

By E-mail to cbritton@hrsa.gov, 340BPricing@hrsa.gov

September 30, 2024

Carole Johnson
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Johnson & Johnson Health Care Systems Inc. (“J&J”) 340B Rebate Model

Dear Administrator Johnson:

As HRSA knows, J&J is committed to the 340B program as it was originally intended, to serve as an important safety net program for vulnerable patients. Transparency is needed to ensure that 340B discounts are truly benefiting those vulnerable patients and to help modernize and ensure the sustainability of the 340B program. I am writing in response to your letter of September 27, 2024 regarding J&J’s planned implementation of a limited-scope 340B program rebate model (“Rebate Model”) for purchases of two J&J medicines by large, financially robust 340B disproportionate share hospitals (“DSH entities”).

HRSA’s Response to J&J’s Rebate Model Is Detrimental to Patients, Unlawful, and Punitive. HRSA’s decision to respond to J&J’s planned implementation of the Rebate Model by moving to terminate J&J’s Pharmaceutical Pricing Agreement (“PPA”) is severely detrimental to vulnerable patients across the country. If HRSA took this unprecedented step, it would mean that millions of Medicare and Medicaid patients throughout the nation would lose access to life-saving and life-enhancing medicines made by J&J—including therapies that treat cancer, cardiovascular disease, mental illness, and autoimmune conditions. Besides threatening harm to the patients whom J&J is committed to serve and for whose benefit the 340B program was intended, HRSA’s actions are inconsistent with federal law, which permits J&J’s proposed rebate model. The 340B statute unequivocally contemplates rebates as a mechanism for manufacturers to offer the 340B price to covered entities. To the extent HRSA has authority to direct a pricing mechanism, which is not at all clear, it may do so only through the PPA. Nothing in the PPA specifies the mechanism to be used for effectuating the 340B price, so manufacturers retain the ability to utilize rebate models at their discretion.

The Rebate Model Protects 340B Claims and Promotes Program Integrity. HRSA is aware that J&J’s Rebate Model changes neither the scope of 340B-eligible prescriptions nor the 340B ceiling price for J&J’s medicines. All covered entities, including DSH entities, will retain the same ability they have today to access 340B pricing. The Rebate Model brings needed transparency to the 340B program through real-time data validation of just two facts: whether a DSH entity actually (1) purchased and (2) dispensed a 340B priced medicine. The commercially standard data used is already provided by DSH entities to manufacturers, payers, and other program stakeholders today. This basic transparency is fully consistent with HRSA’s own mission of ensuring accountability, transparency, and adherence to the 340B program’s stated purpose.

The Rebate Model targets duplicate discounts, not 340B-eligible claims. Duplicate discounts are prohibited by the 340B statute—and yet HRSA’s own covered entity audits demonstrate the rampant abuse occurring in the program today. *See* U.S. Gov’t Accountability Off., GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements* 13 (Dec. 14, 2020) (finding nearly 35% of HRSA’s 2012-2019 audits resulted in a finding of duplicate discounting, and 44% resulted in a finding of diversion); HRSA, Program Integrity: FY22 Audit Results, <https://www.hrsa.gov/opa/program-integrity/fy-22-audit-results> (last updated July 24, 2024) (finding evidence of duplicate discounts in at least 28 of the 199 covered entity audits HRSA has finalized for 2022 to date); HRSA, Program Integrity: FY23 Audit Results, <https://www.hrsa.gov/opa/program-integrity/fy-23-audit-results> (last updated Sept. 20, 2024) (finding evidence of duplicate discounts in at least 25 of the 159 covered entity audits HRSA has finalized for 2023 to date). Moreover, in just the past two years, J&J has identified thousands of transactions in which DSH covered entities received a 340B discount and then submitted or caused to be submitted a claim for a Medicaid rebate in violation of the 340B statute.

Audits are not solving the problem. As HRSA knows, J&J’s efforts to identify and address program abuse through HRSA-approved audits of covered entities have been thwarted; nearly all of the entities for whom HRSA approved J&J audit requests have violated federal law by refusing to cooperate. Some have gone so far as to file suit against HRSA to invalidate the audit approvals. Plainly, audits alone are not a viable means for J&J to obtain information necessary to detect unlawful duplicate discounts and diversion as they occur.

It is indisputable that the integrity of the 340B program has suffered immense harm in recent years, all without clear benefit to the patients it is intended to serve. Instead, duplicate discounts and diversion benefit for-profit entities like pharmacy benefit managers and their affiliates exploiting the 340B program for financial gain. J&J’s Rebate Model is a necessary first step toward restoring the 340B program’s intended purpose of enabling the program to operate efficiently and effectively in today’s complex healthcare system. J&J is disappointed that HRSA has made an unfortunate and unjustified decision to pursue punitive sanctions instead of accepting J&J’s request for a meeting to discuss J&J’s goals of advancing patient access and furthering program transparency and integrity, which J&J believes HRSA shares.

J&J’s Commitment to Patients Leaves It No Choice But To Forgo Implementation of the Rebate Model Pending Resolution of These Issues. J&J is proud of its strong and unwavering commitment to its patients. Due to HRSA’s unwarranted threats of excessive and unlawful penalties, J&J has no choice but to forgo implementation of the Rebate Model pending resolution of these issues. J&J nonetheless continues to believe that the Rebate Model is not only legally permissible but sorely needed to improve the integrity of the 340B Program and provide an effective mechanism for manufacturers to comply with their obligations under the Inflation Reduction Act’s de-duplication and 340B price effectuation requirements. J&J reserves all of its legal rights with respect to this matter.

Johnson & Johnson

J&J values its relationship with HRSA and remains interested in meeting with you to continue engagement on the benefits that the Rebate Model will offer to 340B stakeholders. Please do not hesitate to contact me to continue our discussions on these critical issues.

Sincerely,



Scott White
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North America Innovative Medicine

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