



December 16, 2024

Via Electronic Mail to 340BPricing@hrsa.gov

Chantelle Britton
Director, Office of Pharmacy Affairs
Health Resources & Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Ms. Britton:

I write on behalf of Sanofi-Aventis U.S. LLC (“Sanofi”) in response to HRSA’s December 13, 2024 letter regarding Sanofi’s proposed Credit Model for the 340B Program. In its letter, HRSA concludes that “Sanofi’s credit proposal, if implemented, violates Sanofi’s obligations under the 340B statute,” both because the Secretary has not approved Sanofi’s proposal, and because Sanofi’s proposal would purportedly “require certain covered entity types to purchase certain Sanofi products at prices that exceed” the permissible 340B ceiling price. HRSA has threatened Sanofi with civil monetary penalties and termination of Sanofi’s Pharmaceutical Pricing Agreement if Sanofi proceeds to implement its proposal.

Sanofi respectfully disagrees with HRSA’s position. Section 340B does not require the Secretary to pre-approve a manufacturer’s use of credits or rebates to effectuate the 340B discount. In addition, Sanofi’s proposed Credit Model fully complies with Section 340B. And certainly, Sanofi’s decision to proceed with its proposal would not justify the draconian punishment threatened by HRSA—sanctions that would inflict enormous harm on not only Sanofi but also the countless patients whose health is dependent on the government’s continued coverage of Sanofi medicines.

Although Sanofi is confident that HRSA’s threatened imposition of these penalties would not survive scrutiny, Sanofi is unwilling to put patients at risk in order to pursue its proposal. As a result, Sanofi has decided to pause the implementation of its planned Credit Model, which was scheduled to launch in January 2025. Instead, Sanofi today filed a lawsuit in the U.S. District Court for the District of Columbia to vindicate its ability to pursue its plans. Sanofi looks forward to settling this matter in court.

Very truly yours,

Scott Bray

Scott Bray
Head - Operations Excellence • Sanofi US
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