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Advancing Health in America

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August 28, 2024

The Honorable Carole Johnson
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20852

Dear Administrator Johnson:

On behalf of our more than 2,000 member hospitals and health systems participating in the 340B Drug Pricing Program, the American Hospital Association (AHA) appreciates the Health Resources and Services Administration's (HRSA) response to Johnson & Johnson's (J&J) most recent attempt to undermine the 340B Drug Pricing Program by unilaterally imposing a "rebate" model, rather than the longstanding "upfront discount" model that the Secretary of Health and Human Services (HHS) has allowed since the outset of the program. **As HRSA correctly recognized, J&J's actions violate federal law. We urge you to take immediate enforcement action if J&J moves forward with these illegal measures, including by assessing civil monetary penalties for intentionally overcharging 340B hospitals.**

On August 23, J&J announced that it would be dramatically transforming its approach to 340B pricing for two of its most popular products, Stelara and Xarelto. Historically, J&J offered upfront discounts to 340B hospitals when they purchase these drugs. Starting on October 15, however, J&J will require all disproportionate share hospitals participating in the 340B Drug Pricing Program to purchase these drugs at full price and apply for a rebate from J&J. Under the new program, these hospitals will be required to submit certain data to J&J when they purchase the drugs at full price. After J&J verifies the drug's 340B status, it will send disproportionate share hospitals a rebate for the difference between the amount paid and the discounted 340B price.

This new J&J policy is a fundamental change in how the 340B program has operated for over 30 years. Regrettably, however, it is not a change in how J&J and other drug companies operate. **J&J's adoption of this rebate model is yet another example of a drug company seeking to squeeze every possible penny from the hospitals and health systems that care for America's underserved patients.** While it may not seem like much on paper, the change from an upfront discount model to a rebate model

inflicts significant financial and administrative costs on hospitals. Under this new rebate model, 340B hospitals will be forced to spend their limited resources acquiring these drugs at exorbitantly high prices while they wait months for J&J to honor its 340B obligations. This flies in the face of Congress' intent in establishing the 340B program and could jeopardize patients' access to these drugs. In addition, disproportionate share hospitals, which already operate on the thinnest of margins, will be forced to develop pricey administrative mechanisms to make and track rebate requests. And J&J will essentially transform itself into the ultimate arbiter of whether a rebate should be approved and paid, with the likely consequence of J&J denying rebates to hospitals that they appropriately owe.

Perhaps worst of all, J&J is yet again engaging in 340B vigilantism. While J&J may contend that this new policy is needed to improve program transparency, Congress did not permit drug companies to take the law into their own hands. *See* A*stra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 114 (2011) ("Congress placed the Secretary (acting through her designate, HRSA) in control of § 340B's drug-price prescriptions."); Health Resources and Services Administration, Release No. 2011 – 1.1, Clarification of Non-Discrimination Policy (2012) ("A manufacturer may not condition the offer of 340B discounts upon a covered entity's assurance of compliance with section 340B provisions."). Much like its interference with contract pharmacy arrangements during the height of the COVID-19 pandemic, the motives behind J&J's new policy are not as pure as it suggests. This new rebate policy — like the drug companies' contract pharmacy policies that preceded it — is a money-making scheme dressed up as a program integrity measure.

It also is not lost on hospitals and health systems that Stelara and Xarelto are two of the ten drugs whose prices were recently negotiated by the Centers for Medicare & Medicaid Services under the Inflation Reduction Act (IRA). J&J's new policy is nothing more than a tit-for-tat response intended to make up for lost revenues that it could incur due to the lower prices it is required to charge Medicare patients under the IRA. Strikingly, all of this comes from a company that had more than *$85 billion* in revenues in 2023.

Thankfully, HRSA has recognized the unlawfulness of J&J's actions. When the AHA first got wind that J&J was considering this rebate model, we reached out to your office to register our concerns. Soon after J&J officially announced this policy, HRSA notified the AHA that it determined J&J's rebate model "is inconsistent with the 340B statute, which requires Secretarial approval of any such proposal. The Secretary has not approved J&J's rebate model." We agree with this analysis and commend HRSA for taking such a clear, forceful stand against J&J's mercenary behavior.

The 340B statute provides: "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 … does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the

preceding calendar quarter, reduced by the rebate percentage described in paragraph (2)." 42 U.S.C. § 256b(a)(1) (emphasis added). **The italicized portion of this text is critical, as it expressly delegates to the HHS Secretary the authority to approve any "rebate" sought by a manufacturer**.

The legislative history of the 340B statute further supports this understanding. The House Report accompanying the relevant bill made clear in *three different places* that the Secretary would have discretion to determine when the price reduction would apply:

- "*The Secretary would have the discretion to determine the mechanism (rebate, point-of-purchase discount, or otherwise) for assuring this price reduction*, which would apply only to drugs for which payment is not made separately to the clinic or other protected purchaser by a State Medicaid program."
- "[M]anufacturers, as a condition of receiving Federal Medicaid matching funds on their covered outpatient drugs, would have to enter into an agreement with the Secretary of HHS to provide price reductions (whether through a discount, rebate, or other mechanism) to these "covered entities" on covered outpatient drugs. These price reductions would be at least as great as those which Medicaid receives under the rebate program. *They would be implemented, at the discretion of the Secretary, either by a point-of-purchase discount, a rebate, or other mechanism*."
- "The Committee bill does not specify whether "covered entities" would receive these favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism. A mechanism that is appropriate to one type of "covered entity," such as community health centers, may not be appropriate to another type, such as State AIDS drug purchasing programs. *The Committee expects that the Secretary of HHS, in developing these agreements, will use the mechanism that is the most effective and most efficient from the standpoint of each type of "covered entity."*

H.R. Rep. No 102-384, 102d Cong., 2d Sess., pt. 2, at 8, 12, 16 (1992) (emphases added).[1]

HHS has interpreted the 340B statute this way consistently from the program's inception. As HRSA has explained, "Initially, HRSA guidance for the section 340B program described only a discount process." Notice Regarding Section 602 of the

[1] Courts have routinely relied on this House Report when interpreting the 340B statute. *See, e.g.*, *American Hospital Association v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020); *AbbVie v. Fitch*, Civil No. 1:24-cv-184-HSO-BWR, 2024 WL 3503965, at *3 (D. Miss. July 22, 2024); *Genesis Health Care, Inc. v. Becerra*, No. 4:19-CV-01531-RBH, 2023 WL 7549156, at *1 (D.S.C. Nov. 3, 2023); *PhRMA v. McClain*, 645 F.Supp.3d 890, 896 (E.D. Ark. 2022); *Eli Lilly & Co. v. Cochran*, 526 F.Supp.3d 393, 398 (S.D. Ind. 2021).

Veterans Health Care Act of 1992 Rebate Option, 62 Fed. Reg. 45,823, 45,824 (Aug. 29, 1997). In fact, HRSA issued guidance in 1993 and 1994 stating that upfront discounts — not rebates — must be made available to 340B covered entities. *See* Limitation on Prices of Drugs Purchased by Covered Entities, 58 Fed. Reg. 27289, 27291 (May 7, 1993); Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25110, 25113 (May 13, 1994).

HRSA has made only one exception to this practice, allowing the use of a rebate model in a limited circumstance. *See* Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 — Rebate Option, 63 Fed. Reg. 35239 (June 29, 1998). But when it did so, the HHS Secretary issued guidance only after soliciting stakeholder feedback through the notice-and-comment process. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Rebate Option, 62 Fed. Reg. 45,823, 45,824 (Aug. 29, 1997). (Needless to say, J&J did not afford HRSA the opportunity to engage in a comment process here.) And the agency's notice explicitly noted that Congress gave the HHS Secretary discretion to determine the most effective mechanism for providing 340B pricing. *See id*.

Given this text, legislative history, and consistent agency practice, the AHA is confident that courts will uphold HRSA's longstanding reading of the 340B statute. Most important, HRSA's interpretation of the relevant statutory phrase — "taking into account any rebate or discount, as provided by the Secretary" — is textually sound. The Supreme Court's recent decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S. ——, 144 S.Ct. 2244, only reinforces that conclusion. HRSA's reading deserves "due respect" under *Loper Bright* for two reasons. *First*, the 340B statute authorizes the Secretary to "exercise a degree of discretion" regarding the mechanism for implementing a 340B price reduction. *Id*. at 2263. Both the statutory text ("as provided by the Secretary") and the House Report make pellucidly clear that Congress "empower[ed the Secretary] to prescribe rules to 'fill up the details' of a statutory scheme." *Id*. (quoting *Wayman v. Southard*, 10 Wheat. 1, 43, 6 L.Ed. 253 (1825)). *Second*, due respect is "especially warranted" here because HRSA's interpretation was "issued roughly contemporaneously with enactment of the statute and remained consistent over time." *Id*. at 2258. HRSA endorsed the discount model and recognized its own discretion in the mid-1990s, not long after the 340B statute was passed. Critically, it has maintained that interpretation until the present day — including as recently as last week when HRSA explained that the Secretary had not approved J&J's rebate model. This "longstanding practice of the government" matters. *Id*. (quotation marks omitted).

All in all, it is clear that J&J has crossed a line. Even (and perhaps especially) if it is merely testing HRSA's resolve by only applying this new rebate policy to two drugs, HRSA must act swiftly to prevent J&J and others from pursuing the same unlawful activity. The statute affords HRSA a variety of tools to deter this kind of transgressive behavior. **HRSA should immediately impose civil monetary penalties on J&J to send a clear message that drug companies cannot take unilateral action at the expense of 340B hospitals and the vulnerable patients they serve**.

We appreciate your ongoing support of the 340B Drug Pricing Program and stand ready to work with you to prevent J&J and other drug companies from implementing these seismic policy shifts without Secretarial approval. Please contact me if you have questions.

Sincerely,

/s/

Chad Golder
General Counsel