

December 1, 2020

[Name]
[Title]
[Facility Name], [340B ID]
[Address]
[City], [State] [Zip]

I am writing to provide an update on voluntary discounts presently available to a subset of your 340B customers for purchases of Amgen® orphan designated drugs.

Per the Office of Pharmacy Affairs in the Health Resources & Services Administration (HRSA), for covered entities that qualify under 42 U.S.C. §256b (a)(4)(M – O) that participate in the 340B Program, the term "covered outpatient drug" does not include orphan drugs designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition; and therefore, manufacturers aren't required to provide these covered entities' orphan drugs under the terms of the 340B Program.

Consistent with the HRSA guidance, effective January 1, 2021 Amgen® will no longer offer voluntary, "340B like" discounts on Amgen® orphan designated drugs to participating 42 U.S.C. §256b (a)(4)(M – O) covered entities. This will not apply to any orphan designated products for which we have entered into a separate, bilateral arrangement with one of these impacted organizations.

Amgen® does not intend to seek to recoup any voluntary discounts provided prior to January 1, 2021.

This change does not impact grantees and Disproportionate Share Hospitals that participate in the 340B program under 42 U.S.C. §256b (a)(4)(A – L).

Any questions regarding this matter can be directed to 340Brelations@amgen.com.

Sincerely,



Kave Niksefat
Vice President, U.S. Value and Access