Johnson & Johnson Health Care Systems Inc.
1000 US Highway 202 South
Raritan NJ 08869 United States

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Re: Johnson & Johnson Health Care Systems Inc. 340B Rebate Model

Johnson & Johnson Health Care Systems Inc. (J&J) has participated in the federal 340B drug pricing program for more than 30 years and remains deeply committed to the 340B program as it was originally intended. We also respect and appreciate the critical role that 340B covered entities play in addressing the healthcare needs of underserved populations. However, the healthcare system has changed significantly over the years, and it has been well documented that the 340B program has unfortunately been subject to increasing abuse by for-profit entities far afield from the limited set of safety net covered entities the program is designed to benefit.[1]

For this reason, J&J has announced a program to offer 340B pricing to certain large 340B hospitals ("Disproportionate Share Hospitals" or "DSH" covered entities) on two products, STELARA and XARELTO, through a rebate model. The rebate model will not apply to Federally Qualified Health Centers, rural referral centers, and other types of covered entities. This rebate model will increase transparency and improve program integrity while safeguarding the 340B program's long-term viability.

For the benefit of interested parties, J&J provides the following additional guidance and explanation of its rebate model:

1. **Patients should benefit from the 340B program**. 340B is a critical part of the healthcare safety net in this country. Congress crafted the 340B program to enable manufacturers to continue providing deep discounts to a limited set of safety net providers serving vulnerable patients. However, skyrocketing growth in the program has increased the need for transparency and accountability to ensure that 340B discounts are truly benefiting those patients. Transparency is also critical to shed light on for-profit pharmacy benefit managers and pharmacy chains currently using 340B for their own financial benefit.[2]

2. **J&J's rebate model will modernize the 340B program and provide important safeguards to advance program integrity.** Today's 340B program is far removed from the narrowly structured program Congress created in 1992. "Replenishment" models for example, are now commonly used by covered entities to manage virtual 340B inventories. The rebate model operates in a similar fashion using the same data. J&J's rebate model will bring much needed transparency to the 340B program and allow for efficient validation that a 340B covered entity has both purchased and dispensed a 340B-priced medicine. The rebate program will enable J&J to carry out its 340B obligations while protecting program integrity, consistent with the 340B statute's prohibitions

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[1] *See* HHS-OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 4, 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf; U.S. Gov't Accountability Off., GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements* (Dec. 14, 2020), https://www.gao.gov/assets/gao-21-107.pdf; U.S. Gov't Accountability Off., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 30 (June 2018), https://www.gao.gov/assets/700/692697.pdf; Nicole Longo, PhRMA, *PBMs using 340B program to drive profits at patients' expense* (Mar. 28, 2024), https://phrma.org/Blog/PBMs-using-340B-program-to-drive-profits-at-patients-expense.

[2] *See* Aaron Vandervelde et al., For-Profit Pharmacy Participation in the 340B Program, BRG, at 3 (Oct. 2020), https://www.thinkbrg.com/insights/publications/for-profit-pharmacy-participation-340b/.

again duplicate discounts and diversion.[3] The rebate model will allow J&J to efficiently identify and eliminate duplicate discount requests from other government and commercial programs. Hospitals will receive 340B rebates first, and other rebate requests will be addressed afterwards as appropriate.

3. **J&J's rebate model uses standard, reasonable business practices for efficient and timely rebate payment.** J&J will pay 340B rebates within 7-10 days after hospitals submit commercially standard data demonstrating simply that a hospital covered entity has purchased and dispensed STELARA or XARELTO. These requested data are the same data that hospitals submit to commercial payers and which payers then submit to J&J for rebates. Accordingly, J&J anticipates that hospitals that submit timely rebate claims will receive rebates *before* their payment is due on initial purchases of product from wholesalers under standard payment terms. HRSA has always maintained that 340B participation comes with administrative obligations to preserve program integrity and to fulfill manufacturer requests for standard information as part of customary business practices. The rebate model fully aligns with those objectives and HRSA principles.

4. **The rebate model does not impact the universe of eligible 340B claims, nor does it change the 340B ceiling price**. The rebate model validates that a hospital covered entity has (1) purchased the drug and (2) dispensed the drug. Accordingly, implementation of the rebate model should not affect J&J's or hospitals' revenue on 340B-eligible purchases of STELARA and XARELTO. To the extent hospitals believe increased 340B transparency will increase their expenditures—which would indicate they are currently using 340B for *ineligible* transactions—that only reinforces the need for the rebate model. To put it plainly, all purchases of STELARA and XARELTO that were previously 340B-eligible will remain 340B-eligible. Only demands for the 340B price that are not authorized by the 340B statute will be excluded under the rebate model.

5. **J&J has clear legal authority to implement a rebate model.** The 340B statute clearly and unequivocally contemplates rebates as a mechanism for manufacturers to offer the 340B price to covered entities.[4] The statute does not require 340B prices to be offered through an up-front discount. To the extent the statute is interpreted to authorize HRSA to direct a specific pricing mechanism, HRSA would have to exercise such discretion through its agreement with manufacturers—the Pharmaceutical Pricing Agreement (PPA). The PPA contains no term addressing the mechanism to be used for offering 340B prices to covered entities. Accordingly, manufacturers retain full discretion to offer the 340B price to covered entities through a rebate model.

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J&J remains committed to ensuring the integrity and sustainability of the 340B program for the benefit of patients the program should serve.

[3] *See* 42 U.S.C. § 256b(a)(5)(A), (B) (prohibiting "duplicate discounts or rebates" and diversion of 340B-priced drugs).

[4] 42 U.S.C. § 256b(a)(1), (a)(5).