacies through Merck's vendor, Second Sight Solutions (see www.340BESP.com) for Merck to voluntarily honor 340B discounts and chargebacks for all eligible contract pharmacies. If the hospital or CH covered entity registers and submits 340B claims data originating from all eligible contract pharmacies, 340B discounts and chargebacks will be voluntarily honored for all eligible contract pharmacy transactions once the registration and 340B claims data have been processed. The updates to Merck's 340B Program integrity initiative for the states listed above do not affect Merck's policy in other states. Merck nonetheless encourages 340B covered entities in other states that are designating a single contract pharmacy to voluntarily submit limited claims data for their single contract pharmacy transactions for purposes of 340B Program integrity and transparency.

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 Merck's covered outpatient drugs that are predominantly dispensed through retail, specialty, and outpatient pharmacies. 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 contract pharmacy designation?

A: Changes to the single contract pharmacy and/or 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: Is there a limitation on how far back replenishment orders can be placed and still receive 340B pricing, once eligibility for the single contract pharmacy designation and/or specialty pharmacy designation has been processed by our wholesaler?

A: Contract pharmacy replenishment orders for those covered entities registered with 340B ESP™ will be honored for dispenses within the prior forty-five (45) days. Please allow for ten (10) business days for the single contract pharmacy and 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 WEST VIRGINIA

June 6, 2024

Dear 340B Covered Entity,

Effective June 6, 2024, contract pharmacy arrangements between 340B covered entities located in West Virginia and their contract pharmacies are exempt from Merck's 340B Program integrity initiative. In all other states, Merck will continue to apply the policy as announced to covered entities in April 2024. Please refer to our policy dated April 12, 2024, or to our Frequently Asked Questions document, for information regarding that policy.

WINREVAIR™ (sotatercept-csrk) will continue to be available through a limited specialty pharmacy network. Effective June 6, 2024 for WINREVAIR, 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.