



September 22, 2021

Mr. Dan Lopuch
Managed Market Finance
Novartis Pharmaceuticals Corporation
One Health Plaza, 135/4110F
East Hanover, New Jersey 07936

Dear Mr. Lopuch:

By letter dated May 17, 2021, HRSA instructed Novartis Pharmaceuticals Corporation (Novartis) to comply with its 340B statutory obligations and to immediately begin offering Novartis' covered outpatient drugs at the 340B ceiling price to covered entities that dispense the discounted medications through their contract pharmacy arrangements. HRSA informed Novartis that continued failure to provide the 340B price to covered entities utilizing contract pharmacies could result in civil monetary penalties.

Given Novartis' continued refusal to comply,¹ HRSA has referred this issue to the HHS Office of the Inspector General (OIG) in accordance with the 340B Program Ceiling Price and Civil Monetary Penalties Final Rule.²

Sincerely,

/Michelle Herzog/

Michelle Herzog
Acting Director
Office of Pharmacy Affairs

¹ Novartis provided HRSA its basis for refusing to comply in a letter dated May 27, 2021.

² 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017); 42 C.F.R. §10.11(a)