



September 22, 2021

Mr. Gerald Gleeson
Vice President and Head, Sanofi US Market Access Shared Services
Sanofi
55 Corporate Drive
Bridgewater, New Jersey 08807

Dear Mr. Gleeson:

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

Given Sanofi's 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 Sanofi provided HRSA its basis for refusing to comply in a letter dated June 1, 2021.

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