

September 27, 2024

Joaquin Duato
Chairman and Chief Executive Officer
Johnson & Johnson
Via email

Dear Joaquin Duato:

I am writing in response to Johnson & Johnson's (J&J) September 19, 2024, letter regarding J&J's decision to proceed with implementation of an unapproved rebate proposal for sales of certain covered outpatient drugs to particular covered entities.

In letters sent on August 14, 2024, and September 17, 2024, the Health Resources and Services Administration (HRSA) made clear that the 340B statute requires Secretarial approval of any rebate mechanism. Despite communicating this point to J&J multiple times, J&J's communications to HRSA, including J&J's September 19, 2024, letter, have not requested Secretarial approval.

Accordingly, as outlined in HRSA's September 17, 2024, letter, if J&J proceeds with implementing its rebate proposal without Secretarial approval, it will violate section 340B(a)(1) of the Public Health Service Act. If J&J has not notified HRSA that it is ceasing implementation of its rebate proposal by September 30, 2024, HRSA will begin the process outlined in J&J's Pharmaceutical Pricing Agreement related to terminating the agreement. In addition, if J&J moves forward with implementation of its rebate proposal, HRSA will initiate a referral to the HHS Office of Inspector General pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi).

To forestall these actions, J&J should – per HRSA's September 17, 2024, letter – inform HRSA by no later than September 30, 2024, that it has ceased implementation of its rebate proposal. Your response should be sent to Chantelle Britton, Director of HRSA's Office of Pharmacy Affairs at cbritton@hrsa.gov.

Sincerely,

/s/ Carole Johnson

Carole Johnson

cc: Lena Kane, Senior Director Government Contract and Compliance, Johnson & Johnson
Perry Knight, Vice President, Law, Strategic Customer Group, Johnson & Johnson