



Understanding 340B— What You Need to Know

For AR HFMA

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Agenda

340B Basics

Timeline of 340B

340B in 2026

Offensive financial strategies

Q&A and Closing



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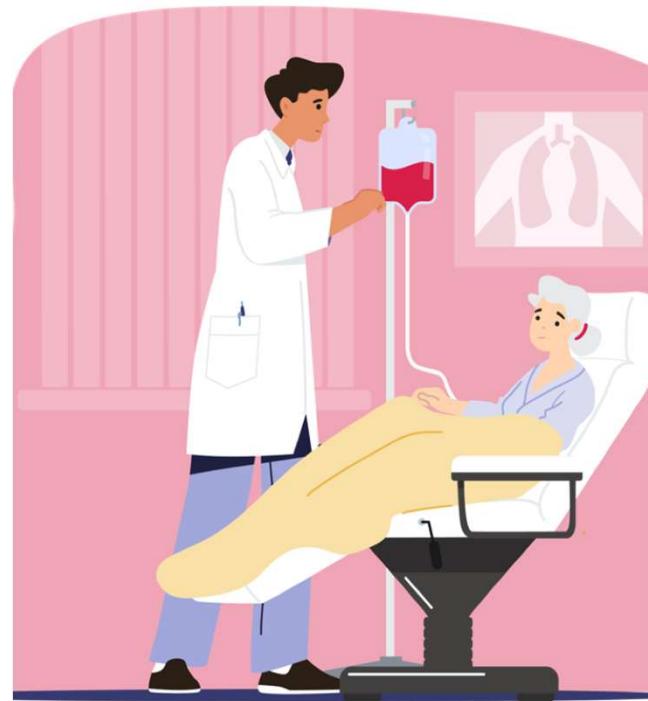


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340B Basics

- Purpose
 - How the program works
 - How facilities leverage their program benefits
- Roadblocks
 - Drug Manufacturers
- How 2025 ended for 340B



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340B Timeline

- 1992 340B Introduced
- 1994 OPA Guidance on Clinics
- 1996 Contract Pharmacy Process, Mfg Audit Guidelines & Patient Definition
- 2010 Multiple Contract Pharmacies Allowed; ACA becomes Law; Eligibility Expanded
- 2011 Orphan Drug Exclusion
- 2012 HRSA Audits begin
- 2013 GPO Prohibition
- 2014 Orphan Drug Legal Challenges
- 2015 Omnibus Guidance Draft Released
- 2017 Omnibus Guidance & Civil Penalties Withdrawn
- 2018 Medicare Part B Cuts
- 2019 Civil Monetary Penalties
- 2020 Alternative Dispute Resolution
- **2021-2023 Pharma Manufacturer Restrictions and Multiple Lawsuits/Court Cases**
- **2024 Lifted restrictions; ongoing variations**
- **2025 Rebates! MFP! IRA! REBATES!**
- **2026 Rebate pause!**



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2026 changes to 340B

- Inflation Reduction Act (IRA)
- 340B Rebate Pilot Program



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Inflation Reduction Act (IRA)

- Federal Legislation passed 2022.
- Affects Medicare Part D starting 2026 & Medicare Part B in 2028.
- Introduction of Maximum Fair Price (MFP) for selected products.
- There are 10 initial products for 2026 and beginning in 2027 and subsequent years additional products will be added to the list annually.
- 2026 products include Eliquis, Enbrel, Entresto, Farxiga, Imbruvica, Januvia, Jardiance, Novolog & Fiasp products, Stelara, and Xarelto.
- 2027 products include Ozempic/Rybelsus/Wegovy, Trelegy Ellipta, Xando, Pomalyst, Ofev, Ibrance, Linzess, Calquence, Austedo/Austedo XR, Breo Ellipta, Xifaxan, Vraylar, Tradjenta, Janumet/Janumet XR, and Otezla/Otezla XR.



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Covered Entity Impact with IRA

- Reduced 340B savings:
 - Some contract pharmacies are carvings these products out of the program due to the operational complexity.
 - Reimbursement from Medicare Part D payors at MFP is significantly less than what covered entities would have received prior to January 1, 2026.
- Operational Complexity:
 - Contract pharmacy relationships where these products are not carved out.
 - Covered entities with retail owned pharmacies must navigate the Medicare Transaction Facilitator and MFP rebate payment.
- Product list continues to grow each year and Medicare Part B being added in 2028.
- Manufacturers enacting pricing strategies:
 - Many 2026 IRA products saw significant WAC pricing decreases January 1, which will impact 340B price in July.
 - 2027 manufacturer for Xifaxan (Bausch) left the 340B program without formal announcement in 2025.



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How does IRA relate to Rebate Model?

- Some say the rebate model can be considered an unintentional outcome of the IRA due to the duplicate discount provision.
 - Pilot rebate model only includes IRA listed drugs.
- Important to note that there are two unique differences:
 - The IRA MFP applies to the products regardless of pilot rebate model.
 - The IRA MFP applies only to Medicare Part D payors (& Part B starting 2028); the rebate model will apply to all payors and all universes of administration (including medical).



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340B Rebate Model Timeline

- August 2024 covered entities received notice from J&J that a rebate model would begin (without HRSA approval) fall 2025.
- Fall 2024 HRSA sent a letter to J&J stating if they implemented a rebate model they would be removed from the Medicaid Drug Rebate Program (MDRP) entirely and J&J did not implement model.
- November 2024 Sanofi sent a rebate model notice to covered entities for all Sanofi products that would begin (without HRSA approval) early 2025.
- Late 2024 HRSA sent a letter to Sanofi stating if they implemented a rebate model they would be removed from the Medicaid Drug Rebate Program (MDRP) entirely and Sanofi did not implement model.
- 2024/2025 Manufacturers filed lawsuit against HRSA for implementation of a rebate model.
- May 2025 Judge ruled that HRSA does have authority to provide and implement rebate models and needed to provide guidance within a certain time frame.
- August 2025 rebate models were approved by HRSA, allowing for public comment and stating manufacturer applications to participate were due by September 15, 2025.
- October 30th, 2025, HRSA approved rebate model applications for 8 manufacturers and 9 products (2026 IRA products) with an original January 1, 2026, start date.
- November 14th, 2025, HRSA approved the rebate pilot program for the last manufacturer, Novartis, with an April 1, 2026, start date.
- December 2025 American Hospital Association filed lawsuit for a restraining order preventing implementation of rebate models on January 1, 2026.
- December 29, 2025, Judge ruled that the restraining order was granted and rebate models would not begin on January 1, 2026.
- December 2025 / January 2026 the ruling was appealed to higher courts and as of January 7, 2026, the higher court upheld the restraining order at this time, and further hearings are scheduled.



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What would 340B look like under a rebate model?

- Products that were not approved as part of the rebate pilot program would with 340B like they do today.
- For the rebate approved products, there would be no up-front 340B discount on the purchasing of this product and covered entities would have to follow a process to recoup that discount from the manufacturers should they choose to participate.
 - 340B covered entity will replenish the 340B product at WAC (standard retail) pricing.
 - Covered entity submits to claim information to a platform of the manufacturers choice (Beacon) and the claim information is validated against purchase data the manufacturer receives as normal process through the wholesaler.
 - If the claim is validated, and manufacturer agree, the rebate is then remitted within 10 days to the covered entity.
 - Covered entity would need a plan for reconciliation of payments and disputes should rebates be denied.
- If a covered entity did not want to submit claims data, they would lose out 340B savings associated with these products.



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Covered Entity Impact with Rebate Model

- Cash flow strain:
 - Timing of payments from contract pharmacy and rebate.
 - Timing of payment of wholesaler invoices.
- Operational complexity:
 - Policy & Procedure updates
 - Submission of claims data to multiple platforms
- Administrative burden:
 - Additional time & education on 340B oversight- standard program monitoring, rebate monitoring.
- Reduced 340B savings realization.
- Patient Assistance Program(s) disruption:
 - Examples: cash, copay assistance, additional services



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Covered Entity Strategies

- Make sure you have a working relationship with your TPA and understand how they are strategizing with you.
- Review your vendor contracts on a regular basis:
 - Contract Pharmacy Network
 - Wholesaler contracts
- The IRA pricing for 2027 products was published November 2025, and analysis can be completed now for potential financial impact.
- Make data driven decisions.
- While the rebate model is on pause, make sure your covered entity and partners are prepared should it move forward.
- Create internal alignment for 340B strategy across all teams.
 - Pharmacy
 - Clinic staff
 - C-Suite



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Resource Links

CMS 2026 IRA Fact Sheet: [Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026](#)

CMS 2027 IRA Fact Sheet: [Fact Sheet: Medicare Drug Price Negotiation Program 2027](#)

HRSA 340B Rebate Model Pilot: <https://www.hrsa.gov/opa/340b-model-pilot-program>

HRSA 340B Program Home Page: [340B Drug Pricing Program | HRSA](#)

Apexus Prime Vendor 340B Resources: [340B Prime Vendor Program | 340B Drug Pricing Program Partner](#)



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Definitions:

Inflation Reduction Act (IRA): Federal legislation passed in 2022 with many goals one of those being lowering prescription drug pricing. The legislation introduced Medicare Drug Price Negotiation program and Maximum Fair Price (MFP) point.

Maximum Fair Price (MFP): A negotiated price point between CMS and manufacturers for selected products. It is the maximum reimbursement for products that have been selected for participation. Maximum Fair Price point applies to Medicare Part D claims in 2026 and Medicare Part D and B in 2028.

Medicare Transaction Facilitator (MTF): Platform that plays an essential role in implementation of the Medicare Drug Price Negotiation program. It facilitates the data exchange between dispensing entities and PBMS to the federal government to support payment workflows of MFP associated rebates.

340B Price: Average Manufacturer Price (AMP) – Unit Rebate Amount (URA). The 340B price allows for significantly reduced price for outpatient drugs for eligible covered entities and can result in savings on average between 20 and 50% off retail or wholesaler prices.

340B Rebate Model: A pilot program that consist of a selected group of drugs, which are the products selected for the 2026 IRA MFP implementation. The program is HRSA approved and removed up front discounts on the 340B price for these products and makes it a rebate system where covered entities must submit data after an applicable dispense and purchase has been made. The rebate will be the difference between the listed Wholesale Acquisition Cost (WAC) and 340B price.



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Thank you for attending.

Questions?



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