Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080

October 22, 2025

Via Email

[redacted]

Re: Novartis Notice Regarding 340B Pricing for Novartis Products

Dear Covered Entity,

On behalf of Novartis Pharmaceuticals Corporation and its affiliates ("Novartis"), I am writing regarding your entity's eligibility to access 340B pricing for Novartis products as a sexually transmitted disease ("STD") covered entity under section 340B(a)(4)(K) of the Public Health Service Act ("PHSA"). Novartis takes its obligations under the 340B Program seriously and supports its core mission to increase access to outpatient drugs for uninsured, low-income, and other vulnerable patients.

We understand that the Health Resources and Services Administration ("HRSA") has designated your entity as an STD covered entity because it receives Section 318 grant contributions for the treatment of STDs.[1] Under the plain language of the 340B statute and applicable HRSA guidance, STD covered entities are uniquely situated in that they are entitled to 340B pricing only where the drug is:

(i) used to provide services that fall within the scope of the grant funding that is the basis for eligibility (i.e., the treatment or prevention of STDs), and
(ii) is dispensed to an individual who qualifies as a "patient" of the entity.

As discussed below, your entity does not, and cannot, satisfy these conditions for any of Novartis's products, because no Novartis products are indicated for the treatment or prevention of STDs. Therefore, your entity is not entitled to 340B pricing as to Novartis products under its STD covered entity designation, and Novartis will be terminating such access to 340B pricing as of November 3, 2025.

Scope-of-the-Grant Requirement. Under the 340B statute, a hospital or clinic may qualify as an STD covered entity if it receives "funds under section 247c of this title (relating to treatment of sexually transmitted diseases) . . . through a State or unit of local government, but only if the entity

[1] To the extent your entity's grant funding is in the form of in-kind contributions, it is also ineligible to participate in the 340B Program in first instance. Novartis does not believe the receipt of in-kind contributions can qualify an entity for STD covered entity status.

is certified by the Secretary."[2] The cross-referenced Section 247c refers to Section 318 of the PHSA, which authorizes the United States Secretary of Health and Human Services to provide "grants" to States, units of local governments, and other entities for the prevention, control, and treatment of STDs.[3] These provisions make clear that any entity qualifying as an STD covered entity is eligible for 340B-priced drugs only insofar as the entity uses those drugs within the scope of that grant funding, *i.e.*, the treatment or prevention of STDs. HRSA has confirmed the scope-of-the-grant requirement in an FAQ posted on its website, explaining that "STD (318 grantee) clinics that participate in the 340B Program may purchase and dispense any 340B drugs associated with a service for which the covered entity is responsible, including contraceptives, to that patient, to the extent it aligns with [the] patient definition *and . . . is consistent with the scope of the grant*."[4] The scope-of-the-grant requirement is also consistent with 42 U.S.C. § 256b(a)(7)(D), which requires HRSA to track covered entity purchases solely as to certain grantees, including STD grantee covered entities.

Your entity does not qualify for 340B pricing for any Novartis products as an STD covered entity because those products cannot be used to perform services within the scope of its Section 318 STD grant. None of Novartis' products are indicated for the treatment or prevention of STDs. As a result, there is no circumstance in which treatment of a patient at your entity with any Novartis product would be connected to the scope of the Section 318 STD grant upon which your entity's 340B eligibility is based. Because your entity cannot satisfy the scope-of-the-grant requirement as to any Novartis product, Novartis is not obligated to offer 340B pricing to your entity.

340B "Patient" Requirement. Your entity is also ineligible for 340B pricing for Novartis products because it would result in improper diversion in violation of the 340B "patient" requirement, which in turn also would render your entity ineligible for 340B participation more broadly. The 340B statute limits access to 340B drugs to those individuals who qualify as a "patient" of the covered entity. Specifically, covered entities are required to "meet the requirements described in paragraph (5)," which includes a prohibition on the diversion of a 340B drug "to a person who is not a patient of the entity."[5] As a result, if an entity dispenses or administers a 340B drug to a non-patient, it has violated the requirements of paragraph (5) and is not entitled to 340B pricing in the first instance.[6]

HRSA has defined the term "patient" narrowly, particularly in relation to grantee covered entities. HRSA has explained that an individual qualifies as a "patient" of an STD covered entity "only if . . . the individual receives a health care service or range of services from the covered entity *which is consistent with the service or range of services for which grant funding . . . has been provided*

[2] 42 U.S.C. § 256b(a)(4)(K).
[3] *Id.* § 247c(b)-(d).
[4] 340B FAQs, HRSA, https://www.hrsa.gov/opa/faqs (emphases added).
[5] 42 U.S.C. § 256b(a)(4), (5).
[6] *Id.* § 256b(a)(4).

to the entity."[7] If such an entity dispenses or administers a 340B drug to individual who is not receiving STD treatment, or where the 340B drug is not used or indicated for the treatment or prevention of STDs, the purchasing covered entity has improperly diverted the drug to a non-patient in violation of the diversion prohibition. In short, the drug itself must be provided in connection with a grant-supported service (i.e., the treatment or prevention of STD). HRSA has specifically affirmed this limitation on the patient definition, noting that an STD covered entity "may purchase and dispense any 340B drugs *associated with a service for which the covered entity is responsible*, including contraceptives, to that patient, to the extent it aligns with [the] *patient definition and is consistent with the scope of the grant*."[8]

As previously mentioned, patients at your entity who receive Novartis products would not, and could not, receive those products through the range of services for which the Section 318 STD grant has been provided, given that Novartis products do not treat or prevent STDs. The sale or transfer of Novartis products at 340B pricing would therefore result in improper diversion to non-patients, in violation of the 340B statute. As a result, Novartis is not obligated to extend 340B pricing for any Novartis products to your entity . However, your entity may still access these products at the commercial, non-340B price, consistent with the terms offered to our non-340B customers.

Thank you for your careful attention to this matter. Should you have any questions, Novartis welcomes the opportunity to engage with you constructively. Please contact us at Novartis.340B@novartis.com.

Sincerely,

Shannon McCrudden
VP, Managed Markets Finance
Novartis Pharmaceuticals Corporation
One Health Plaza, East Hanover, NJ 07936

[7] 61 Fed. Reg. 55,156, 55,157-58 (Oct. 24, 1996) (emphasis added).
[8] HRSA, 340B FAQs, https://www.hrsa.gov/opa/faqs (emphases added).