Managing Manufacturer 340B Policies & What Comes Next

Spenser Turnage, 340B ACE
Director, Manufacturer Policy Support
FQHC 340B Compliance

OHIO PHARMACISTS ASSOCIATION

340B Midwest Regional Conference & Expo
August 24 & 25, 2026

DISCLOSURE STATEMENT

- Spenser Turnage has no relevant financial relationship(s) with ineligible companies to disclose.

- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

LEARNING OBJECTIVES

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

- Review recent changes in contract/in-house pharmacy landscapes and the types of restrictions imposed by manufacturers
- Illustrate the steps involved to restore 340B access through data sharing & designating contract pharmacies to health center associated sites
- Discuss what we know so far regarding the impending HRSA Rebate Model Pilot

Changes in Manufacturer 340B Contract Pharmacy Policy

- In-house claims collection policies have been the most disruptive new change of 2026
- Claims must be submitted for entity-owned pharmacies as well as for clinic-administered drugs
- How these policies can be enforced has been inconsistent
  - Eli Lilly shut off pricing to ~50 hospitals
  - Novo Nordisk is threatening to shut off pricing for the entire CP portfolio if EOP claims aren't submitted
  - Additionally, the concept of a "submission balance" has been replaced by a new methodology referred to as "purchase validations"

New Platform - Truzo

- Entirely new platform for contract pharmacy eligibility management
- Works very differently from ESP, so there are few lessons learned from one platform that will transfer
- NPIs, DEAs & HINs must be manually entered for every designation
- Submission files must be separated by 340B ID
- For at least one manufacturer, designations are required even though grantees can have access to an unlimited number of CPs with claim submissions

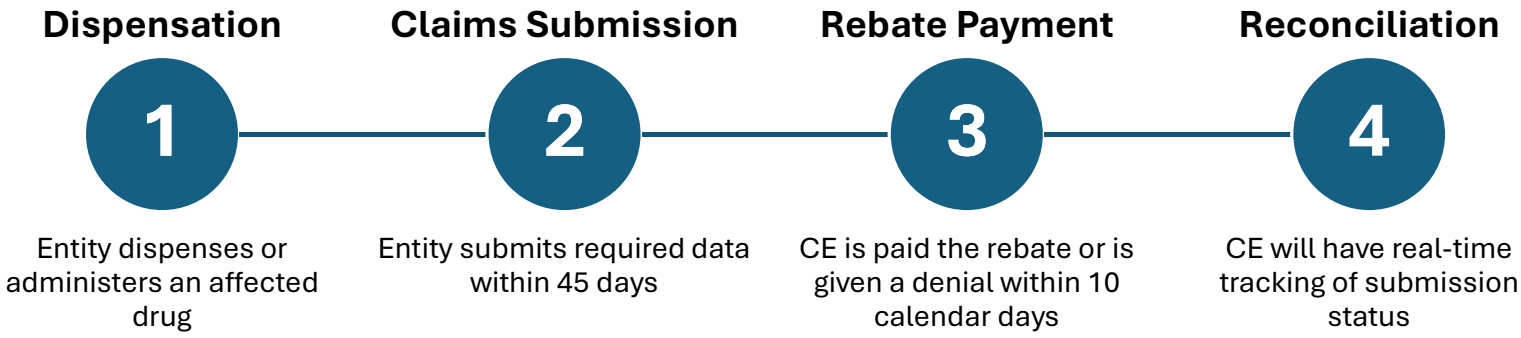
Restoring 340B Access

- Make designations where allowed and be prepared to submit claims where required
  - In-house retail and administered claims may be required
- Some manufacturers still allow unlimited CP access with claims submission
  - New risks with this approach based on certain manufacturers' policies
- Identifiers must be managed in both platforms (DEA, NPI & HIN)
- Assume all claims data must be submitted within 45 days of dispense
  - Some evidence that a window on replenishment is being enforced as well
  - Could pose problems for physical inventory models

HRSA 340B Rebate Model

HRSA 340B Rebate Model

- Rebate Payments within 10 Calendar Days
- Unit-Level Rebate Payments
- 15-Day Grace Period for Unreplenished Accumulations (Up to 2 Packages)
- Incomplete Data: The 10-Day Clock will Restart Once the Complete Data is Submitted



HRSA 340B Rebate Model – Data Requirements

Pharmacy Claims Data Fields
1.Date of Service 2.Date Prescribed 3.Rx Number 4.Fill Number 5.NDC-11 6.Quantity Dispensed 7.Prescriber ID 8.Service Provider ID 9.340B ID 10.Rx BIN 11.Rx PCN ~~12.Group Number ID (optional)~~

Medical Claims Data Fields
1.Date of Service 2.Claim Line Number 3.Claim Number 4.Unit of Measure 5.NDC-11 6.Quantity 7.Rendering Physician ID 8.Service Provider ID 9.340B ID 10.Health Plan Name 11.Health Plan ID 12.Health Plan ID Qualifier (optional) ~~13.HCPCS Code (optional)~~ ~~14.HCPCS Modifiers (up to 4) (optional)~~

HRSA 340B Rebate Model – Plan Requirements

1. Identify the chosen platform (costs must be borne by manufacturer)
2. Must give 90 days notice to CEs and other stakeholders
3. Purchase mechanism must stay the same (340B wholesaler accounts with WAC prices)
4. Technical assistance/customer service, allowing a CE to engage the manufacturer in good faith
5. IT data security & data collection is limited to the approved data fields
6. IT Platform and Manufacturer must have PHI & PII security in place
7. Manufacturers must let HRSA know if the plan will provide exceptions that don't apply to all CEs

HRSA 340B Rebate Model – Denials & Disputes

- Manufacturers required to document and report denied claims, including:
  - Basis for each denial
  - Status of any associated dispute
- HRSA will monitor denial patterns
  - Manufacturers that have a pattern of non-compliance may be removed from the pilot
- The Pilot will provide a pathway to challenge denied claims, including timelines for review and response
  - Information will be public "within 30 calendar days of the Pilot's effective date"
  - Could be as late as January 31, 2027
- If the dispute remains unresolved, covered entities must use the Administrative Dispute Resolution Process (ADR)
- Claims cannot be denied for "diversion or Medicaid duplicate discounts pursuant to section 340B(a)(5)(A) and (B) of the Public Health Service Act"
- Rebates cannot be denied based on purchase data (lack of WAC purchases)

HRSA 340B Rebate Model – Timeline & Affected Drugs

August 3, 2026 — Federal Register Notice

August 24, 2026 — Manufacturers' Plans Due

September 24, 2026 — Approved Plans Released

January 1, 2027 — Pilot Start

April 30, 2028 — First Year Evaluation Due

	Manufacturer	Drug
1	AbbVie	Imbruvica Linzess Vraylar
2	Amgen	Enbrel Otezla; Otezla XR
3	Astellas	Xtandi
4	AstraZeneca	Calquence Farxiga
5	BI	Jardiance Ofev Tradjenta
6	BMS	Eliquis Pomalyst
7	GSK	Breo Ellipta Trelegy Ellipta
8	Merck	Janumet; Janumet XR Januvia
9	Novo Nordisk	Ozempic; Rybelsus; Wegovy
10	Pfizer	Ibrance
11	Teva	Austedo; Austedo Xr

NEED MORE INFORMATION?

- Spenser Turnage, 340B ACE
- spenser@fqhc340b.com