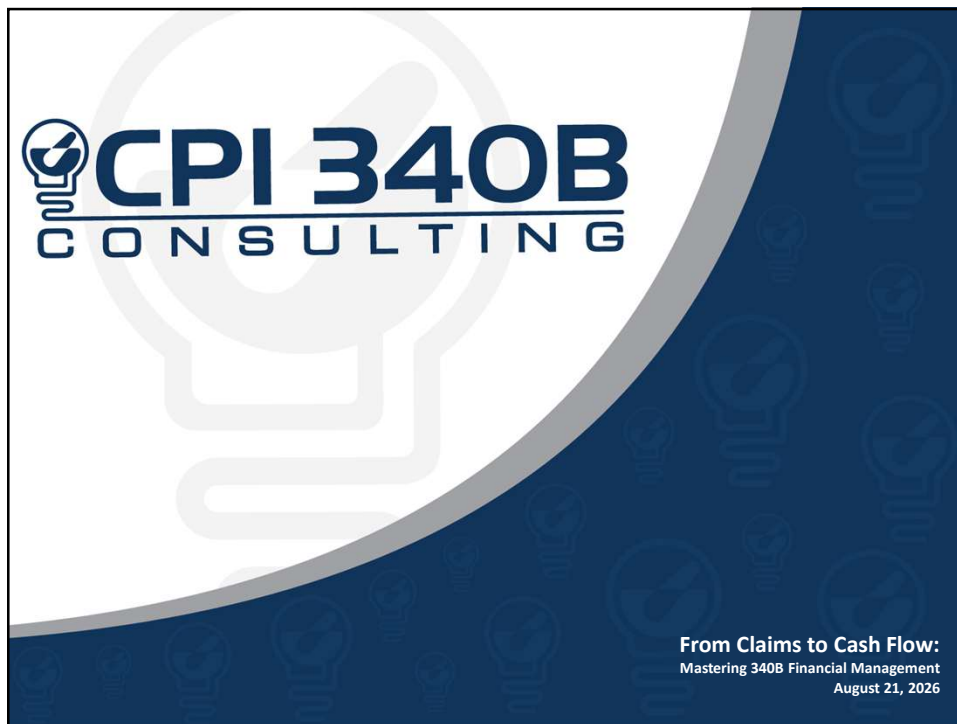




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Presenter Introductions



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Who Are We?



We are Contract Pharmacy Insight: CPI or CPI 340B



- We are headquartered in Missouri.
- We work on 340B programs, mostly in AR, MO, and surrounding states.
- We have accountants, pharmacists, nurses, attorneys, and IT/analytics staff.
- All we do is 340B.
- We measure our success in increased 340B savings for our clients.

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What We Do



We audit, operate, and optimize 340B programs for FQHCs and hospitals.



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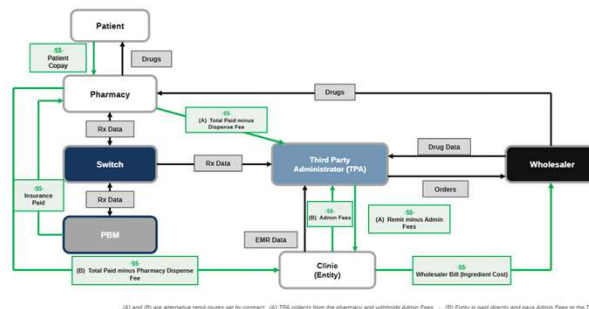


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Why Do We Exist?

As it turns out, 340B Contract Pharmacy is heavy.

Simplified 340B Transaction



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Conflicts of Interest to Disclose

- CPI's clients are Covered Entities participating in the 340B Drug Pricing Program.
- CPI operates with a fiduciary responsibility to those clients.
- CPI is not a public accounting firm. All recommendations regarding 340B accounting should be discussed with your financial statement auditor.

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Scope of Presentation



This presentation is focused on 340B in the **community pharmacy**, not 340B use in a clinic or hospital setting.



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Learning Objectives



Upon completion of this session, participants will be able to:

1. Describe the foundational principles of the 340B Drug Pricing Program, including its statutory intent and the distinction between retrospective and prospective 340B claims.
2. Identify the key stakeholders involved in a 340B program.
3. Trace the flow of funds within a 340B program.
4. Evaluate the financial implications of common accounting methods used to record 340B program activity.
5. Explain how recent federal policy developments — including the Medicare Drug Price Negotiation Program and the proposed 340B Rebate Pilot Program — intersect with the 340B program.
6. Summarize the current landscape of manufacturer-imposed 340B restrictions.

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SECTION 1

340B Foundations

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What is 340B?



- 340B is part of a Federal statute:
 - The “Veterans Health Care Act of 1992,” enacted section **340B** of the Public Health Service Act (PHSA)
 - “**Limitation on Prices of Drugs Purchased by Covered Entities**,” codified at 42 U.S.C. § 256b.
- Certain health systems (“Covered Entities”) are eligible to participate.
- 340B is **not** funded by the government; **it is funded by the drug manufacturers**. The manufacturers fund this program by providing their drugs at discounted, but statutorily-defined, prices.
- Created in part as an incentive to control drug prices, 340B has an “inflation penalty” where the 340B price goes down if a manufacturer raises a drug price faster than the rate of inflation.

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The Intent of 340B



“It is the sense of Congress that the purpose of the drug discount program under section 340B...is to stretch scarce Federal resources and **help safety net providers maintain, improve, and expand patient access to health care services** by requiring drug manufacturers, as a condition of participation in the Medicaid program...and the Medicare program..., **to provide discounts at the point of purchase to covered entities** that serve a disproportionate share of low-income and underserved patients or medically vulnerable patients.”

SUSTAIN 340B Act, Sec. 2, Sense of Congress, August 2026

“Put simply, the purpose of the 340B program was to **provide a means to make 340B entities profitable** in order for those 340B entities to ‘stretch scarce Federal resources as far as possible’.”

“HRSA’s restrictive definition of the term ‘patient’ limits the scope of the 340B program, limits the profitability of ‘covered entities,’ **and frustrates the goal of the 340B statute, which is to make ‘covered entities’ profitable...**”

US District Court, Genesis Health Care vs HHS/HRSA, November 2023

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Two Different Parts of 340B



1. The part that generates savings (makes \$) for a Covered Entity

- Also called “Retrospective”.
- This part happens in the background; claim is billed to patient insurance like normal.
- Patient copays are not affected.

2. The part that saves money for patients (Covered Entity makes \$0)

- Also called “Prospective”.
- This part is an active decision by the pharmacy at the time of dispensing; claim is billed to 340B-specific bin/pcn/group.
- Patient pay amount is typically the 340B drug cost plus a modest flat pharmacy dispense fee and admin fee.

For a given pharmacy claim, these two paths are mutually exclusive; it is one or the other, not both.

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How is Money Made (Savings Generated) by 340B?

- 340B Covered Entities (CEs) get a discount on drugs they purchase. CEs can buy expensive products at a discount – sometimes a very deep discount.
- The CE then sells their 340B drugs at **NORMAL RETAIL PRICE** to insurance companies through in-house pharmacies or their contract pharmacy network.
- The CE buys lower than retail and then sells at normal retail price to third-party payors. Expenses and pharmacy fees are paid out of this amount pursuant to a contract.

We are skipping some details, but that is it.

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SECTION 2

Key Stakeholders

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Parties Involved in 340B



- Covered Entity – the primary beneficiary of 340B program
 - Hospitals: CAH, Children's, DSH, RRC, SCH
 - Grantees: FQHCs, RWCs, STD Clinics
- CE Business Partners
 - Contract Pharmacies
 - Third Party Administrators (TPAs)
 - Consultants / Auditors
- HRSA – regulatory authority
 - OPAIS – 340B database
 - Apexus – Federal government's vendor tasked with providing 340B education
- Manufacturers – obligated to provide the 340B discount to CEs
 - AstraZeneca, BMS, Eli Lilly, GSK, Novo Nordisk, etc.
- Payers / PBMs – provide payment to pharmacies for prescription claims
 - AR BCBS / CVS Caremark, Centene / Express Scripts, United Healthcare / Medimpact
- Wholesalers
 - Cardinal, Cencora (Amerisource Bergen), McKesson, Morris & Dickson, etc.
- Other Involved Parties
 - Second Sight Solutions: 340B ESP, Beacon
 - Kalderos: Truza

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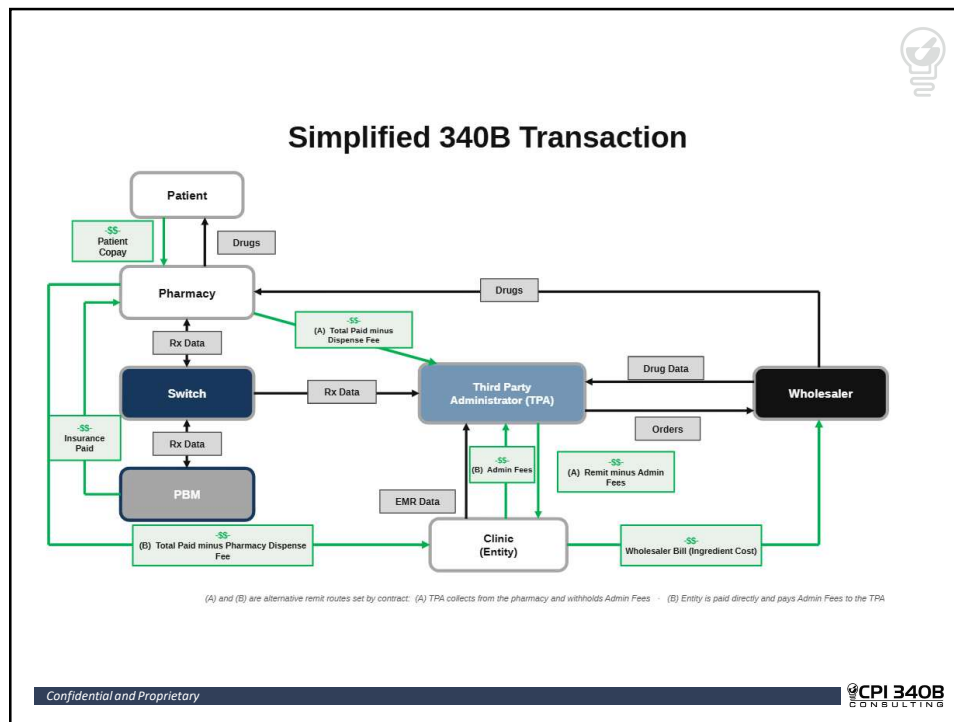
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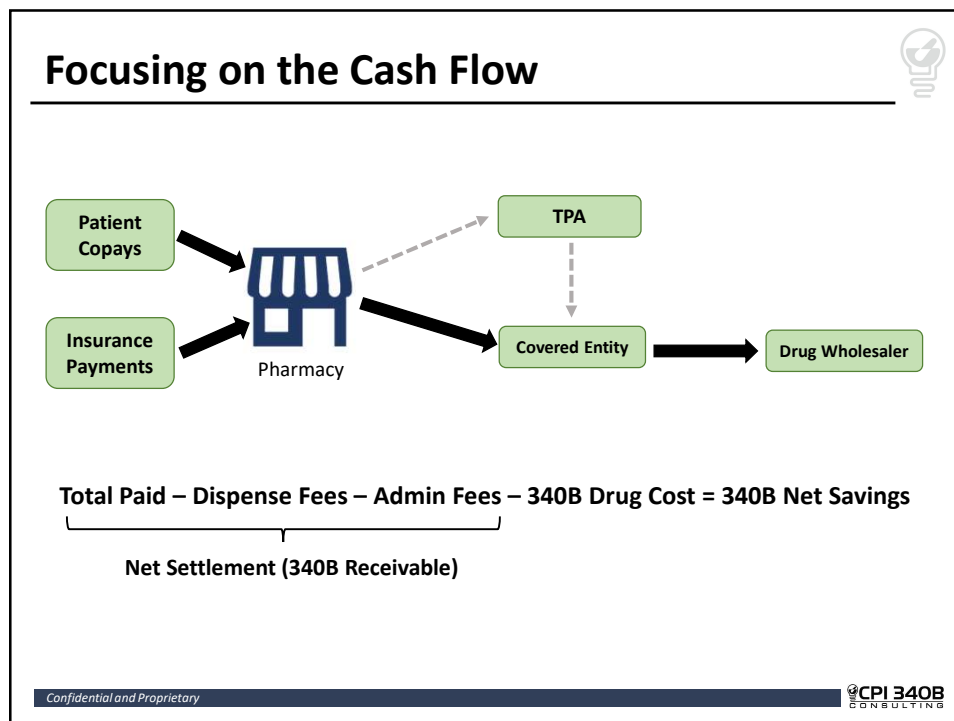
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Flow of Funds

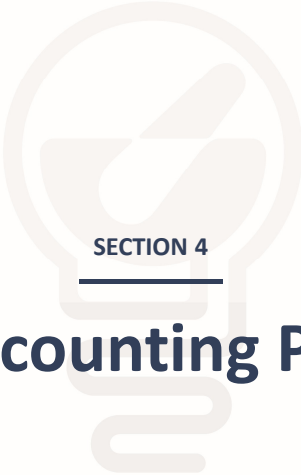
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SECTION 4

340B Accounting Practices

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340B Revenue Recognition

340B revenue recognition methods we commonly see in practice:

Cash	Accrual Claim invoice date	Accrual Pharmacy date of service
340B revenue is booked as deposits are received.	340B revenue is booked according to pharmacy invoices. - This is an accrual to claim processed date or the period of product replenishment, depending on the invoicing basis. NOTE: One 340B contract pharmacy network could include both types of invoicing logic, which could result in inconsistencies in accrual basis.	340B revenue is accrued to pharmacy date of service (date of dispense).

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Poll: 340B Revenue Recognition Method

Which 340B revenue recognition method are you using?

- A. Cash
- B. Accrual based on invoice date
- C. Accrual based on pharmacy date of service
- D. Not a 340B entity

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340B Revenue Recognition

340B revenue recognition methods we see in practice:

Cash	Accrual Claim invoice date	Accrual Pharmacy date of service
• Pros • Simple to operate • Ties exactly to the bank • No estimation required • Cons • Recognition lags economic event by weeks to months • Poor matching to economic event • Obscures how much is earned but uncollected • Poor way to run a business • Doesn't allow forecasting • Doesn't identify problems • Not financially sophisticated	• Pros • Accrues without estimation (the invoice is a hard document) • Smooths part of the lag • Ties cleanly to TPA invoice records • Cons • Lag between date of service and recognition • Revenue is limited to what is invoiced; potentially understates revenue due to lag in replenishment for pharmacies that have a replenishment-based invoicing configuration • Inconsistencies in invoicing logic for pharmacies could create higher risk of financial audit findings • Potentially obscures how much is earned but not invoiced	• Pros • Best matching (books to the period that earned it) • Earliest visibility • Consistency • Proven (from our experience) to be most defensible in a financial audit • Future-proof for a rebate world • Cons • Requires expertise and claim-level data discipline • Introduces a late-qualification tail to manage • Needs a stated policy for reversals and true-ups

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340B Revenue Recognition



Matching

The economic event is the dispense.



Auditability

The accrual ties to a claim-level dataset with defined attributes — DOS, adjudicated amounts, qualification flag — not a management estimate.



Decision-usefulness

Claim-level DOS accrual is what reveals actual trends for analysis.

Accrual

Pharmacy date of service

- Pros
 - Best matching (books to the period that earned it)
 - Earliest visibility
 - Consistency
 - Proven (from our experience) to be most defensible in a financial audit
 - Future-proof for a rebate world
- Cons
 - Requires expertise and claim-level data discipline
 - Introduces a late-qualification tail to manage
 - Needs a stated policy for reversals and true-ups

Why use the "approved claims" filter? We are not accruing on all dispenses and guessing a qualification rate — the population is defined and evidenced before a dollar is booked.

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340B Revenue Recognition



How do I build this process?



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340B Revenue Recognition



Example CPI Monthly Savings Statement:

	Jul-25	Aug-25	Sep-25	Oct-25	Nov-25	Dec-25	Jan-26	Feb-26	Mar-26	Apr-26	May-26	Jun-26	12 Months Total
Total Paid from all 340B Rx Claims	\$ 3,018,363	\$ 2,874,169	\$ 2,908,807	\$ 3,055,190	\$ 2,787,024	\$ 3,508,200	\$ 2,378,992	\$ 2,355,181	\$ 2,978,697	\$ 2,776,929	\$ 3,025,747	\$ 3,207,012	\$ 34,870,604
Estimated 340B Ingredient Cost	952,583	946,655	952,753	988,764	903,066	1,136,192	913,112	928,892	1,210,927	1,128,194	1,251,046	1,333,160	\$ 12,074,144
340B Gross Savings	2,065,780	1,927,514	1,956,054	2,066,426	1,883,958	2,372,008	1,465,880	1,426,289	1,767,770	1,648,735	1,774,701	1,873,852	\$ 22,796,460
Fees													
Third Party Administrator Fees	26,484	22,826	29,388	26,563	25,050	29,134	23,378	22,161	27,828	26,650	25,687	26,251	\$ 305,710
Savings Plan Administrator Fees	641	590	606	709	598	749	495	495	640	666	594	632	\$ 7,492
Switch Fees	2,552	2,483	2,515	2,831	2,518	3,308	2,553	2,901	3,214	3,028	3,012	2,997	\$ 35,912
Contract Pharmacy Dispense Fees	552,448	533,943	543,528	563,684	518,715	658,415	437,625	436,997	547,216	504,237	548,170	585,493	\$ 6,411,687
Pharmacy Remediation Fees*	533	1,841	-	1,065	933	608	901	726	562	1,423	877	1,478	\$ 10,947
PDM Remediation Fees*	2,814	896	12,277	2,704	10,295	15	850	63	5,585	9,209	1,102	6,202	\$ 52,012
Gateway Fees	1,300	1,300	1,300	1,300	1,300	1,500	1,500	1,500	1,500	1,200	1,200	1,200	\$ 16,500
Total Fees	587,173	563,976	589,702	599,055	559,619	693,729	487,301	484,843	586,566	546,412	581,641	629,253	\$ 6,858,260
Net 340B Savings	\$ 1,478,607	\$ 1,363,538	\$ 1,366,352	\$ 1,467,371	\$ 1,324,339	\$ 1,678,279	\$ 978,579	\$ 941,446	\$ 1,181,204	\$ 1,102,323	\$ 1,193,060	\$ 1,244,600	\$ 15,938,200

*Remediation Fees are on a current month cash basis because they are not easily accrued to the month of occurrence.

This report is a consolidated view of 340B Savings from approved claims for a 340B contract pharmacy network, accrued to the pharmacy date of service.

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340B Revenue Recognition



Example 340B Monthly Journal Entry:

	Jul-26
Total Paid from all 340B Rx Claims	\$ 3,317,579
Estimated 340B Ingredient Cost	1,462,847
340B Gross Savings	1,854,732
Fees	
Third Party Administrator Fees	22,537
Savings Plan Administrator Fees	310
Switch Fees	3,165
Contract Pharmacy Dispense Fees	601,625
Pharmacy Remediation Fees*	1,703
PDM Remediation Fees*	1,323
Gateway Fees	1,200
Total Fees	631,863
Net 340B Savings	\$ 1,222,869

Account	Debit	Credit
Administrative Fees	\$27,211	
Dispensing Fees	\$604,652	
340B Receivable	\$2,685,716	
Revenue		\$3,317,579

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340B Revenue Recognition



Common Question:



Can I book Total Paid as revenue since my organization will never receive the full Total Paid amount?

The principal/agent judgment: the entity purchases the inventory and bears the inventory risk – supporting principal for the drug, with the pharmacy dispensing and collecting as agent.

Document the judgment; run fees through expense.

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340B Revenue Recognition



Common Questions:



What about reversals?

Claims can be subsequently reversed due to a variety of factors (to maintain 340B compliance, to accommodate pharmacy inventory concerns, etc.)



What about historical uplift?

Claims can be captured after the close of the month. Examples include referrals due to additional documentation required for approval, historical reprocessing following configuration optimization, etc.

In either case, historical differences must be accounted for.

.....but how?

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340B Revenue Recognition



Some options we see in practice:

- Ignore it (not recommended)
 - Could cause material misstatements.
- Combine historical changes with current month figures.
 - Takes away from the benefit of accruing based on date of service.
 - Inflates months based on processing activity, which interferes with accurate trend analysis.
- Restate prior months
 - Not very feasible
 - Materiality of amounts typically doesn't constitute restatement
 - Historical fluctuations are not due to 'errors'; they are more like changes in estimates, which typically receive prospective treatment.
- Create subaccounts for each account used in standard monthly entry.
 - This allows tracking of historical activity but maintains DOS accrual

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340B Revenue Recognition



One option: Track historical changes in subaccounts.

340B Contract Pharmacy Savings Statement	Aug-25	Sep-25	Oct-25	Nov-25	Dec-25	Jan-26	Feb-26	Mar-26	Apr-26	May-26	Jun-26	Jul-26	Net Historical Change
Total Paid from all 340B Rx Claims	\$ 2,874,163	\$ 2,908,807	\$ 3,055,190	\$ 2,787,924	\$ 3,508,223	\$ 2,578,392	\$ 2,353,181	\$ 2,984,236	\$ 2,796,730	\$ 3,045,236	\$ 3,423,872	\$ 3,317,579	\$ 291,761
Estimated 340B Ingredient Cost	946,655	952,753	988,764	901,066	1,136,596	913,112	928,892	1,214,950	1,144,586	1,267,505	1,458,889	1,462,847	162,051
340B Gross Savings	1,927,507	1,956,054	2,066,426	1,886,857	2,371,627	1,665,280	1,424,289	1,769,286	1,652,144	1,777,731	1,964,983	1,854,732	129,710
Fees													
Third Party Administrator Fees	22,926	23,398	26,563	25,050	29,137	23,378	22,181	28,789	26,852	25,903	27,363	22,537	2,474
Savings Plan Administrator Fees	590	686	709	598	749	493	495	640	666	594	622	310	146
Switch Fees	2,481	2,515	2,831	2,518	3,308	2,553	2,901	3,214	3,018	3,012	2,997	3,165	146
Contract Pharmacy Dispense Fees	533,341	543,526	563,684	518,715	656,430	437,625	436,997	547,656	505,572	550,471	618,394	601,625	28,919
Pharmacy Remediation Fees*	1,841	-	1,085	933	608	901	726	562	1,423	877	1,478	1,703	28,919
PDM Remediation Fees*	896	12,277	2,704	10,295	15	850	63	5,585	9,209	1,102	6,227	1,323	28
Gateway Fees	1,300	1,300	1,500	1,500	1,500	1,500	1,500	1,500	1,200	1,200	1,200	1,200	28
Total Fees	563,976	583,702	599,055	559,610	691,747	467,301	464,843	587,927	547,950	583,159	658,821	631,863	28,002
Net 340B Savings	\$ 1,363,532	\$ 1,372,352	\$ 1,467,371	\$ 1,327,246	\$ 1,679,880	\$ 997,979	\$ 959,447	\$ 1,181,360	\$ 1,104,194	\$ 1,194,572	\$ 1,306,162	\$ 1,222,869	\$ 129,710

Account	Debit	Credit
Administrative Fees - prior-period subaccount	\$2,464	
Dispensing Fees - prior-period subaccount	\$36,538	
340B Receivable - prior-period subaccount	\$222,729	
Revenue - prior-period subaccount		\$261,731

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340B Drug Cost Recognition



Common Question:

A/R

How should I account for 340B Drug Cost?

Several entities we work with book based on wholesaler invoices (most common). We have also seen some entities accrue 340B drug cost based on date of service to adhere to the matching principle (not as common).

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340B Drug Cost Recognition



Based on Date of Service

- Amounts would come from 340B claims data that reflects price file data (what the 340B drug cost *should have been* at a specific point in time).

Based on Wholesaler Invoices

- Amounts would come from actual invoices paid to wholesalers

Whichever basis you use, it is important to monitor actual drug spend compared to drug cost based on date of service over time.

A variance greater than ~2% (when looking at the average across several months) could reflect price file issues that need to be addressed.

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340B Receivable Tracking



Common Question:

A/R

What about tracking 340B A/R?

Even though invoicing reports may not be used for revenue recognition, it is still very important to track contract-pharmacy level A/R. Sophisticated reporting and performance monitoring holds no value if pharmacies are not paying you.

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340B Receivable Tracking



- Tracking 340B pharmacy invoices is not always a simple process...
- For reference, a contract pharmacy network with ~40 contract pharmacies could require at least six different types of reports showing amounts owed from pharmacies.
 - Each TPA provides different reporting.
 - Each billing configuration (qualification-based vs. replenishment-based) requires different reporting.
 - Some reports are actual invoices, while some are data reports.
 - A certain level of expertise is required to build the tracking process.

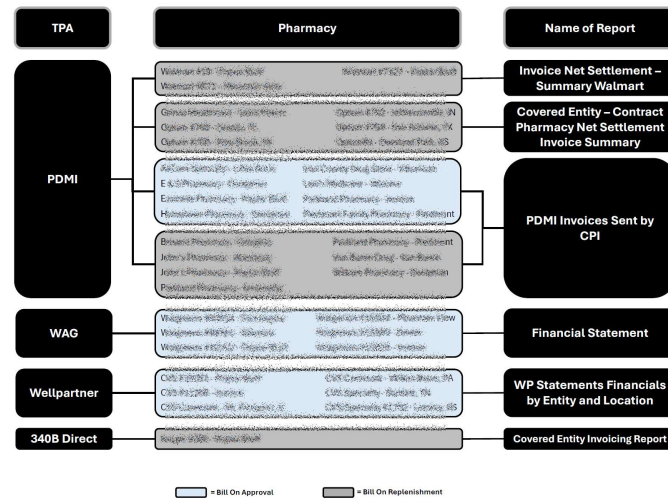
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340B Receivable Tracking

Example graphic showing complexity of gathering invoicing reports to track receivables:



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Poll: 340B Receivable Tracking

Your 340B receivable is growing significantly year over year. What should your first move be?

NOTE: 340B revenue is booked based on pharmacy date of service using approved claims.

- A. Call the pharmacies – they must be paying late.
- B. Celebrate – 340B volume is up!
- C. Check the TPA invoice cycle.
- D. You can't answer yet.

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340B Receivable Tracking



- **Correct answer: You can't answer yet!** The first thing you should do is break down your receivable to determine where the issue is – because it is not always that pharmacies are behind.
- In a process where 340B revenue is recognized based on pharmacy date of service, several different factors can inflate your 340B receivable:
 - Pharmacies get behind on 340B invoices.
 - If you have a solid tracking process, this is the simplest thing to check (so start here)
 - Claim-level lags between approval and invoicing:
 - TPA invoicing error
 - Lag in replenishment (relevant for replenishment-based invoicing)
 - Reflected in inflated inventory accumulator.
 - *NOTE: Replenishment lag can be significant for Walmart pharmacies.*
 - Inappropriate configurations can block replenishment altogether.

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340B Receivable Tracking



- **Key Takeaways:**
 - A date-of-service-based revenue accrual can reveal issues that would go undetected if a process only relied on what is invoiced/received.
 - Tracking a 340B receivable should go beyond tracking pharmacy payments.

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Poll: 340B In-House Pharmacy



Does your entity operate an entity-owned ("in-house") pharmacy that dispenses outpatient prescriptions to patients?

- A. Yes; access is limited to employees only.
- B. Yes; access is limited to employees and transitions of care prescriptions.
- C. Yes; access is limited to medical patients of our health system.
- D. Yes; anyone can use our pharmacy.
- E. No; seeking retail pharmacy license though.
- F. No; content without an in-house pharmacy.

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340B Accounting



Common Question:



What about my entity-owned pharmacy?

For purposes of calculating 340B Net Savings, the logic is essentially the same as with contract pharmacy.
(NOTE: consider whether you internally transfer between an entity 'account' and a pharmacy 'account' to address pharmacy dispense fees).

340B accounting should be separate from pharmacy accounting. To get a full picture of entity-owned pharmacy profitability, you must also account for all pharmacy operating expenses and allocated overhead.

Entity-Owned pharmacy profitability (when starting with 340B Net Savings):

$$\begin{array}{r}
 (+) \text{ 340B Net Savings} \\
 (+) \text{ Non-340B Revenue} \\
 (-) \text{ All pharmacy expenses} \\
 \hline
 (=) \text{ Net Pharmacy Profit/(Loss)}
 \end{array}$$

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340B Accounting



340B Savings Statement isolated to one in-house pharmacy (shows 340B Net Savings if entity-owned pharmacy was a contract pharmacy):

	Aug-25	Sep-25	Oct-25	Nov-25	Dec-25	Jan-26	Feb-26	Mar-26	Apr-26	May-26	Jun-26	Jul-26	12 Month Total
Total Paid from all 340B Rx Claims:	\$ 301,623	\$ 287,063	\$ 303,294	\$ 284,583	\$ 341,278	\$ 301,411	\$ 206,413	\$ 245,171	\$ 239,756	\$ 243,993	\$ 251,635	\$ 281,354	\$ 3,196,573
Estimated 340B Ingredient Cost	185,005	177,180	186,888	180,871	221,871	115,048	117,750	139,905	133,919	140,245	140,188	170,886	\$ 1,907,475
340B Gross Savings	116,618	109,884	116,407	103,612	119,407	86,363	88,662	105,266	105,837	103,747	111,447	110,468	\$ 1,289,098
Fees													
Third Party Administrator Fees	6,152	6,806	7,080	6,184	-	135	86	9	-	51	129	10	\$ 26,653
Savings Plan Administrator Fees	-	-	-	-	-	865	914	893	1,026	949	872	981	\$ 6,405
Switch Fees	121	128	134	112	135	180	157	176	181	161	179	171	\$ 1,834
Gateway Fees	-	-	-	-	-	-	-	-	-	-	-	-	\$ -
TPA Referral Fees	935	1,406	1,425	1,722	1,243	-	-	-	-	-	-	-	\$ 6,731
Carve Out Fees	-	-	-	-	-	-	-	-	-	-	-	-	\$ -
Contract Pharmacy Dispense Fees	63,244	61,616	63,264	59,282	71,325	42,617	43,909	51,842	50,891	51,292	52,686	60,975	\$ 672,943
Contract Pharmacy Remediation Fees	-	-	-	-	-	-	-	-	-	-	-	-	\$ -
Total Fees	70,452	69,956	71,809	67,310	72,704	43,797	45,066	53,938	52,097	52,453	53,865	62,186	\$ 714,768
Net 340B Savings	\$ 46,166	\$ 39,928	\$ 44,598	\$ 36,302	\$ 46,703	\$ 42,566	\$ 43,596	\$ 51,328	\$ 53,739	\$ 50,295	\$ 57,572	\$ 58,282	\$ 574,330

*Remediation Fees are on a current month cash basis because they are not easily accrued to the month of occurrence

To get a full picture of pharmacy profitability, you would need to add non-340B revenue and deduct all additional pharmacy-related expenses. You would also need to add dispense fees back in, assuming internal transfers are not taking place for the entity-owned pharmacy dispense fees.

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SECTION 5

Federal Policy Developments

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IRA Medicare Drug Price Negotiations



- The Inflation Reduction Act was signed into law in 2022.
- One of the many provisions of the IRA permitted Medicare to negotiate better prescription drug prices with manufacturers for select drugs.
- These negotiations result in an established Maximum Fair Price (MFP).
- Once the negotiated MFP goes into effect for a selected drug, the total reimbursement to pharmacies from Medicare will be:

MFP + Dispensing Fee

- For any of the selected drugs when the payer is Medicare, the effectuated cost of the drug can either be MFP or 340B, never both.

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IRA Drug Selection for MFP Negotiations



2026	2027	2028	2029 (and beyond)
Eliquis Enbrel Entresto Farxiga Imbruvica Januvia Jardiance Novolog/Fiasp Stelara Xarelto	Austedo Breo Ellipta Calquence Ibrance Janumet Linzess Ofev Otezla Ozempic/Rybelsus/Wegovy Pomalyst Tradjenta Trelegy Ellipta Vraylar Xifaxan Xtandi	Anoro Ellipta Biktarvy Botox Cimzia Cosentyx Entyvio Erleada Kisqali Lenvima Ocrencia Rexulti Trulicity Verzenio Xeljanz; Xeljanz XR Xolair	+20 (Part D & Part B spending)

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Now, let's talk about a different, but intersecting rebate model that is coming in 2027...

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340B Rebate Model Pilot Program

340B REPORT

BREAKING NEWS

HRSA Releases New 340B Rebate Pilot with 2027 Start

Date

July 31, 2025 William Newton, Editor-in-Chief 340B Report

- Beginning 1/1/27, there are 25 drugs CEs will no longer purchase from wholesalers at the 340B price.
 - Actual implementation will be based on HRSA's approval of manufacturer plans.
- For the 25 drugs in the pilot program manufacturers will "effectuate" access to the 340B price by providing a retrospective 340B Rebate (WAC – 340B).
- This applies regardless of payer (Medicare, Commercial, Self Pay, etc.).

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340B Rebate Model Pilot Program Drugs



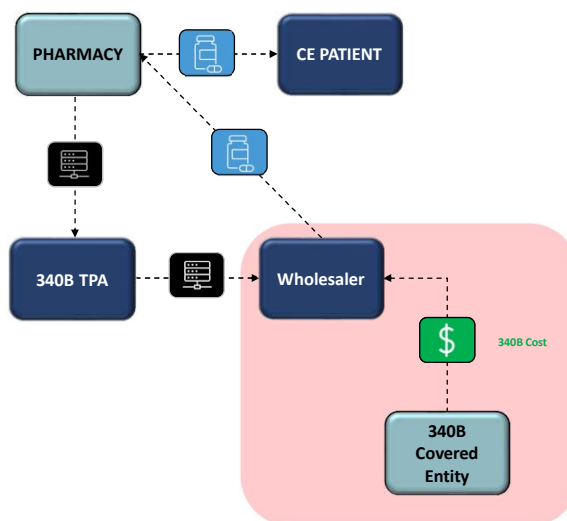
January 1, 2027		
Eliquis	Austedo	Pomalyst
Enbrel	Breo Ellipta	Tradjenta
Entresto	Calquence	Trelegy Ellipta
Farxiga	Ibrance	Vraylar
Imbruvica	Janumet	Xifaxan
Januvia	Linzess	Xtandi
Jardiance	Ofev	
Novolog/Fiasp	Otezla	
Stelara	Ozempic/Rybelsus/	
Xarelto	Wegovy	

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340B Process Today (upfront 340B discount)

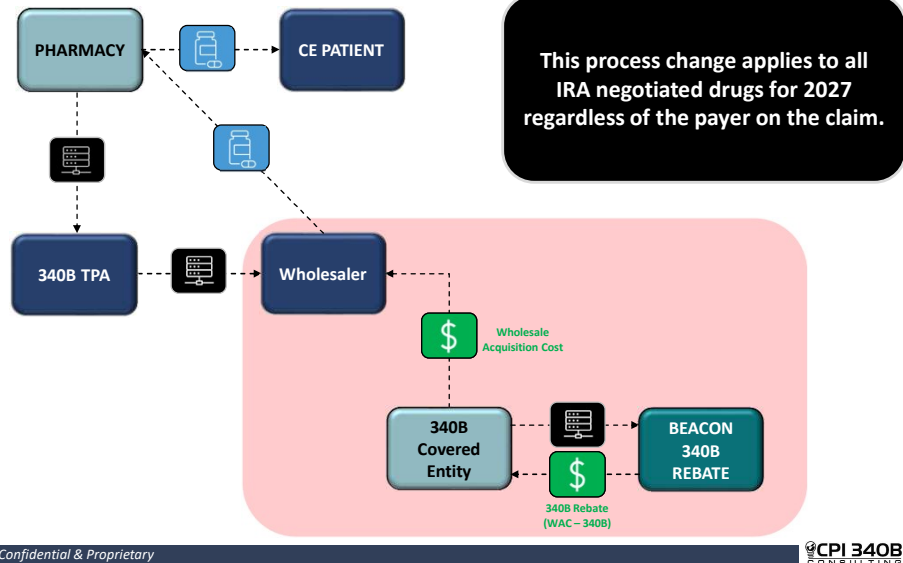


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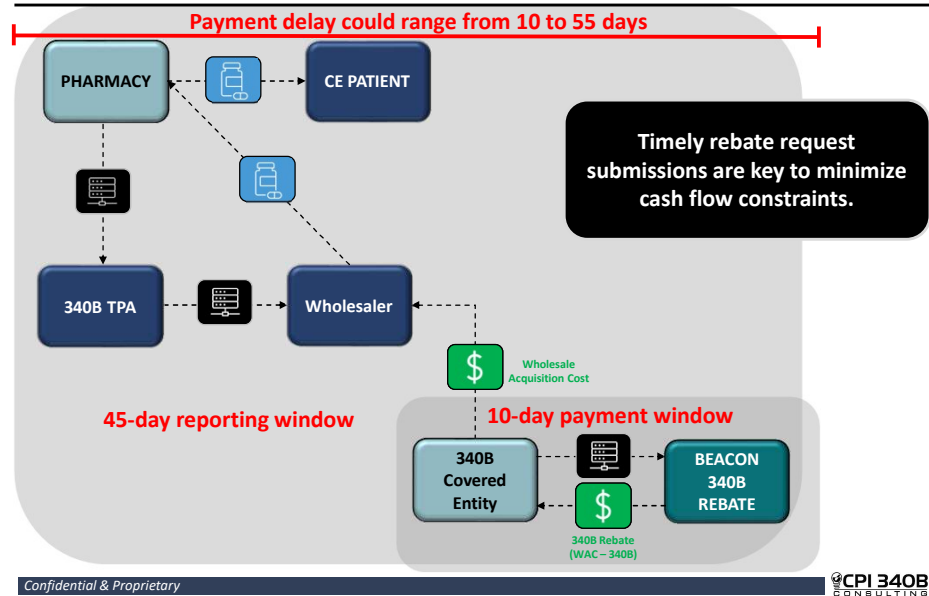
48

340B Process in Rebate Model



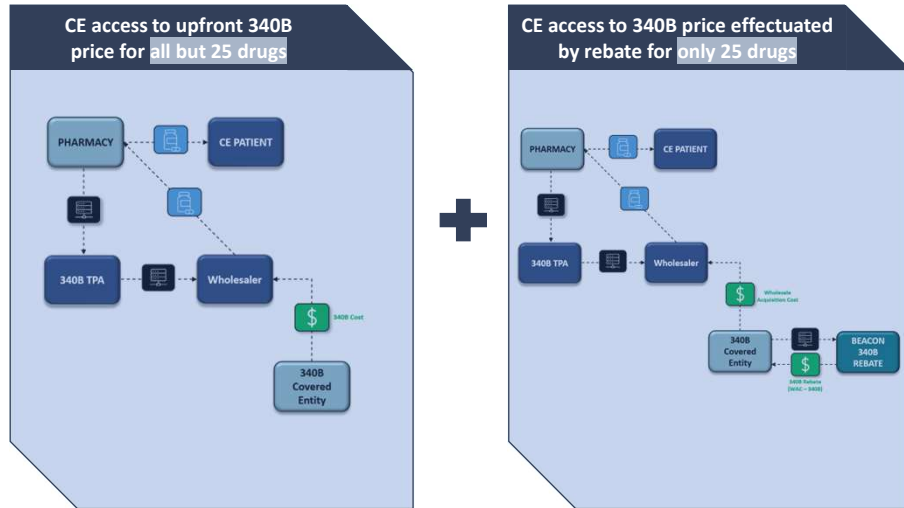
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340B Process in Rebate Model



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340B Process in 2027



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340B Rebate Pilot - Impact

- CEs will experience a major cash flow shift.
- CEs will have a new 340B data sharing requirement (Beacon).
- CEs will need to develop new processes for rebate reconciliation and rebate receivables.
- 340B TPAs need to build the tools necessary to support this new model.
- Patient access and CE savings impact could be significant depending on industry readiness by 1/1.
 - Insured claims denied because they fail the profitability filter during TPA evaluation.
 - 340B self pay claims adjudicate at WAC+ prices because the TPA is using the wholesaler price file.
 - Without proper tools at the TPA, CEs could opt to block all claims for the 25 drugs from their 340B program entirely.

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340B Rebate Pilot - Advocacy Efforts

- HRSA's proposed **2026** 340B Rebate Pilot was halted by a federal district court due to lack of compliance with the Administrative Procedures Act.
 - Some legal experts have indicated there is still room for an injunction due to deficiencies in following the Administrative Procedures Act again.
- SUSTAIN 340B Act – co-sponsored by Senator Boozman – would codify 340B as an upfront discount, not a rebate program.
- Talking points for CEs:
 - Un- and under-insured patients' access to 340B products on 1/1/27 will be impacted.
 - There will be cash flow implications for CES because of the 340B rebate pilot.
 - There will be additional costs to CEs to manage data uploads and tracking of rebates.
 - Some of the large chains may opt to have these drugs carved out of 340B programs either entirely or partially because they are not prepared to meet the new requirements, which impacts CE savings.
 - The MFP caused covered entities to lose ~20%+ of their 340B savings in 2026 and is expected to reduce savings by an additional 15% in 2027.

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340B Rebate Pilot - Preparation

- ☐ Register for Beacon 340B Rebate Platform.
- ☐ Determine Beacon rebate request submission process.
 - Self submission
 - TPA submission
 - Consultant submission
- ☐ For in-house pharmacies carving in Medicaid, have a plan for Medicaid billing on 340B rebate drugs.
 - If continuing to carve-in, must be able to bill the 340B ceiling price, which will not be in the wholesaler price files feeding dispensing software.
 - If planning to carve-out all Medicaid claims, ensure finance team is prepared for this additional cash flow shift.
- ☐ Have a plan for 340B self pay billing.
 - Again, the 340B price will not be listed in the price files from wholesalers. Will need to be able to adjudicate these claims from an ad hoc file pulled from Beacon.

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340B Rebate Pilot – Preparation (cont'd)



- ☐ Assess 340B TPA readiness and configure program accordingly.
 - Will they be ready to process third party and self pay claims for rebate NDCs using the 340B ceiling price file from Beacon?
 - If they are performing the rebate request submission on your behalf, are they also reporting the responses in their own system?
 - If opting out of participation in the rebate model, block all rebate NDCs.
- ☐ Mitigate patient harm.
 - Consider pharmacies filling 90-day supplies for self pay patients in early December.
 - Consider therapeutic alternatives where appropriate (the options are limited).
- ☐ Clear virtual inventory accumulations before end of year.
 - If a 2026 claim is unreplenished within 2026, the CE will have to purchase the inventory at WAC and not be eligible for a 340B rebate.
 - If 2026 accumulated inventory cannot be replenished before the end of 2026, the claims should be removed from the 340B program to minimize CE financial harm.
- ☐ Engage finance team.
 - 2027 will bring reduced savings because of the MDPNP expansion and some stakeholders potentially opting to block all rebate drugs from 340B.
 - 2027 will bring cash flow disruption because of the 340B Rebate Pilot Program.
 - Develop Beacon rebate receivables process.
 - Consider requesting increased credit limits and payment terms on 340B wholesaler accounts.

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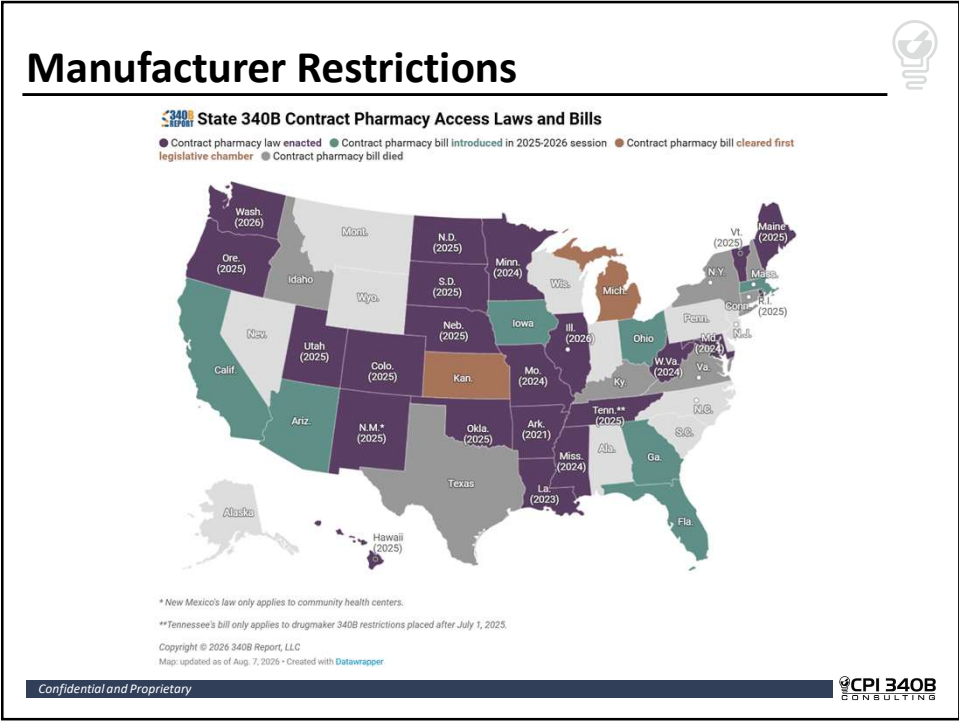
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SECTION 6

Manufacturer Restrictions

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Thank You!

Questions?



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