# Manufacturer Restrictions: Rebate Edition

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# DISCLOSURE STATEMENT

- Chelsea Violette has no relevant financial relationship(s) with ineligible companies to disclose.

## LEARNING OBJECTIVES

At the completion of this activity, the participant will be able to:

- Review recent changes in the contract pharmacy landscape and typs of restrictions imposed by manufacturers
- Illustrate the steps involved to restore 340B access through data sharing and designating contract pharmacies to health center associated sites
- Compare and contrast strategies used by FQHCs to mitigate the impact to medication access and FQHC operational margin

# 340B Rebate Model Pilot Program

- **Purpose:** The pilot allows manufacturers to pay rebates post-purchase to covered entities, shifting away from the traditional upfront discount model.
- **Eligibility and Scope:** Participation is limited to manufacturers with Medicare Drug Price Negotiation Program agreements for initial price applicability year 2026, covering drugs on the Medicare Drug Price Negotiation Selected Drug List.
- **Application and approval process:**
  - Manufacturers submit plans by September 15, 2025, with approvals announced by October 15, 2025, and an effective date of January 1, 2026.
  - Implementation requires prior approval from HRSA.
  - Manufacturer plans that exceed or go beyond criteria defined by OPA must include detailed justification and will be subject to additional review by OPA prior to implementation.

https://federalregister.gov/d/2025-14619

| 2026 MFP Drugs | | |
|---|---|---|
| **Brand** | **Manufacturer** | **Rebate Lawsuit?** |
| Eliquis | Bristol-Myers Squibb* | Yes |
| Enbrel | Amgen | |
| Entresto | Novartis* | Yes |
| Farxiga | AstraZeneca (& Prasco) | |
| Imbruvica | AbbVie | |
| Januvia | Merck | |
| Jardiance | BI/Lilly | Yes (Lilly) |
| Novolog/FIASP | Novo Nordisk | |
| Stelara | Johnson & Johnson* | Yes |
| Xarelto | Johnson & Johnson* | Yes |

# 340B Rebate Model Pilot Program

**Plan requirements:**

- Ensure no additional administrative costs are passed to covered entities
- Provide 60 days' notice before implementation with instructions for registering for any IT platforms
- Maintain existing distribution mechanisms (e.g., 340B wholesaler accounts with pre-rebate prices loaded),
- Provide technical assistance and secure IT platforms for data submission, including HIPAA compliance
- Cannot deny rebates just for diversion or duplicate discount concerns
  - Rationales for claims denials may include deduplication for MFP or 340B rebate provided to another entity on the same claim
- Limit collection of the data to the pilot approved elements listed:

1. Date of Service
2. Date Prescribed
3. RX number
4. Fill Number
5. 11 Digit National Drug Code (NDC)
6. Quantity Dispensed
7. Prescriber ID
8. Service Provider ID
9. 340B ID
10. Rx Bank Identification Number (BIN)
11. Rx Processor Control Number (PCN)

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# New Pharmacy Payment & 340B Perspective

| | Medicare Transaction Facilitator | Rebate Pilot |
|---|---|---|
| Data Submission Timeframe | Up to 7 days from Plan Sponsor to DDPS to MTF | Up to 45 days from CE to Rebate IT Platform |
| Manufacturer Refund Timeframe | 14 Days | 10 Days |
| Approximate Total | 21 Day | 55 Days |
| Refund Level | Unit | Unit Or Package (MFR determines) |

## Prospective 340B Claims Identification:

- Dispensing can **voluntarily include** a "340B Claim Identifier" (**20**) when submitting Part D claims through the MTF. This **signals** to manufacturers indicating the **claim is being billed for a 340B drug**.
- Once flagged, manufacturers review the claim data. **If** they reasonably determine the **340B** ceiling price is **lower than the MFP**, they **withhold the MFP refund** and log that decision in the claim-level payment records.

## Retrospective 340B Claims Identification:

- CMS reiterated that it will "**continue to explore the feasibility** of incorporating 340B-related transactional data **from 340B covered entities or their** third-party administrators (**TPAs**) identifying claims eligible into MTF processes in the future," including considering **incorporating asynchronous 340B data into the MFP validation procedures**.

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# Previously Proposed Rebate Model Elements

| Manufacturer | Platform | Impacted Entities | Required Data Elements | Rebate Upon |
|---|---|---|---|---|
| Bristol Myers Squibb (BMS) | Beacon (BRG) | All CEs | Not specified in lawsuit | Dispense Unit or Full Package |
| Eli Lilly | Truzo (Kalderos) | All CEs | Utilization Data (CAD, EO Rx, & CRx) | Dispense Unit |
| Johnson & Johnson (J&J) | Beacon (BRG) | DSH | Purchase & Utilization Data (CAD, EO Rx, & CRx) | Full Package |
| Novartis | Not specified in lawsuit | DSH | Not specified in lawsuit | Full Package |
| Sanofi | Beacon (BRG) | CAH, DSH, RRC, SCH, CH/CHC | Purchase & Utilization Data (CAD, EO Rx, & CRx)<br>Encounter Data (Hospitals only) | Full Package |

# Initially Proposed Impacted Drugs

| BMS | Eli Lilly | | J&J | Novartis | | | Sanofi | |
|---|---|---|---|---|---|---|---|---|
| Eliquis | Adcirca | Mounjaro | Stelara | Adakveo | Ilaris | Tabrecta | Admelog | Sevelamer |
| | Alimta | Olumiant | Xarelto | Afinitor | Jadenu | Taflinar | Ambien | Soliqua |
| | Amyvid | Omvoh | | Aimovig | Kesimpta | Tasigna | Apidra | Toujeo |
| | Baqsimi | Retevmo | | Alomide | Kisqali | Tegretol | Arava | Zolpidem |
| | Baricitinib | Reyvow | | Arzerra | Kymriah | Tobradex | Avalide | |
| | Basaglar | Synjardy | | Beovu | Leqvio | Tobrex | Av pro | |
| | Bebtelovimab | Taltz | | Betopic S | Locametz | Trileptal | Doxe ferol | |
| | Cyramza | Tauvid | | Coartem | Lutathera | Tykerb | Dupix | |
| | Ebglyss | Tradjenta | | Cosentyx | Mayzent | Vijoice | Enoxaparin So | |
| | Emgality | Trijardy | | Desferal | Mekinist | Votrient | Flomax | |
| | Erbitux | Trulicity | | Diovan | Myfortic | Xolair | Insulin Glargin | |
| | Forteo | Verzenio | | Diovan HCT | Neoral | Zolgensma | Ibesarta | |
| | Humalog | Zepbound | | Egaten | Netspot | Zortress | Key | |
| | Humatrope | | | Entresto | Piqray | Zykadia | s | |
| | Humulin | | | Exforge | Pluvicto | | Leflunomide | |
| | Insulin Lispro | | | Exforge HCT | Promacta | | Lovenox | |
| | Jardiance | | | Exjade | Rydapt | | Multaq | |
| | Jaypirca | | | Fabhalta | Sandimmune | | Plavix | |
| | Jentadueto | | | Femara | Sandostatin | | Priftin | |
| | Kisunla | | | Gilenya | Scemblix | | Primaquine | |
| | Lyumjev | | | Gleevec | Simulect | | Renvela | |

*BMS, J&J, and Sanofi drugs not listed here still managed in 340B ESP, based on respective Contract Pharmacy Policies

Based on the previous proposals, how would these rebate models work?

# How Would Entities Get Their Rebates Through Beacon?

Covered entities buy the relevant drugs at a commercial/WAC price

→

Covered entities submit **purchase data** to Beacon

- Beacon determines if purchases are 340B eligible

→

Covered entities submit **utilization claims data** to Beacon

- All claims - medical, entity-owned pharmacy, contract pharmacy
- Required to submit data within X days (e.g., 45 days for J&J, 30 days for Sanofi)

↓

Hospital CEs submit healthcare **encounter data** to Beacon

→

Once approved **utilizations reach a full package size**, Beacon will start the process of sending the rebate/credit to the covered entity

- Funds go directly to the CE bank account
- "We anticipate that this process will take 7-10 days"
  – Beacon Webinar on 8/28/2024

# Do I Still Need to Submit Data to ESP?

- For the specific manufacturers (e.g., J&J, Sanofi) and those specifically impacted drugs, the CEs will **submit rebate claim data through Beacon**.
- **Designation will still happen in the ESP platform**.
- If a rebate policy only applies to certain types of covered entities, then other CE types will continue to use ESP.
- If a rebate policy only applies to certain drugs, then CEs will **continue to use ESP for other drugs from that manufacturer**, if applicable (e.g., DSH hospitals would continue to use ESP for other J&J drugs besides STELARA and XARELTO)

Source: J&J Notice to 340B End Customers Regarding Purchases of STELARA and XARELTO, August 23, 2024

# What About the Truzo Platform?

Truzo is the rebate model management platform provided by Kalderos

Eli Lilly is the only manufacturer that has announced its intended use of the platform at this point

All knowledge of the platform at this point is from the description of the process in Eli Lilly's lawsuit and the limited materials on Kalderos' website

# How Does the Rebate Process Work Through Truzo?

Entity purchases drug through wholesaler at WAC

→

Entity dispenses or administers drug to patient of the covered entity

→

Entity submits claims data to Truzo for 340B eligible utilizations within a “reasonable” time from date of service

↓

**Truzo confirms 340B eligibility based on:**

a. Entity active in OPAIS
b. CRx registered on OPAIS and conforms with manufacturer policy (designations move from 340B ESP to Truzo)
c. Claim is not a duplicate
d. For RRC, SCH, CAH, or CAH, claim is not for an orphan drug
e. Claim is submitted within a “reasonable” time from date of service

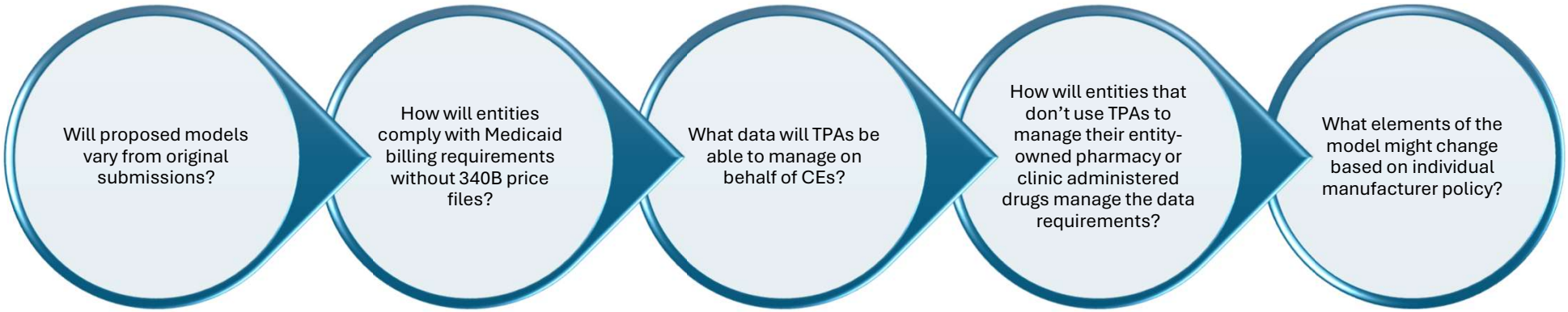
→

Truzo evaluates claims within 10 business days of submission and issues credit to entity (WAC - 340B) through weekly cash replenishments (at dispensed unit)

→

Denied credit payments may be disputed through the Truzo platform, which may require additional documentation

# Remaining Unknowns



# NEED MORE INFORMATION?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