

Office of Special Health Initiatives Rockville, MD 20857

October 20, 2022

Phil Rinnander Executive Director, Finance Customer Contract Management Merck Sharp & Dohme Corp. (Merck) 351 North Sumneytown Pike North Wales, Pennsylvania 19454

Dear Phil Rinnander:

By letter dated May 6, 2022, HRSA instructed Merck to comply with its 340B statutory obligations and to immediately begin offering Merck's covered outpatient drugs at the 340B ceiling price to covered entities that dispense the discounted medications through their contract pharmacy arrangements. HRSA informed Merck that continued failure to provide the 340B price to covered entities utilizing contract pharmacies could result in civil monetary penalties.

Given Merck'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,

/Emeka Egwim/

Emeka Egwim, PharmD, RPh LCDR, U.S. Public Health Service Director, Office of Pharmacy Affairs

¹ Merck provided HRSA its basis for refusing to comply in a letter dated May 19, 2022.

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