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HRSA-J&J Dispute Over 340B Rebate Plan Again Underscores Need For Program Reform

by Cathy Kelly

Johnson & Johnson plans to shift 340B price concessions on Stelara and Xarelto to rebates for some hospitals beginning in October, allowing for more company oversight of claims.

That didn't take long. [Johnson & Johnson](#) ignited a new 340B confrontation between pharmaceutical manufacturers and the Health Resources and Services Administration with its recently disclosed plan to shift up-front 340B discounts for Stelara and Xarelto to back-end rebates for certain types of hospitals.

The conflict between manufacturers and HRSA and 340B "covered entities" is a consequence of the 340B program outgrowing its original intent and the reality that the law instituting the program offers very limited guidance on key issues on its operation.

Congress has been developing legislation that could improve 340B program oversight and clarify its scope, but the slow process has encouraged manufacturers to move independently. (Also see "[Bipartisan House Support Remains Elusive In 340B Reform Effort](#)" - Pink Sheet, 4 Jun, 2024.)

Key Takeaways

- Johnson and Johnson is blazing a new trail in the 340B program by shifting up-front 340B discounts on Stelara and Xarelto to back-end rebates, which will increase company oversight of the price concessions.
- The move may have been encouraged by a recent pharma appeals court win involving manufacturer restrictions on contract

J&J *announced* the change 23 August to disproportionate share hospitals, which are those eligible for extra government reimbursement based on the number of low-income patients they serve.

The move would represent a significant change in the way manufacturers provide 340B price concessions to eligible providers and require DSH hospitals to wait until drug claims are processed by a third party before rebates are released.

“We believe this update will significantly improve program integrity while at the same time enabling covered entities to obtain the 340B price on eligible 340B sales,” J&J said.

The company plans to officially implement the shift on 15 October, although it will allow a six-month grace period initially for hospitals to adjust their systems.

“As of that date, [J&J] will no longer process wholesaler chargebacks for the 340B ceiling price on purchases of Stelara or Xarelto by DSH covered entities,” the company said.

HRSA Objects That Plan Was Not Preapproved

HRSA responded to J&J’s announcement with a warning to the company that the “proposal to implement a 340B rebate model is inconsistent with the 340B statute, which requires [the agency’s] approval of any such proposal.”

HRSA “has not approved J&J’s rebate model, and “has communicated this information to J&J,” the agency said, adding that it “will take appropriate actions as warranted.”

Whether HRSA will be able to stop the plan is unclear. The situation follows a recent win by manufacturers imposing restrictions on 340B discounts to contract pharmacies, where a US appeals court ruled the law does not categorically prohibit manufacturers from imposing conditions on the distribution of 340B-covered drugs. (Also see "[340B Contract Pharmacy Confusion: Another US Court Sides With Pharma, States Enact Roadblocks](#)" - Pink Sheet, 23 May, 2024.)

Manufacturers’ three and-a-half year campaign to restrict the 340B discounts flowing through contract pharmacies has been driven by an interest in finding ways to create more oversight of whether 340B price concessions are obtained appropriately.

pharmacies.

- The move also may have been prompted by concerns that Xarelto and Stelara could be subject to both 340B discounts and Medicare negotiated prices beginning in 2026 due to a lack of government oversight.

Several companies have been requiring providers to turn over claims data before agreeing to provide discounts on drugs dispensed by contract pharmacies. (Also see "[340B Drug Diversion: Sanofi Suit Seeks Evidence In Pharmacy Contracts With Hospitals](#)" - Pink Sheet, 20 Jun, 2024.)

‘Straw That Broke The Camel’s Back’?

J&J’s announcement also came on the heels of Medicare unveiling reduced prices for the first 10 drugs subject to the negotiation process established by the Inflation Reduction Act. The negotiated prices were announced 15 August. (Also see "[A Better Deal: Medicare Discounts Surpass Estimated PBM-Negotiated Rebates](#)" - Pink Sheet, 16 Aug, 2024.)

Under the law, drugs subject to negotiated “maximum fair prices” in Medicare are not supposed to be subject to 340B discounts as well. But the US Centers for Medicare and Medicaid Services will not lead the policing effort, which is expected to prompt manufacturers to implement their own systems. (Also see "[The Next 340B Battle: Discount Duplication With Medicare Negotiated Prices](#)" - Pink Sheet, 30 Jul, 2024.)

CMS also is deferring to HRSA on J&J’s situation. "Regarding the Medicare drug price negotiation, CMS encourages the primary manufacturer of the selected drug to engage with covered entities, and their vendors that assist in identifying 340B claims, to comply with obligations to provide the 340B ceiling price to a covered entity where appropriate," the agency told the *Pink Sheet*.

As the only manufacturer with two drugs on the list, Stelara and Xarelto, J&J would be expected to want more transparency for 340B price concessions. Other manufacturers with negotiated drugs likely will follow.

The added complication from the potential overlap with Medicare negotiated prices may have been “the straw that broke the camel’s back on what they are concerned is 340B ‘leakage,’” regulatory consultant and 340B expert Bill Sarraille suggested in a LinkedIn post.

“The problem would grow immeasurably worse under the IRA with [CMS] having abandoned any pretense of having its [Medicare transaction facilitator] contractor meaningfully identify duplicate 340B and Medicare ‘fair price’ discounts,” he said.

The Issue Of Eligible Patients

Furthermore, “the [J&J] announcement references the required submission of medical claims data, a pretty clear signal it will be testing for [340B] patient definition violations,” Sarraille observed. That is an issue the company “is clearly wanting to test with the audits it has initiated ... and that two prominent 340B hospitals are trying to block through litigation.”

340B Health, an advocacy organization representing providers, challenged J&J’s action in a 22

August *letter* to HRSA.

“The rebate approach denies 340B pricing at the time the drug is purchased and creates the opportunity to deny post-sale 340B rebates based on the manufacturer’s, and not HRSA’s, determination regarding compliance,” the group said.

“Such an approach violates the 340B statute,” which requires that manufacturers “‘offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price’ ... and to HRSA’s longstanding interpretation of the statute, which prohibits conditioning 340B discounts on concerns about non-compliance,” 340B Health argued.