

# 12 things to know about J&J's 340B Rebate Model Policy

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## 01

### **J&J's 340B Rebate Model Policy only applies to 340B DSH hospitals and only to Stelara and Xarelto**

- J&J will continue to offer 340B pricing on all covered outpatient drugs.
- The only change is that the 340B price for Stelara and Xarelto will be offered through a rebate to 340B DSH hospitals after valid claims data is processed.
- 340B pricing on all of our other covered outpatient drugs will remain available through chargebacks.

## 02

### **Patient access should not change**

- This rebate model does not change which transactions are eligible for 340B pricing and does not change the 340B price.
- Congress intended 340B to benefit underserved patients, and we hope DSH hospitals will share 340B rebates directly with patients accordingly.

## 03

### **J&J rebates will be paid promptly upon timely submission of claims**

- 340B DSH hospitals' cashflow should not be impacted by the rebate model.
- Claims submitted for 340B rebate will be validated automatically, and 340B DSH hospitals will be able to see immediately whether a claim was accepted for rebate (and submit any adjustments if necessary). Validated files are then sent for payment which will happen in 7-10 days.
- These requested data are the same data that hospitals submit to commercial payers and which payers then submit to J&J for rebates.
- Through discussions with industry experts, our understanding is that most hospitals have 15 -30 day payment terms with their wholesalers. Our system will process rebates 7-10 days after claims are received.
- If claims are submitted in a timely manner, CEs will receive their rebate before payment is due to wholesalers (based on industry standard payment terms).
- We understand covered entities may have voluntarily negotiated nonstandard terms with wholesalers in return for additional discounts on 340B products. The statute does not require manufacturers to accommodate such nonstandard arrangements in their price offer.

## 04

### **J&J's Rebate Model Policy applies to all DSH covered entity utilization**

- All utilization of Stelara and Xarelto from 340B DSH hospitals will be subject to the rebate model – whether the unit was dispensed from an in-house pharmacy or designated contract pharmacy or administered in an outpatient clinic.

## 05

### **In states where J&J has carved out covered entities from J&J's Bill-to/Ship-to policy, 340B DSH hospitals must still participate in J&J's 340B Rebate Model Policy**

- Carve-outs for J&J's Bill-to/Ship-to policy are not applicable to the rebate model.
- 340B DSH hospitals must submit claims from both the in-house and contract pharmacy to be compliant with the rebate policy.

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**J&J's 340B rebate model policy applies to all NDCs for Stelara and Xarelto**

07

**J&J's 340B rebate model is fully consistent with the statute**

- The 340B statute specifically references rebates as a mechanism for offering the 340B price.
- The statute does not require 340B prices to be offered through an up-front discount. Accordingly, manufacturers retain the discretion to offer 340B pricing to covered entities through multiple mechanisms, including a rebate model.
- J&J's 340B Rebate Model Policy is expected to mitigate legally prohibited program abuses by improving transparency.
- We communicated with HRSA about our plans prior to the announcement and continue to do so today.

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**340B discounts are affected by market factors and CMS statutory calculations**

- 340B pricing is derived from the Medicaid rebate calculation - two key drivers of which are the level of commercial-sector discounting and CMS-defined inflation penalties.
- In 2024, nearly all of Stelara's 340B discount results from competitive commercial-sector discounting to enable patient access.
- In 2024, more than half of Xarelto's 340B discount results from competitive commercial-sector discounting to enable patient access. The remainder of Xarelto's 2024 340B discount is a function of CMS regulation which calculates the inflation penalty by product strength.
- For these J&J drugs, the vast majority of current 340B discounts reflect competitive discounts offered in the private sector to enable patient access to J&J products – not price increases.

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**J&J's rebate for Stelara and Xarelto will be based on WAC**

- J&J's rebate will be calculated as WAC-340B ceiling price.
- If a 340B DSH hospital has a commercial arrangement with a wholesaler for lower pricing, J&J's rebate amount will not change. J&J's rebate will still be calculated as WAC-340B ceiling price.

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**J&J's 340B rebate model will support "MFP" effectuation but is not the sole reason for it**

- J&J's decision to implement its 340B Rebate Model Policy is separate from CMS's announcement of "MFP".
- The claims required under J&J's rebate model will be used to identify and eliminate subsequent duplicate rebate requests from multiple other government and commercial programs – including "MFP" in 2026.
- J&J will not hold 340B rebate payments in anticipation of subsequent rebate requests from other programs. 340B rebates will be paid first.
- J&J will not reduce the 340B rebate amount to account for the "MFP" until January 1, 2026.

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**J&J's rebate model will only validate that a 340B DSH hospital purchased and dispensed a product**

- J&J's rebate model requires industry-standard data elements on the product purchase and the product dispense.
- Product dispense data can be a pharmacy benefit claim from an in-house or designated contract pharmacy or a medical benefit claim from an outpatient clinic (for physician-administered products).

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**Claims for uninsured patients can be submitted through the 340B rebate system**

- If a covered entity dispenses Xarelto or Stelara to a patient without insurance, a "claim" for 340B rebate purposes can still be generated by the covered entity using "CASH" as the value for the BIN/PCN numbers.