



July 31, 2023

**NOTICE TO 340B COVERED ENTITIES IN LOUISIANA AND ARKANSAS
REGARDING AN UPDATE TO THE MERCK 340B PROGRAM INTEGRITY INITIATIVE,
[SEE PAGE 6](#)**

**NOTICE TO 340B COVERED ENTITIES NOT IN LOUISIANA AND ARKANSAS
REGARDING MERCK'S 340B PROGRAM INTEGRITY INITIATIVE,
[SEE PAGE 2](#)**

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



May 10, 2023

Dear 340B Covered Entity,

I am writing to inform you of updates to the 340B Program integrity initiative that Merck has implemented in order to help ensure compliance with the 340B Program requirements. Effective on **June 12, 2023**, 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?

- An entity enrolled in the 340B Program as a hospital or Consolidated Health Center Program (CH) covered entity that has its own in-house outpatient pharmacy capable of dispensing 340B-discounted Merck products will **no longer be eligible** to have 340B-discounted Merck products delivered to contract pharmacies. 340B purchased products will **only** be shipped/delivered to the in-house outpatient pharmacy.
- This update to the 340B Program integrity initiative 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 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.
 - Covered Entities must take action by **May 26, 2023** in order for single contract pharmacy location designations to take effect on the effective date of these policy updates. Covered Entities that have already designated a single contract pharmacy on 340B ESP™ **will need to re-designate** a single contract pharmacy on the platform.
 - Merck will no longer require 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.
- This update to the 340B Program integrity initiative will now 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. Merck, on a voluntary basis, previously permitted hospital and CH covered entities to request an exemption from its policy for such wholly-owned contract pharmacies. Under this update, that exemption will no longer be available as of June 12, 2023.
 - 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.

What is not changing?

- 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.
- The policy 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 this initiative. As of the effective date of this policy update, the applicable Merck products include: BELSOMRA, JANUVIA, JANUMET, JANUMET XR, STEGLATRO, STEGLUJAN, SEGLUROMET, and VERQUVO.

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 May 10, 2023)

Q: What is changing with respect to Merck's 340B Program integrity initiative beginning June 12, 2023?

A:

- An entity enrolled in the 340B Program as a hospital or Consolidated Health Center Program (CH) covered entity that has its own in-house outpatient pharmacy capable of dispensing 340B-discounted Merck products **will no longer be eligible** to have 340B-discounted Merck products delivered to contract pharmacies. 340B purchased products will **only** be shipped/delivered to the in-house outpatient pharmacy.
- A 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 and registered on the HRSA database.
 - If a hospital or CH covered 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 update to the 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.
 - 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 will no longer require 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.

Q: What is not changing with respect to Merck's 340B Program integrity initiative?

A:

- 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.
- The policy 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 this initiative.
 - As of the effective date of this policy update, the applicable Merck products include: BELSOMRA, JANUVIA, JANUMET, JANUMET XR, STEGLATRO, STEGLUJAN, SEGLUROMET, and VERQUVO.

Q: 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.
- Covered Entities must take action by **May 26, 2023** in order for single contract pharmacy location designations to take effect on the effective date of the policy.
- Covered Entities that have already designated a single contract pharmacy on 340B ESP™ **will need to re-designate** a single contract pharmacy on the platform.

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: 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. Previously, Merck voluntarily applied an exemption for such contract pharmacies. As of the effective date of this policy update, the voluntary application of this exemption will end. 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: Is Merck still requiring the submission of limited 340B claims data for claims originating from contract pharmacies?

A: No. Effective June 12, 2023, Merck is eliminating this requirement related to the submission of limited 340B claims data. 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. 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. As of the effective date of this policy update, the applicable Merck products include: BELSOMRA, JANUVIA, JANUMET, JANUMET XR, STEGLATRO, STEGLUJAN, SEGLUROMET, and VERQUVO.

Q: How can a 340B covered entity change its contract 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 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 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 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 LOUISIANA AND ARKANSAS REGARDING AN UPDATE TO THE MERCK 340B PROGRAM INTEGRITY INITIATIVE



July 31, 2023

Dear 340B Covered Entities,

I am writing to inform you of updates to the 340B Program integrity initiative that Merck has implemented in order to help ensure compliance with the 340B Program requirements. Effective on **July 31, 2023**, 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.

These changes to our 340B Program integrity initiative will apply only in two states: Arkansas and Louisiana. In those two states, effective **July 31, 2023**, Merck will apply the following policy:

- For orders placed on or after July 31, 2023 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 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) by **August 25, 2023**.
- If a hospital or CH covered entity is not registered and submitting data by **August 25, 2023**, Merck will no longer voluntarily honor 340B contract pharmacy discounts and chargebacks; however, registration will continue to be available through Merck's vendor, Second Sight Solutions (see www.340BESP.com). If the hospital or CH covered entity subsequently registers and submits 340B claims data originating from all eligible contract pharmacies, 340B discounts and chargebacks will be voluntarily honored for transactions at all eligible contract pharmacies once the registration and 340B claims data has been processed.
- 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. Covered Entities that have already designated a single contract pharmacy on 340B ESP™ located within 40 miles of the covered entity parent site and registered on the HRSA database **will not need to re-designate** a single contract pharmacy on the 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.
- This policy change will apply only in Arkansas and Louisiana, and it will apply only to hospital and CH covered entities. All federal grantee covered entities (apart from CH grantee entities) will continue to be exempt from this policy.
- This policy also 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 this initiative. The 340B ESP website at www.340BESP.com provides a list of NDCs applicable to the Merck 340B Program integrity initiative. As of the effective date of this policy update, the applicable Merck products include: BELSOMRA, JANUVIA, JANUMET, JANUMET XR, STEGLATRO, STEGLUJAN, SEGLUROMET, and VERQUVO.
- 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 340B 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.

- In all states except Arkansas and Louisiana, Merck will continue to apply the policy as announced to covered entities in May 2023, which took effect on June 12, 2023. Please refer to our letter dated May 10, 2023, or to our Frequently Asked Questions document, for information regarding that policy.

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 July 31, 2023)

Q: What is changing with respect to Merck's 340B Program integrity initiative beginning July 31, 2023?

A: The changes to Merck's 340B Program integrity initiative effective **July 31, 2023** will apply only in two states: Arkansas and Louisiana. In those two states, effective **July 31, 2023**, Merck will apply the following policy:

- For orders placed on or after July 31, 2023 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 for the hospital or CH covered entity, 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) by **August 25, 2023**.
- If a hospital or CH covered entity is not registered and submitting data by **August 25, 2023**, Merck will no longer voluntarily honor 340B contract pharmacy discounts and chargebacks; however, registration will continue to be available through Merck's vendor, Second Sight Solutions (see www.340BESP.com). If the hospital or CH covered entity subsequently registers and submits 340B claims data originating from all eligible contract pharmacies, 340B discounts and chargebacks will be voluntarily honored for transactions at all eligible contract pharmacies once the registration and 340B claims data has been processed.
- 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. Covered Entities that have already designated a single contract pharmacy on 340B ESP™ located within 40 miles of the covered entity parent site and registered on the HRSA database **will not need to re-designate** a single contract pharmacy on the 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.
- This policy change will apply only in Arkansas and Louisiana, and it will apply only to hospital and CH covered entities. All federal grantee covered entities (apart from CH grantee entities) will continue to be exempt from this policy.
- This policy also 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 this initiative. The 340B ESP website at www.340BESP.com provides a list of NDCs applicable to the Merck 340B Program integrity initiative. As of the effective date of this policy update, the applicable Merck products include: BELSOMRA, JANUVIA, JANUMET, JANUMET XR, STEGLATRO, STEGLUJAN, SEGLUROMET, and VERQUVO.

In all other states except Arkansas and Louisiana, Merck will continue to apply our policy as announced to covered entities in May 2023, which took effect on June 12, 2023, and is as follows:

- 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 340B-discounted Merck products is not eligible to have 340B-discounted Merck products delivered to contract pharmacies; for hospital and CH covered entities, 340B purchased products will only be shipped/delivered to the in-house outpatient pharmacy.
- A 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 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.
- Except as noted above for Arkansas and Louisiana, Merck no longer requires—and will continue to not require—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.
- This 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.

- This policy also 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 this initiative. The 340B ESP website at www.340BESP.com provides a list of NDCs applicable to the Merck 340B Program integrity initiative. As of the effective date of this policy update, the applicable Merck products include: BELSOMRA, JANUVIA, JANUMET, JANUMET XR, STEGLATRO, STEGLUJAN, SEGLUROMET, and VERQUVO.
- 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 340B 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.

Q: Who should I contact if I have questions about the updates to Merck's policy in Arkansas and Louisiana effective July 31, 2023?

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: 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: 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, 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 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. Applicable for Arkansas and Louisiana, beginning **July 31, 2023**, a wholly-owned pharmacy may be designated as the single contract pharmacy location for a hospital or CH entity that lacks an in-house 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; additionally, in these two states, if the requested claims data are provided by hospital or CH covered entities by **August 25, 2023**, Merck will continue to voluntarily honor 340B discounts for contract pharmacy transactions for these covered entities, including multiple contract pharmacy arrangements.

Q: Is Merck still requiring the submission of limited 340B claims data for claims originating from contract pharmacies?

A: Applicable for Arkansas and Louisiana, for orders placed on or after July 31, 2023 by an entity enrolled in the 340B Program as a hospital or as a Consolidated Health Center Program (CH) covered entity, Merck will again 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) by **August 25, 2023** for Merck to continue voluntarily honoring 340B discounts and chargebacks for all eligible contract pharmacies. If a hospital or CH covered entity is not registered and submitting data by **August 25, 2023**, Merck will no longer voluntarily honor 340B contract pharmacy discounts and chargebacks; however, registration will continue to be available through Merck's vendor, Second Sight Solutions (see www.340BESP.com). If the hospital or CH covered entity subsequently 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. For all states other than Arkansas and Louisiana, Merck eliminated the requirement related to the submission of limited 340B claims data effective June 12, 2023. The updates to Merck's 340B Program integrity initiative for Arkansas and Louisiana do not affect Merck's policy in other states. Merck nonetheless encourages 340B covered entities in states other than Arkansas and Louisiana 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 Arkansas and Louisiana but not for other states?

A: Louisiana and Arkansas 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 these two states.

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. As of the effective date of this policy update, the applicable Merck products include: BELSOMRA, JANUVIA, JANUMET, JANUMET XR, STEGLATRO, STEGLUJAN, SEGLUROMET, and VERQUVO.

Q: How can a 340B covered entity change its contract 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 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 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 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.