

### So Now What? Moving on LB168 & 340B

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# Legal

This presentation should not be considered as legal advice.

 PHV strongly recommends contacting your legal team for advice on how to proceed with changes to your 340B program operations







#### Prairie Health Venture Background



State Contract Pharmacy Protection Bills -Summary of Bills

-Ad Campaigns

-State Comparison

LB168 Next Steps

-Timelines

-Analysis & Budgeting

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340B Hot Topics

-IRA & Rebates

-MTM Qualifications

-CBRM

-Odds and Ends



## Prairie Health Ventures Background

- Health Care Alliance of 59 non-profit Hospitals
  - 700+ Affiliates
- Owned and Directed by Member Hospitals
- Provides a range of services including Group Purchasing, ACO, USAC Consulting, 340B Consulting
- 340B management and consulting to more than 30 Rural hospitals for over a decade
  - 340B Align
  - 340B Program Management







### **Contract Pharmacy State Bills**

More than 32 States have introduced contract pharmacy protection bills

- South Dakota was the first in 2025 to pass their bill
- \* 13 other States passed bills (5 this year)

Nebraska:

- \* LB168 signed into law April 9th, 2025
- Emergency clause- effective immediately upon Governor signature
- Dark money ads focus 340B on transgender health, immigration, reproductive health, and 340B "mark-ups"

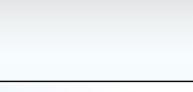
### Other 340B State Provisions:

- Reporting Requirements
- Direction on use of savings
- Carve out different Entity Types









Domestic Policy Caucus

#### 340B: FUELING MASSIVE PHARMACY CHAINS, KILLING MAINSTREET



#### 340B is a massive, out... more







### LB 168 vs Other State Bills

#### <u>Nebraska</u>

- Prohibits

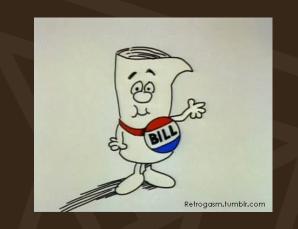
   manufacturers from
   directly or indirectly
   restricting 340B drugs
   to CE's and their
   contract pharmacies
  - Including through any claims, utilization or purchase data requirements
  - AG or County Attorney could take enforcement actions

#### <u>Arkansas</u>

- Prohibits Restrictions
- Upheld by 8<sup>th</sup> District
  Appellant Court
- First to send enforcement order
- \$50K per manufacturer for each 6 month period out of compliance
- 32 manufacturers lift restrictions

#### <u>Minnesota</u>

- Prohibits Restrictions
- <u>0</u> enforcement mechanism
- Judge ruled in favor or Pharma due to no harm could be levied





### LB 168 vs Other State Bills

### South Dakota

- Passed bill in March
  2025
- CE or pharmacy can file civil action
- Only Merck lifted restrictions

#### <u>Kansas</u>

- Passed in 2024 with multiple manufacturers lifting restrictions
- AG "No language… prohibits manufacturers from deny, restricting, prohibiting with 340B"
- Most restrictions added back

### <u>Missouri</u>

- Passed in 2024
- Judge dismissed multiple arguments, but still deliberating on a few
- 18 manufacturers lifted restrictions



### LB168: Next Steps

### Effective Immediately

### 340B Rostering Period = First 15 days of every quarter

### Should I unblock restrictions now?

- <u>NO!</u>
- Wait for manufacturers to announce release of restrictions
- If/When manufacturers release restrictions:
  - Consider effective date
  - $_{\circ}~$  Consider inventory and financial concerns for pharmacy
  - Review Contract Pharmacy Network Prescription Map

### Documenting the "Harms":

- Calculate total revenue **not** captured by restrictions at least **quarterly**
- Work with other Nebraska hospital to build case
- "Harm" does not have to be realized (aka negative profit claim)



### LB168: Analysis & Budgeting

- Build your Contract Pharmacy Network Map:
  - Use eRx File and past contract relationships
  - Work with TPA/consultant to contact Chain/Specialty Pharmacies

#### Budget Range by State Scenarios

- Build Analysis considering current restrictions/designations
- Add in manufacturer policy by State (SD, MO, AK) and with no restrictions
- Review Range to create future 340B Budget

#### Considerations:

- Maximum Fair Price (MFP): <u>Starts</u> 1/1/2026
- Tariffs?







### Hot Topics: IRA and Rebate Models

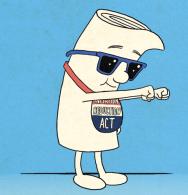
#### IRA: MFP pricing for first 10 drugs starts 1/1/2026

- Manufacturers will pay the lower of **EITHER** MFP or 340B price
- Decreases overall 340B savings at **BOTH** mixed-use and retail/contract pharmacy
- Eliquis, Jardiance, Xarelto, Januvia, Farxiga, Entresto, Enbrel, Imbruvica, Stelara, Novolog
- Considerations:
  - o Exclude MFP/Medicare part D for 10 drugs at contract pharmacy?
  - $_{\odot}$   $\,$  Cut to WAC pricing due to inflationary penalties?
  - Medicare Part B MFP coming 2028

### Rebates:

- Shift from upfront discount to after-WAC purchase rebate
- Use Beacon platform to administer rebate program requiring data uploads
  - Questions:
    - How to refute denials? How to change WAC to GPO? What does Beacon consider eligible encounter? Etc.
- J&J and Sanofi announced and postponed Rebate models in October and December 2024





### Hot Topics: MTM Encounters & CBRM

- MTM as an eligible encounter?
  - Entities currently refuting HRSA audit findings
  - MTM completed by entity owned pharmacy
  - Pharmacist = "Health Care Professional"
  - Encounter documented in EMR at eligible clinic location
  - Qualify scripts AFTER MTM completion



- Credit Based Replenishment Model:
  - Virtually credit/re-bill retail/contract pharmacy retail purchases to 340B account
  - Eliminates need for physical 340B inventory to be sent
  - Great for NDC Shortages/out of stock or missed savers
  - Cardinal = CBRM
  - McKesson = VRR
  - ABC/Cencora = ISP



## Odds and Ends

- Modifiers
  - 1/1/2024 <u>All</u> entities should report TB Modifiers on 340B Medicare Claims "purchased" through 340B
  - <u>Best Guess Approach</u>: Auto-apply modifiers on "Outpatient, Non-medicaid, No Orphans, Part B, No Generics, No RHC"
    - Optional: Positive Savers, Status K and G NDCs"
    - Consider Top 10-25 drugs if burdensome
- OPAIS Updates
  - Update Medicare Cost Report dates within 30 days of filing cost report



https://www.cms.gov/medicare/medicarefee-for-servicepayment/hospitaloutpatientpps/downloads/b illing-340b-modifiers-under-hospitalopps.pdf

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# Thank you!