HRSA
Health Resources & Services Administration

5600 Fishers Lane
Rockville, MD 20857

December 13, 2024

BY EMAIL

Paul Hudson
Chief Executive Officer
Sanofi-Aventis U.S. LLC
Paul.Hudson@sanofi.com

Dear Paul Hudson:

The Health Resources and Services Administration (HRSA) understands that Sanofi-Aventis U.S. LLC (Sanofi) has publicly announced plans to implement a credit model for sales of certain covered outpatient drugs to particular covered entities starting January 6, 2025. By way of this correspondence, HRSA provides warning that this unapproved credit proposal violates Sanofi's obligations under the 340B statute, and HRSA expects Sanofi to cease implementation of it.

Specifically, in a notice dated November 22, 2024, to 340B covered entities regarding purchases of select Sanofi Products, Sanofi stated that it would be effectuating 340B discounts via the new credit model as of January 6, 2025, for disproportionate share hospitals, critical access hospitals, rural referral centers, and sole community hospitals and as of March 1, 2025, for consolidated health centers. These covered entity types would be required to place an order for a Product through their wholesaler at the Product's Wholesaler Acquisition Cost (WAC) and then submit purchase and claims data to Sanofi's third-party tool, which would then determine whether to issue a credit payment to the covered entity representing the difference between the WAC and the 340B price.

Additionally, Sanofi's November 22, 2024, notice states that effective March 1, 2025, hospital covered entities would be required to submit healthcare encounter data so Sanofi can make its own determination regarding whether the claim complies with HRSA's 1996 patient guidelines. In particular, the notice stated that Sanofi would use the criteria that "the individual receiving a dispense (1) is currently receiving medical care from the covered entity, and (2) receives a prescription in connection with health care services provided by the covered entity."

As HRSA noted in its November 12, 2024, letter to Sanofi, the 340B statute states that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, *as provided by the Secretary*) to the manufacturer" shall not exceed the statutory ceiling price. 42 U.S.C. § 256b(a)(1) (emphasis added). The statute also provides that the ceiling price "represents the maximum price that covered entities may permissibly be required to pay for the drug," and that said agreement "shall require that the manufacturer offer each covered entity covered

outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.*

The Secretary has not "provided" that the credits described in Sanofi's notice should be "tak[en] into account" in the "amount required to be paid" for select Sanofi Products by certain covered entity types. If Sanofi implements its credit proposal without Secretarial approval, it will violate Section 340B(a)(1) of the Public Health Service Act (PHSA).

According to its Notice, Sanofi intends to unilaterally (i.e., without Secretarial approval) charge certain covered entities WAC for covered outpatient drugs, starting January 6, 2025. In other words, Sanofi's credit proposal would require certain covered entity types to purchase certain Sanofi products at prices that exceed "the maximum price[s] that covered entities may permissibly be required to pay" for those drugs. This, too, violates Section 340B(a)(1) of the PHSA.[1]

Because Sanofi's credit proposal, if implemented, violates Sanofi's obligations under the 340B statute, it subjects Sanofi to potential consequences, such as termination of Sanofi's Pharmaceutical Pricing Agreement (PPA). *See Astra USA v. Santa Clara Cnty.*, 563 U.S. 110 (2011). As stated in the PPA, even apart from "a violation of the Agreement," the Secretary may "terminate the Agreement" for "other good cause." In addition, the 340B statute provides for "[t]he imposition of sanctions in the form of civil monetary penalties" on "any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1)." 42 U.S.C. § 256b(d)(1)(B)(vi).

HRSA expects Sanofi to cease implementation of its credit proposal immediately and to inform HRSA no later than December 20, 2024, in order to provide adequate notice to covered entities. Please provide your response to Chantelle Britton, Director of HRSA's Office of Pharmacy Affairs at cbritton@hrsa.gov.

Sincerely,

/s/ Carole Johnson

Carole Johnson
Administrator

cc:
Scott Bray
Head, Operations Excellence, US Market Access & Pricing, Sanofi
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[1] Sanofi's notice states that the credit payment is subject to Sanofi's unilaterally imposed requirements for the timely submission of "purchase and claims data" by a covered entity, as well as Sanofi's "validation" of said data. In short, the notice makes clear that issuance of the "340B Credit" is conditioned on Sanofi's prior approval at Sanofi's sole discretion.

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