

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.