

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



April 2022

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 monitor operations and help ensure compliance with the 340B Program requirements. Beginning on May 31, 2022, Merck will no longer voluntarily honor 340B discounts or chargebacks for contract pharmacy transactions for covered entities enrolled in the 340B Program as a Consolidated Health Center Program ("CH covered entities") that have not begun to provide 340B claims data for all claims originating from their contract pharmacies, unless the CH covered entity lacks its own in-house pharmacy and designates a single contract pharmacy site of its choice as further described in this letter. We are also writing to inform you of an update to Merck's Frequently Asked Questions which is attached to this letter. 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.

Merck initially implemented our 340B Program integrity initiative in 2020. In August of 2021, we communicated with HRSA and with covered entities regarding updates to our initiative that took effect September 1, 2021. As we noted in those communications, 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 further noted that we are particularly concerned about these and other statutory violations in the context of contract pharmacy transactions. Multiple government reports also have noted and recognized that statutorily prohibited diversion and duplicate discounts are at an increased risk of occurring when contract pharmacies are used. For a number of years, Merck has 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 Merck to honor 340B discounts for such arrangements and transactions.

During the summer of 2020, Merck requested voluntary participation in our 340B Program integrity initiative from covered entities with contract pharmacy arrangements. We had hoped that covered entities would collaborate with Merck through this initiative, and we were disappointed that, after approximately a year of our initiative being in place, participation remained very low. Because it became clear, based on a year of operating the Merck 340B Program integrity initiative as originally designed, that the initiative was not achieving its goal, Merck communicated with HRSA and with covered entities in August 2021 about updates to Merck's 340B Program integrity initiative that took effect September 1, 2021. Our August 2021 communication to covered entities noted that, effective September 1, 2021, Merck would 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 their 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. We further noted in our August 2021 communication that, if hospital covered entities provide the requested claims data, we would again voluntarily honor 340B discounts or chargebacks for contract pharmacy transactions for those covered entities, including multiple contract pharmacy arrangements.

The updates to Merck's initiative that took effect September 1, 2021 have not applied to any federal grantee covered entities eligible for 340B participation under 42 U.S.C. § 256b(a)(4)(A)–(K). For those covered entities, Merck has continued to voluntarily honor 340B discounts and chargebacks for contract pharmacy transactions, including multiple contract pharmacy arrangements, regardless of whether the federal grantee covered entity chooses to submit the limited claims data requested. Since September 1, 2021, Merck has continued to encourage federal grantee covered entities to collaborate with us as part of this program integrity effort by participating in this initiative and providing claims-level data for contract pharmacy transactions. A number of federal grantee covered entities have elected to do so, and we appreciate these entities' participation in our initiative and the opportunity to collaborate with these entities to strengthen 340B Program integrity and sustainability. In addition, as we noted in our August 2021 communication, we have continued to evaluate our initiative and the participation of federal grantees to determine if further updates to our 340B Program integrity initiative may be warranted.

In our ongoing consideration of these issues, beginning on May 31, 2022, Merck will no longer voluntarily honor 340B discounts or chargebacks for contract pharmacy transactions for CH covered entities that have not begun to provide 340B claims data for all claims originating from their contract pharmacies, unless the CH covered entity lacks its own

in-house pharmacy and designates a single contract pharmacy site of its choice as described below. As is the case for hospital covered entities under the Merck 340B Program integrity initiative updates effective September 1, 2021, if the requested claims data are provided by CH covered entities under this additional update to our initiative, we will again voluntarily honor 340B discounts or chargebacks for contract pharmacy transactions for these covered entities, including multiple contract pharmacy arrangements.

As part of the Merck 340B Program integrity initiative, Merck is continuing to make the 340B ESP platform available to all covered entities for purposes of providing the limited claims data Merck is requesting. **Any CH covered entity that does not anticipate meeting the May 31, 2022 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 CH covered entity.** And, as noted, this option also remains available for hospital covered entities that lack an outpatient, on-site pharmacy.

At this time, this update to the Merck 340B Program integrity initiative does not apply to any federal grantee covered entity types other than CH covered entities (*i.e.*, those enrolled in the 340B Program as a Consolidated Health Center Program). We continue to encourage all types of federal grantee covered entities to collaborate with us as part of this program integrity effort by participating in the initiative and providing claims-level data for contract pharmacy transactions. We also will continue to evaluate our 340B Program integrity initiative to determine if further updates may be warranted.

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. Second Sight Solutions has also updated its Terms & Conditions (dated April 6, 2022) that apply to a 340B covered entity's use of the 340B ESP at www.340BESP.com/terms-of-use.

FREQUENTLY ASKED QUESTIONS (Updated April 25, 2022)

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

A: Information about 340B ESP is available at www.340BESP.com. Updated Terms & Conditions (dated April 6, 2022) that apply to a 340B covered entity's use of the 340B ESP is also available at www.340BESP.com/terms-of-use.

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 claims data that covered entities provide for the Merck 340B Program integrity initiative 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 has asked all hospital 340B covered entities with contract pharmacy arrangements to participate in the Merck 340B Program integrity initiative and to begin providing 340B Program claims data for contract pharmacy transactions involving Merck covered outpatient drugs 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.

In addition, Merck is asking all CH 340B covered entities (*i.e.*, 340B covered entities enrolled in the 340B Program as a Consolidated Health Center Program) with contract pharmacy arrangements to participate in the Merck 340B Program integrity initiative and to begin providing 340B Program claims data for contract pharmacy transactions involving Merck covered outpatient drugs by May 31, 2022. Merck will no longer voluntarily honor 340B discounts or chargebacks for contract pharmacy transactions for CH covered entities that have not begun to provide claims data by May 31, 2022, unless the CH covered entity lacks its own in-house pharmacy and contacts Merck to designate a single contract pharmacy site of its choice. **Merck continues to encourage other types of federal grantee covered entities to participate in the Merck Program and to provide claims-level data for their contract pharmacy transactions, but they are not required to at this time under these updates to the Merck 340B Program integrity initiative.**

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

A: Any CH covered entity (*i.e.*, 340B covered entities enrolled in the 340B Program as a Consolidated Health Center Program) that does not anticipate meeting the May 31, 2022 deadline and does not have an outpatient, on-site dispensing pharmacy should contact Merck through 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 CH covered entity. This option also remains available for hospital covered entities that lack an outpatient, on-site pharmacy.

Q: Does Merck's policy apply to contract pharmacies that are wholly owned by a 340B hospital or CH covered entity (*i.e.*, 340B covered entities enrolled in the 340B Program as a Consolidated Health Center Program) or are under common ownership with a 340B health system or CH covered entity?

A: Under Merck's 340B Program integrity initiative, Merck will voluntarily apply the following exemption: 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, 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: Is Merck requesting data for all Merck products?

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

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. Merck is not requesting any claims data for prescriptions filled in covered entities' own outpatient pharmacies.

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

A: Merck is requesting that covered entities participating in our initiative 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 initiative, 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 providing 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.

Q: If a covered entity is registered with 340B ESP™ and has made contract pharmacy designations as part of the Merck 340B Program integrity initiative, does Merck have a policy regarding timing for placing orders for replenishment at 340B pricing once those contract pharmacy designations have been processed?

A: Yes. If a covered entity is registered with 340B ESP™ and has made contract pharmacy designations as part of the Merck 340B Program integrity initiative, Merck's policy is to honor requests for replenishment orders at 340B pricing—for shipment to the designated contract pharmacy location(s)—for prescriptions dispensed to 340B-eligible patients within forty-five (45) days of data submission to 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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