

Rockville, MD 20857

September 22, 2021

Ms. Lynn Robson Vice President, Associate General Counsel, Market Access United Therapeutics Corporation 55 TW Alexander Drive Research Triangle Park, North Carolina 27709

Dear Ms. Robson:

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

Given United Therapeutics' continued refusal to comply,<sup>1</sup> 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.<sup>2</sup>

Sincerely,

/Michelle Herzog/

Michelle Herzog Acting Director Office of Pharmacy Affairs

<sup>&</sup>lt;sup>1</sup> United Therapeutics provided HRSA its basis for refusing to comply in a letter dated June 10, 2021.

<sup>&</sup>lt;sup>2</sup> 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017); 42 C.F.R. §10.11(a)