

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



August 2021

Dear 340B Covered Entities,

I am writing to inform you of a change to the 340B Program integrity initiative that Merck implemented last year to monitor operations and help ensure compliance with the 340B Program requirements (the "Merck Program"). 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. We had hoped that 340B covered entities would broadly embrace the collaborative Merck Program and the opportunity to take meaningful but time-efficient steps to help ensure program integrity, including steps to prevent Medicaid-340B duplicate discounts, which are prohibited by the 340B statute. We are particularly concerned about these and other statutory violations in the context of contract pharmacy transactions. To date, we have voluntarily honored 340B discounts for multiple contract pharmacy arrangements and transactions for 340B hospital and federal grantee covered entities, even though the 340B statute does not require such discounts, and have requested voluntary participation in the Merck Program from covered entities with contract pharmacy arrangements.

Although we had hoped that covered entities would collaborate with Merck through our program integrity initiative, participation to date has been very low, and the Merck Program as originally designed has not achieved that goal. As a result, effective September 1, 2021, we will no longer voluntarily honor 340B discounts or chargebacks for contract pharmacy transactions for hospital covered entities that have not begun to provide 340B claims data for all claims originating from its contract pharmacies, unless the hospital covered entity lacks its own in-house pharmacy and designates a single contract pharmacy site of its choice as described below. If 340B claims data are provided as required under the updated Merck Program, we will again voluntarily honor 340B discounts or chargebacks for contract pharmacy transactions for hospital covered entities.

As part of the Merck Program, Merck is making the 340B ESP platform available to hospital covered entities for this purpose, just as Merck has made the 340B ESP platform available to all covered entities in connection with the original Merck Program that we implemented last year. **Any hospital covered entity that does not anticipate meeting the September 1, 2021 deadline and does not have an outpatient, on-site dispensing pharmacy should contact Second Sight Solutions at www.340BESP.com as soon as possible to arrange for a single contract pharmacy location of its choice to be eligible to receive 340B pricing on behalf of the hospital covered entity.**

At this time, this change to the Merck Program does not apply to federal grantee covered entities eligible for 340B participation under 42 U.S.C. § 256B(a)(4)(A)-(K) and Merck will continue to voluntarily honor 340B discounts and chargebacks for contract pharmacy transactions for these federal grantee covered entities. We continue to encourage federal grantee covered entities to collaborate with us as part of this program integrity effort by participating in the Merck Program and providing claims-level data for contract pharmacy transactions and we will continue to evaluate program participation of federal grantees to determine if further action is warranted.

Merck has maintained a strong commitment to the 340B Program since its inception. Under the updated Merck Program, 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 the Merck Program. If you have any questions about this initiative, please contact Merck at 340Bdata@merck.com.

UPDATED FREQUENTLY ASKED QUESTIONS (Updated 9/22/21)

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

A: Under Merck's Program, Merck will voluntarily apply the following exemption:

Contract pharmacies that are wholly owned by a 340B hospital, or are under common ownership with a 340B health system, are able to request an exemption to become eligible to receive "Bill to/Ship to" replenishment orders of 340B priced drugs. These pharmacies must be registered with HRSA as a contract pharmacy of the 340B hospital.

To apply for a wholly owned contract pharmacy exemption, please contact Second Sight Solutions at 340Besp.com. Second Sight Solutions will supply you the necessary forms and will provide guidance on the required supporting documentation needed to review the request. Merck reserves the right to modify or remove this exemption at any time upon notice.

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: According to the 340B ESP website, getting started with 340B ESP involves the following three steps:

1. 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.
2. Once your account is activated, you will be able to securely upload data to 340B ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities.
3. Login to 340B ESP and submit your 340B Program contract pharmacy claims data on a bi-weekly basis. Once your account is set up, the claims upload process takes ~ 5 minutes.

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

Q: How will the 340B Program claims data that covered entities provide for the Merck Program be used?

A: Data uploaded by 340B Program covered entities will be used to identify and resolve duplicate Medicaid, Medicare Part D and commercial rebates.

Q: When do 340B Program covered entities need to begin providing claims-level data for contract pharmacy transactions?

A: Merck is asking all hospital 340B covered entities with contract pharmacy arrangements to participate in the Merck Program and to begin providing 340B Program claims data by September 1, 2021. Merck will no longer voluntarily honor 340B discounts or chargebacks for contract pharmacy transactions for hospital covered entities that have not begun to provide claims data by September 1, 2021, unless the hospital covered entity lacks its own in-house pharmacy and contacts Merck to designate a single contract pharmacy site of its choice. **Federal grantees are strongly encouraged to participate in the Merck Program and to provide claims-level data for their contract pharmacy transactions, but are not required to at this time under these updates to the Merck Program.**

Q: What if the 340B covered entity does not have an outpatient, on-site dispensing pharmacy?

A: Any hospital covered entity that does not anticipate meeting the September 1, 2021 deadline and does not have an outpatient, on-site dispensing pharmacy should contact Second Sight Solutions at www.340BESP.com as soon

as possible to arrange for a single contract pharmacy location of its choice to be eligible to receive 340B pricing on behalf of the hospital covered entity.

Q: Is Merck requesting data for all Merck products?

A: No. Merck is only requesting data for Merck drugs dispensed through retail, specialty, and outpatient pharmacies registered on the HRSA database as a contract pharmacy. Physician-administered drugs are not part of this program. For covered entities that use 340B ESP™ for the Merck Program, 340B ESP automatically limits the data in your upload file to the applicable NDCs. See the 340B ESP website at www.340BESP.com for the list of NDCs applicable to the Merck Program.

Q: Is Merck requesting data for pharmacies that are registered with HRSA as a covered entity?

A: No. Merck is only requesting data for 340B Program claims that originate from contract pharmacies. Covered entities do not need to provide claims data for prescriptions filled in their own outpatient pharmacies.

Q: How often will I need to upload 340B Program contract pharmacy claims data for purposes of the Merck Program?

A: Merck is requesting that covered entities participating in the Merck Program provide claims-level data for contract pharmacy transactions every two weeks. For covered entities that use the 340B ESP platform for participation in the Merck Program, 340B ESP generates automatic email reminders for submissions.

Q: What technology requirements exist to successfully upload data to 340B ESP™?

A: Information available on the 340B ESP website indicates that 340B ESP™ is compatible with most internet browsers, including Windows Explorer, Google Chrome, Safari, FireFox, and others. Use of 340B ESP requires an internet connection and access to a supported browser to successfully upload data.

Q: I am already supplying data to Second Sight Solutions. Do I need to register again to maintain my contract pharmacy 340B pricing?

A: No. If you have already registered with Second Sight Solutions and are currently supplying data for Merck products, there is nothing more you need to do at this time. You will continue to be able to access 340B pricing for your patients filling their prescriptions at a contract pharmacy.

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.