HRSA
Health Resources & Services Administration

5600 Fishers Lane
Rockville, MD 20857

September 17, 2024

BY EMAIL

Joaquin Duato
Chairman and Chief Executive Officer
Johnson & Johnson

Dear Joaquin Duato:

The Health Resources and Services Administration (HRSA) understands that Johnson & Johnson (J&J) has publicly announced plans to implement a rebate model for sales of certain 340B covered outpatient drugs to particular covered entities as of October 15, 2024. By way of this correspondence, HRSA provides warning that this unapproved rebate proposal violates J&J's obligations under the 340B statute, and HRSA expects J&J to cease implementation of it.

Specifically, in a "Notice to 340B End Customers Regarding Purchases of STELARA and XARELTO," dated August 23, 2024, J&J stated that as of October 15, 2024, disproportionate share hospitals will be required to "purchase STELARA or XARELTO through wholesalers at a commercial price, such as the wholesale acquisition cost (WAC)" and afterwards, J&J may make a "rebate payment" that "equal[s] the difference between (i) WAC and (ii) the 340B ceiling price."

As HRSA noted in its August 14, 2024, letter to J&J, 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).[1] 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.*

[1] The agreement referenced in the statute—your Pharmaceutical Pricing Agreement (PPA) and PPA addendum—"are uniform agreements that recite the responsibilities § 340B imposes, respectively, on drug manufacturers and the Secretary of HHS." *Astra USA v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011). Contrary to J&J's assertions in its correspondence to HRSA, the Supreme Court has made clear that the PPAs reflect the obligations that the statute places on manufacturers who participate in the 340B Program; PPAs "are not transactional, bargained-for contracts" and are simply the manner drug manufacturers "opt into the 340B Program." *Id.*

The Secretary has not "provided" that the rebates described in J&J's notice should be "tak[en] into account" in the "amount required to be paid" for Stelara and Xarelto by disproportionate share hospitals. If J&J implements its rebate proposal without Secretarial approval, it will violate Section 340B(a)(1) of the Public Health Service (PHS) Act.

According to its Notice, J&J intends to unilaterally charge disproportionate share hospitals "commercial price[s], such as [WAC]" for covered outpatient drugs, starting October 15, 2024. In other words, J&J's rebate proposal would require disproportionate share hospitals to purchase Stelara and Xarelto 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 PHS Act.[2]

In correspondence with HRSA, J&J asserts that their proposed rebate model is similar to "replenishment" processes and that this authorizes J&J to unilaterally impose its proposed rebate model without violating the 340B statute. This is incorrect. There are fundamental differences between J&J's proposal and some covered entities voluntarily using inventory replenishment processes to manage their 340B inventory. First, under a typical replenishment structure, a covered entity generally makes an initial purchase at a higher price, then subsequent, ongoing drug purchases are at the 340B price. By contrast, under the J&J proposal, covered entities would be forced to pay a higher price point up front for *every* purchase. This would create significantly higher up-front costs for covered entities. Second, the 340B statute explicitly limits rebate models to those that have been approved by the Secretary. Third, covered entities voluntarily choose to use replenishment processes; J&J's proposal is not voluntary for covered entities.

Because J&J's rebate proposal, if implemented, violates J&J's obligations under the 340B statute, it subjects J&J to potential consequences, such as termination of J&J'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).

[2] J&J's August 15, 2024, notice does not commit to an enforceable timeframe for issuing the "rebate payment." In addition, the notice states that the "rebate payment" is subject to J&J's unilaterally imposed requirements for the timely submission of "Rebate Claim Data" by a covered entity, as well as J&J's "validat[ion]" of said data. In short, the notice makes clear that issuance of the "rebate payment" is conditioned on J&J's prior approval at J&J's sole discretion.

HRSA expects J&J to cease implementation of its rebate proposal immediately and to inform HRSA no later than September 30, 2024, in order to provide adequate notice to covered entities.

Please provide this notification to Chantelle Britton, Director of HRSA's Office of Pharmacy Affairs at cbritton@hrsa.gov.

Sincerely,

/s/ Carole Johnson

Carole Johnson
Administrator

cc:
Lena Kane
Senior Director Government Contract and Compliance, Johnson & Johnson

Perry Knight
Vice President, Law, Strategic Customer Group, Johnson & Johnson