

The Honorable Bernie Sanders
Chairman
Health, Education, Labor, and Pensions
Committee
332 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Cathy McMorris Rodgers
Chairwoman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Bill Cassidy
Ranking Member
Health, Education, Labor, and Pensions
Committee
455 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Re: Johnson & Johnson 340B Rebate Model

Dear Chairman Sanders, Ranking Member Cassidy, Chairwoman McMorris Rodgers, and Ranking Member Pallone,

The National Rural Health Association is writing to raise our concerns around Johnson & Johnson's (J&J) recently announced rebate model applicable to two significant outpatient drugs. **We urge you to take swift action blocking this policy and any similar policies by manufacturers in the future** as this is contrary to the 340B statute and threatens rural hospital viability.

J&J announced that it will no longer offer upfront 340B pricing for two drugs, Stelara and Xarelto, for disproportionate share hospitals (DSH) participating in the 340B program. Instead, beginning October 15, 2024, DSH hospitals will be required to purchase the drugs at full price and submit claims data to J&J. After the data is submitted and reviewed, J&J may offer rebates to the hospital. **We are incredibly concerned that this offers J&J unmitigated power to deny rebates and therefore deny 340B pricing.**

Further, J&J's rebate model is contrary to the 340B statute and its historical interpretation by the Department of Health and Human Services (HHS). While the 340B statute does reference "rebates," it does not give manufacturers the ability to impose its own rebate policies.¹ Rather, the HHS Secretary retains authority to approve the provision of 340B pricing as a rebate or discount at the point of purchase.² Since the program's inception HHS has stated and upheld its policy to provide upfront discounts.³ Further, the Health Resources and Services Administration recently sent a warning letter to J&J mandating that they cease implementation of the rebate model.⁴ NRHA believes that congressional action is still necessary to explicitly provide in the 340B statute that a similar rebate model is not allowed.

¹ 42 U.S.C. § 256b(a)(1) "The 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 for covered outpatient drugs [...] purchased by a covered entity" (emphasis added).

² *Id.*

³ 58 Fed. Reg. 27289, 27291; 59 Fed. Reg. 25110, 25113.

⁴ <https://www.hrsa.gov/sites/default/files/hrsa/opa/sept-2024-hrsa-letter-johnson-johnson.pdf>.



National Rural Health Association

Rural DSH hospitals are safety net providers that participate in the 340B program according to its congressional intent – the stretch scarce federal resources further. 340B is a lifeline program that allows rural safety net providers to keep their doors open, furnish critical services, and keep key service lines open. **A growing number of policies from manufacturers restricting contract pharmacy arrangements, and now the rebate model from J&J, are eroding rural covered entities' 340B savings and threatening their financial viability.**

We urge you to consider legislation to stop restrictions from manufacturers on safety net providers. While we believe J&J's actions are contrary to the 340B statute, it is imperative that Congress explicitly enshrine protections against this policy as well as any restrictions on contract pharmacy arrangements in the 340B statute. Any limitation on 340B savings is detrimental to rural covered entities and J&J's new policy represents another attempt to further erode the program.

If you have any questions or would like to discuss further, please contact NRHA's Government Affairs and Policy Director Alexa McKinley Abel (amckinley@ruralhealth.us).

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Morgan".

Alan Morgan
Chief Executive Officer
National Rural Health Association