Sign Onto Rep. Spanberger, *et al*¸ Letter to HHS

Protecting the 340B Drug Pricing Program

Please join the letter below to HHS, seeking to halt Johnson and Johnson's efforts to undermine the 340B Drug Pricing Program. To sign on the letter, reach out to Lucy Schwartz in Rep. Spanberger's office (lucy.schwartz@mail.house.gov) or Sydney Powers in Rep. Johnson's office (sydney.powers@mail.house.gov).

FULL LETTER TEXT:

Dear Secretary Becerra,

We write to express our concern over the Johnson & Johnson (J&J) plan to upend more than 30 years of federal law by delaying access to 340B Drug Pricing Program (340B) discounts on pharmaceuticals for certain safety-net hospitals. J&J aims to impose new extra-statutory rules for hospitals to follow as a condition of accessing those discounts. This unapproved and unlawful change would have severe consequences for our nation's safety net providers and the patients they serve. We understand that J&J is moving forward with this proposal despite being told by the Health Resources & Services Administration (HRSA) that the company's proposal is inconsistent with the 340B statute. We thank you for your continued efforts to preserve the integrity of 340B and swift response to this announcement thus far, and urge you to use every enforcement tool at your disposal to protect the communities safety-net hospitals serve from this devastating change to 340B.

On August 23, 2024, J&J announced its intent to cease providing upfront 340B discounts, instead instituting a back-end rebate model for disproportionate share (DSH) hospitals that participate in 340B, the largest category of 340B covered entities. Despite the lack of legal authority and existing infrastructure that would be necessary to impose this policy, J&J intends to implement this change on October 15, 2024.

Congress intended 340B to enable the nation's safety-net hospitals that serve a disproportionate share of patients with low incomes as well as those living in rural areas (and other covered entities) to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. A rebate model would severely undermine that purpose. As HRSA has stated, it is not in compliance with the law. Therefore, the Department of Health and Human Services (HHS) should act quickly to prevent the financial impact and burden this change would create for safety-net hospitals across the country.

J&J, or any other manufacturer, does not have the statutory authority to unilaterally restructure the 340B program by determining when, how, and to what subset of drugs or covered entities the upfront 340B discount is provided. The 340B statute requires manufacturers to offer a discounted price on the "purchase" of drugs. Providers must comply with rules governing to whom the drugs are dispensed and other requirements that HRSA oversees. J&J's proposed rebate model violates the statute by requiring providers to purchase drugs at a high sticker price and submit data to the manufacturer for "validation." J&J's rebate model hijacks HRSA's oversight role and delays the benefit of the 340B price until some undetermined date. This approach is to the manufacturer's financial benefit because the company retains those sums for a longer time and creates hurdles for covered entities to claim the discount.

Under the rebate model, impacted safety-net hospitals would be required to purchase drugs at the high sticker price, instead of at the substantially lower 340B discount, and wait for an undetermined period to receive the 340B discount as a rebate. This model would reduce resources available for providing comprehensive services to patients and communities, undermining the core purpose of 340B. 340B DSH hospitals provide high levels of care to patients with low incomes and are responsible for 75% of all hospital care to Medicaid patients and 60% of uncompensated care. 340B savings enables hospitals to expand access to necessary services that improve patient care, subsidize many essential services that operate at a loss, and support community health initiatives.

A rebate model would create significant financial challenges for safety-net hospitals, which already are operating under much lower operating margins than non-340B hospitals. J&J's announcement states that rebate payment would be received within 10 days after the claim is "validated." Without any description of what it means to validate a claim, hospitals could be carrying that high cost for months to the sole benefit of J&J. Many hospitals also would be forced to hire new full-time employees to develop new purchasing arrangements as well as to monitor, validate, and reconcile the rebates. Moreover, there is no existing infrastructure for accumulating and sharing the data that J&J would require for hospital rebate claims.

Medicaid programs throughout the country would also be impacted by this proposal. More than 35 state Medicaid fee-for-service (FFS) programs require covered entities to bill 340B drugs at actual acquisition cost (AAC), which is based on the invoice price paid for that category of drugs. Under J&J's rebate model, the invoice price would be the high sticker price, depriving states of upfront savings and requiring an entirely new infrastructure or process for reconciling payments if a J&J rebate is received.

The rebate approach not only runs contrary to statute, but also defies longstanding HRSA program guidance that distinguishes rebates and retroactive discounts from upfront 340B discounts. In the more than 30-year history of 340B, HRSA has permitted rebates in only one limited circumstance to accommodate state AIDS drug assistance programs (ADAPs). Many ADAPs reimbursed pharmacies for drugs rather than purchasing them directly and therefore were unable to access a 340B discount at the point of purchase.

The 340B program was created to serve our most vulnerable neighbors. J&J actions threaten both the integrity and effectiveness of the program. With these concerns in mind, we respectfully request the following information.

1. What enforcement tools will HHS leverage to ensure that J&J, and any other companies that attempt to use an unapproved rebate model, remain compliant with 340B statutory requirements?

a. For example, will HRSA consider imposing civil monetary penalties against J&J for overcharging disproportionate share hospitals by denying direct discounts on the purchase of 340B drugs and instead offering unapproved rebates?

2. What tools would HRSA have for oversight and monitoring of J&J's rebate model should it take effect, including ensuring that covered drugs are not denied and that discounts are paid to covered entities in a timely manner without facing unnecessary administrative or financial burden?

3. Have any other manufacturers ever sought guidance from HHS regarding the use of a rebate model for covered entities? How has HHS approached these inquiries?

We appreciate HHS's continued efforts to support 340B, and we look forward to partnering with you to ensure 340B continues to enable hospitals to meet their communities' needs. Thank you for your prompt consideration of these important matters.

Sincerely,

Abigail Spanberger
Member of Congress

Dusty Johnson
Member of Congress

Doris Matsui
Member of Congress

Debbie Dingell
Member of Congress

Tracey Mann
Member of Congress

Rob Wittman
Member of Congress

CC: HRSA Administrator Carole Johnson

CC: HRSA Office of Pharmacy Affairs Director Chantelle Britton