



Let's Think Together.®

**340B Rebate Models:
Operational Considerations for
Covered Entities**

Today's Agenda

- Overview of how a rebate/credit model works
- Wholesaler Price File considerations
- Virtual Replenishment considerations
- Split Bill considerations

Note: Some graphics courtesy of PRESENTERMEDIA



A note about operational unknowns



- Each of the drug manufacturers have designed slightly different elements of their rebate/credit policies.
- The drugmakers have proposed using rebate models operated by one of two companies – a unit of Second Sight Solutions (Second Sight) and Kalderos.
- This presentation discusses operational information about the vendors' platforms that is publicly available.

How does the basic rebate model work?

- Covered entities **buy** the relevant drugs at a **commercial/WAC price**
- Covered entities submit **purchase data** to rebate vendor
 - Rebate vendor determines if your purchases are 340B eligible
- Covered entities submit **utilization claims data** to rebate vendor
 - 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)
- Once approved **utilizations reach a full package size**, rebate vendor 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” –Second Sight Solutions Webinar on 8/28/2024

Sanofi nuances

- Covered entities **buy** the relevant drugs at a **commercial/WAC price**
- Covered entities submit **purchase data** to rebate vendor
 - Beacon determines if your purchases are 340B eligible
- Covered entities submit **utilization claims data** to rebate vendor
 - 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 rebate vendor ← Sanofi
- Once approved **utilizations reach a full package size**, rebate vendor 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” –Second Sight Solutions Webinar on 8/28/2024

Sanofi presumptive credit for CH only

Kalderos Nuance

- With the Kalderos rebate platform, which Eli Lilly has said it will use to implement its rebate model, would provide credits/rebates on a unit-by-unit basis

Source: (2024, November 14). ELI LILLY AND COMPANY v. XAVIER BECERRA.
Case 1:24-cv-03220, Document 1

Which purchases are eligible?

- Purchased by a CE
- Purchased after the adoption of the rebate model
- Shipped to:
 - registered CE address of the parent or child site, or
 - An OPAIS registered Shipping Address for the CE, or
 - A contract pharmacy that is **eligible** under the manufacturer's policy

Which utilizations are eligible?

- Used at an eligible location of the CE, or at a contract pharmacy **eligible** under a MFR's policy.
- CE must meet the manufacturer's Orphan Drug policy.
- Dispensed/administered **after** the purchase date.
- Claims submitted within the manufacturer's required time frame (e.g., 30 days, 45 days)
- Fine print: Manufacturers might introduce "other eligibility criteria"

Sources:

- (2024, August 28). Introduction to Beacon [Online Webinar]. Beacon Channel Management
- [Beacon Support Webinars]. (2024, August). Credit Model Overview [Video]. Beacon Support Center.

Some utilizations will require aggregating

- The rebate vendor will assume an upload is a duplicate if the following fields are the same:
 - Product, dispense site, date of dispense, claim ID
- For that reason, the rebate vendor advised that **CEs will need to aggregate some types dispenses**, prior to uploading to the platform.
- Waste example:
 - 0.7 administered, 0.3 wasted
 - If submitted as two pieces, the rebate vendor will not accept both
 - CE must aggregate the two usages (1.0) *before* uploading to rebate vendor

Source: (2024, December 18). FAQ Session [Online Webinar]. Beacon Channel Management

Contract Pharmacy Consideration: Price Files

- Your **Wholesaler Price Files** on your 340B account may now show a WAC price for rebate model drugs. Consider the effects on TPA processes that are built on what used to be a 340B price from the price file.
- **“Winners Only” model at contract pharmacy:** Typically depends on 340B pricing from your wholesaler price files.
- **States that require carve-in and billing Medicaid at Actual Acquisition Cost (AAC):** How will you know the AAC to use for billing?
- **Margin-based Contract Pharmacy Dispensing Fees:** Typically depends on 340B pricing from your wholesaler price files
 - E.g., [Plan reimbursement] minus [340B drug cost] = Margin
 - X% Margin goes to the contract pharmacy as a dispensing fee

How will this impact my virtual replenishment?

Let's consider a couple of elements of one rebate platform:

- a) Purchases will be made at WAC price
- b) Only purchases made on/after the start date are eligible for submission

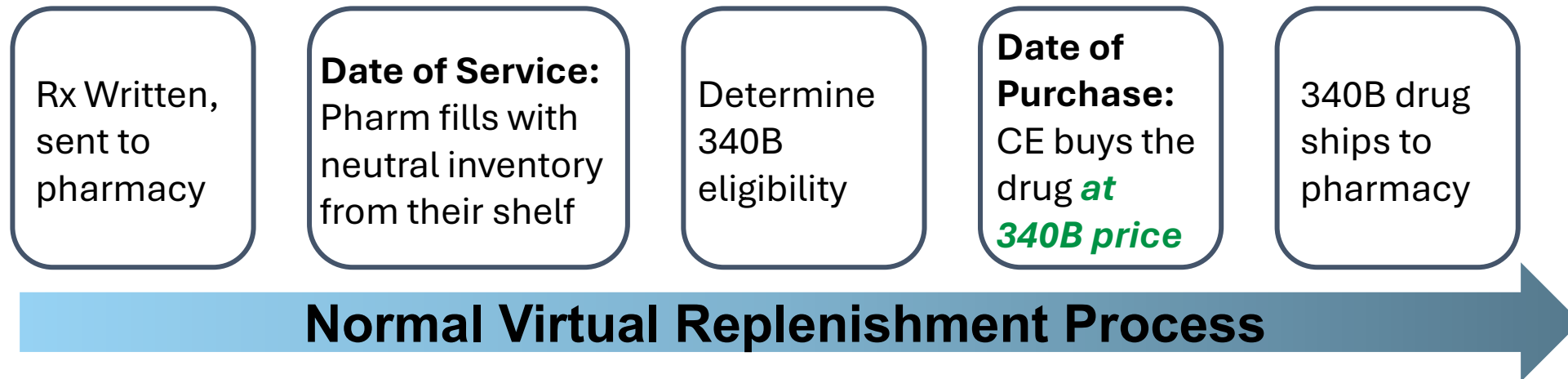
“What is an eligible purchase: Purchase occurred after manufacturer’s adoption of credit model.” Source: (2024, August 28). Introduction to Beacon [Online Webinar]. Beacon Channel Management.

- c) Eligible claims must have a date of service (DOS) **after** the date of the purchase

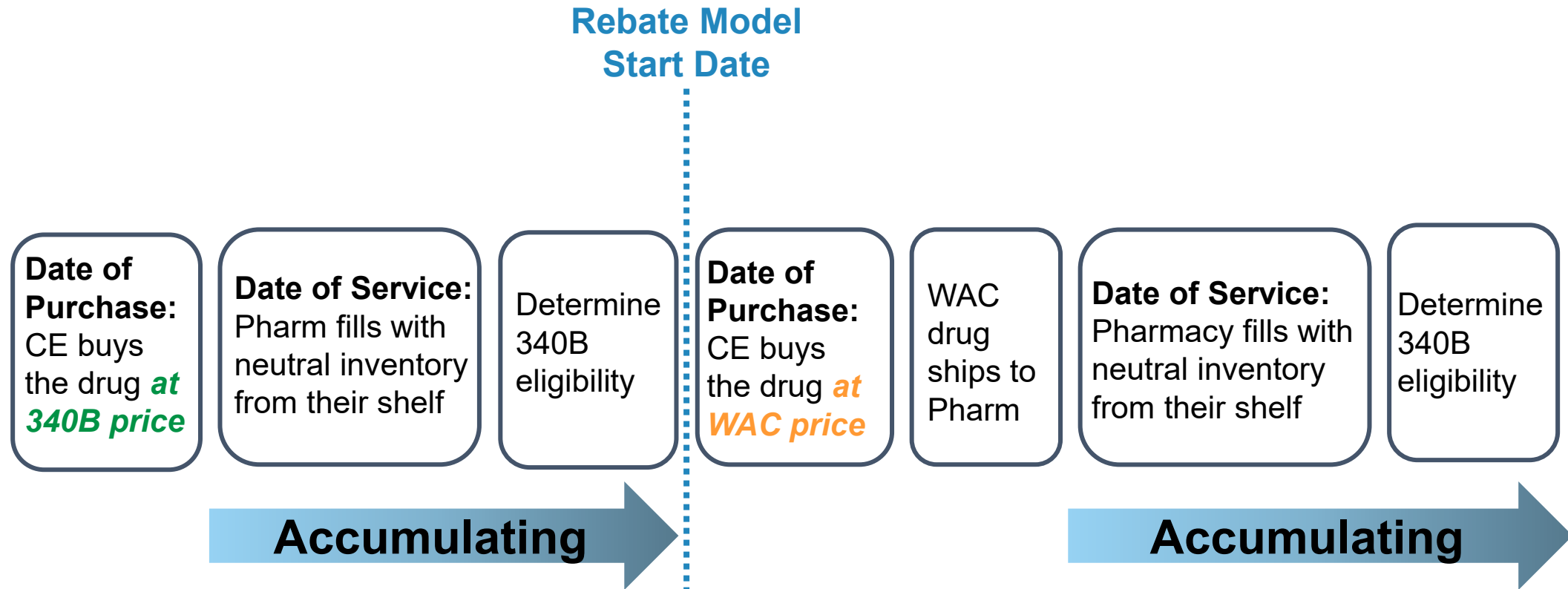
How will this impact my virtual replenishment?

At your contract pharmacies, or entity-owned pharmacy settings if virtual replenishment is used

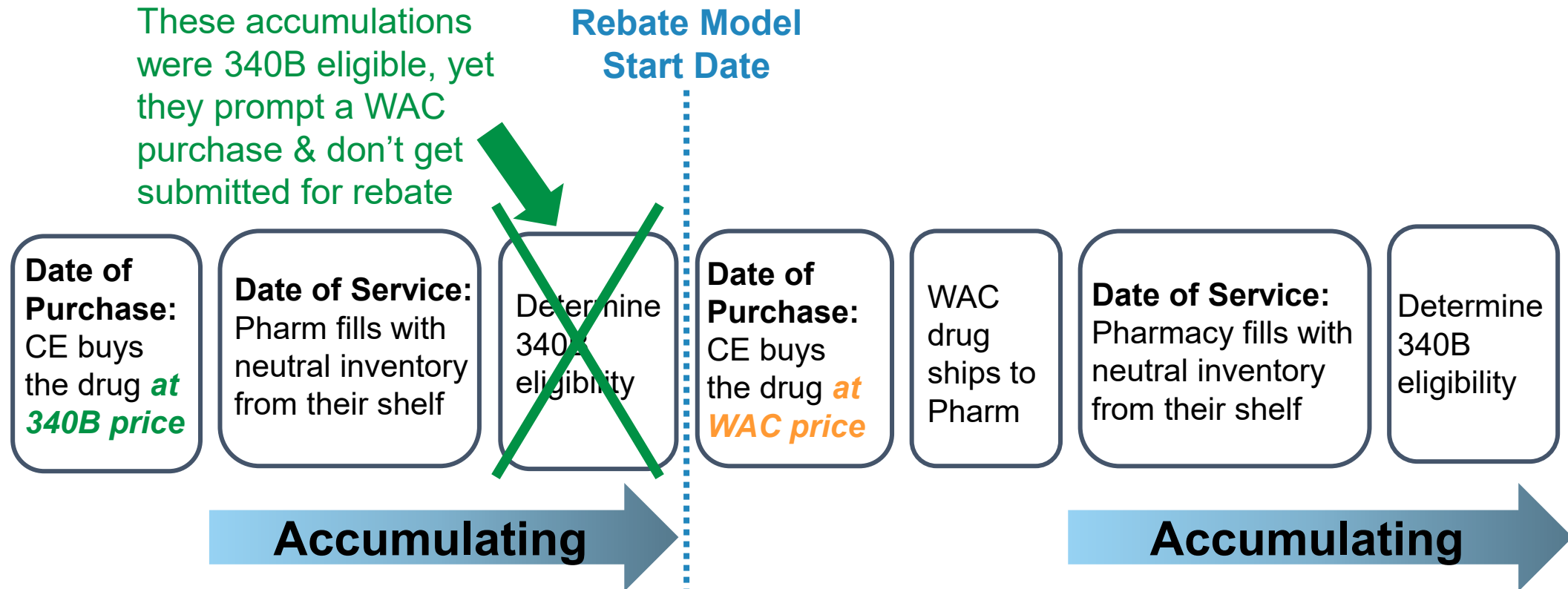
How does pharmacy virtual replenishment **normally** work?



How will this impact my virtual replenishment?



How will this impact my virtual replenishment?



- No clear process to get a 340B discount for the claims that accumulated between the time of the last 340B purchase and the start of the rebate model.
- During a webinar on 12/18/2024, rebate vendor representatives verbally mentioned that individual manufacturers could **choose** whether to accept a limited number of packages from before the start date.

What does this mean for my Split Bill accumulations?

- ***Depending on your wholesaler:*** Under the rebate model, the price available on your 340B purchasing account might **be a WAC price.**
- When it comes time to purchase, your system is likely to look for the cheapest pricing *with* available accumulations.
- Consider: what will happen to your 340B accumulations after exhausting GPO if there is a WAC price on your 340B purchasing account?
 - Once you receive your 340B discount via a rebate/credit after the fact, you may need to go into the accumulator and manually adjust the 340B accumulations.



Would I have still need to submit data to ESP?

- Under the known manufacturer's (e.g., J&J, Sanofi, etc.) rebate plans, their contract pharmacy restrictions remain in place.
- On the respective start date, covered entities will no longer submit claims data through ESP. Instead, they will **submit the rebate claim data through rebate vendor's platform.**
- Designation will still happen in the ESP platform.
- Other types of covered entities continue to use ESP, if the rebate model doesn't apply to their CE type. CEs could need to continue using ESP for other drugs that are not part of the rebate model.

Sources:

- J&J Notice to 340B End Customers Regarding Purchases of STELARA and XARELTO, August 23, 2024
- Source: Sanofi 340B Integrity Initiative Update, dated November 22, 2024. <https://beaconchannelmanagement.com/pages/resources>



Driffin Tucker

Let's Think Together.®

Questions?

Hannah Rowell, 340B ACE

Senior 340B Consultant

hrowell@driffin-tucker.com

229-883-7878