blue

PHARMACY CONSULTING GROUP

The Good, The Bad, The Reality

May 19th, 2025

Jason Prokopik, Pharm.D., 340B ACE

Jason Prokopik, Pharm.D. 340B ACE

Jason Prokopik is a Senior Manager with Blue & Co., LLC on the Indianapolis Reimbursement team specializing in fiscal and operational management related to pharmacy. Jason has worked in pharmacy management for more than 15 years focusing his efforts on improving the financial and operational performance of the firms he represented. He is responsible for helping clients improve workflow, enhance operational efficiencies, and reduce controllable costs.

blue
PHARMACY CONSULTING GROUP

Agenda

1

340B PROGRAM

What is the intended purpose?

2

The Good

How did we get here?

3

The Bad

Where are we at?

4

The Reality

How do we move forward?

blue

PHARMACY CONSULTING GROUP

340B Intention

- According to congressional report language, the purpose of the 340B Program is to enable covered entities “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

- Achieved by requiring pharmaceutical manufacturers to provide front-end discounts on covered outpatient drugs purchased by covered entities that serve the nation’s most vulnerable patient populations.

blue
PHARMACY CONSULTING GROUP

Recent AHA Facts

- Approximately half of all eligible 340B hospitals are in rural areas
- More than 80% of rural hospitals use contract pharmacies for patient access to outpatient drugs and services
- Recent survey found:
  - CAH – impacted by an average of $500 thousand a year
  - DSH – impacted by an average of $3 million a year
- General drug costs have increased approximately 20% between 2019 and 2022

blue
PHARMACY CONSULTING GROUP

340B Drug Facts

- For 30+ years the program has provided financial assistance to safety net hospitals
- Roughly 3,000 hospitals participate
- In 2023, $66.3 billion in 340B discounted purchases which equates to approximately 9% of total (23.5% increase from 2022)
- Estimated 55% decrease in outpatient drug prices

Compared to:

- U.S. prescription drugs sales of $405.9 billion 2022 (8.4% increase)
- Specialty drug spend is approximately 54% of total in 2023
    - Immunology, Oncology, HIV

blue
PHARMACY CONSULTING GROUP

340B Facts

In 2023, the top 10 drugs in terms of 340B purchases represented approximately one third of the total spending in the 340B program.

Brand Name	Primary Indications	2023 Total 340B Sales
Keytruda	Oncology	$6,905,377,755
Biktarvy	HIV	$3,577,083,273
Opdivo	Oncology	$1,953,824,181
Darzalex Faspro	Oncology	$1,891,559,523
Ocrevus	Oncology	$1,850,213,455
Trikafta	Cystic Fibrosis	$1,817,226,143
Humira (CF) Pen	Immunology	$998,809,804
Descovy	HIV	$969,510,516
Entyvio	Immunology	$949,744,300
Durvalumab	Oncology	$889,594,527

blue
PHARMACY CONSULTING GROUP

The Good

blue
PHARMACY CONSULTING GROUP

340B History

- Established by Congress in 1992
- Federally mandated drug pricing program
- Intent was to ensure drug manufacturer's price increases did not divert public funds away from providing patient care
- These price increases were thought to be the result of the Medicaid Drug Rebate Program (MDRP)
- Expanded under Clinton, W. Bush, Obama administration

blue
PHARMACY CONSULTING GROUP

340B History

- Congress enacted Section 340B of the Public Health Service Act, under Section 602 of the Veterans Health Care Act of 1992, which:
  - Enabled safety net providers (covered entities) to purchase some drugs at Medicaid pricing.
  - Exempts prices from the “best price” calculation.

- Manufacturers are **not** obligated to participate in the MDRP or 340B Program.
  - If they choose to do so, the federal government pays for their drugs under Medicare Part B and Medicaid.

blue
PHARMACY CONSULTING GROUP

340B Basics: Eligibility

Hospital Ownership

Government Owned

- Owned or operated by unit of State or local government
- Granted governmental powers by State or local government
- Proof or attestation of ownership must be documented
- HRSA will ask to see this document

Non-Profit

- Private non-profit with a contract with State or local government to provide health care to low-income individuals not entitled to Medicare or Medicaid
- HRSA will ask to see this contract

blue
PHARMACY CONSULTING GROUP

340B Basics: Eligibility

Hospital DSH Requirements

Percentage	Hospital Type
11.75%	DSH Hospital
11.75%	PED Hospital
11.75%	CAN Free Standing
8.00%	RRC Hospital
8.00%	SCH Hospital
N/A	CAH Hospital

HRSA verifies this using the most recently filed cost report:

- Worksheet E, Part A, Line 33

blue
PHARMACY CONSULTING GROUP

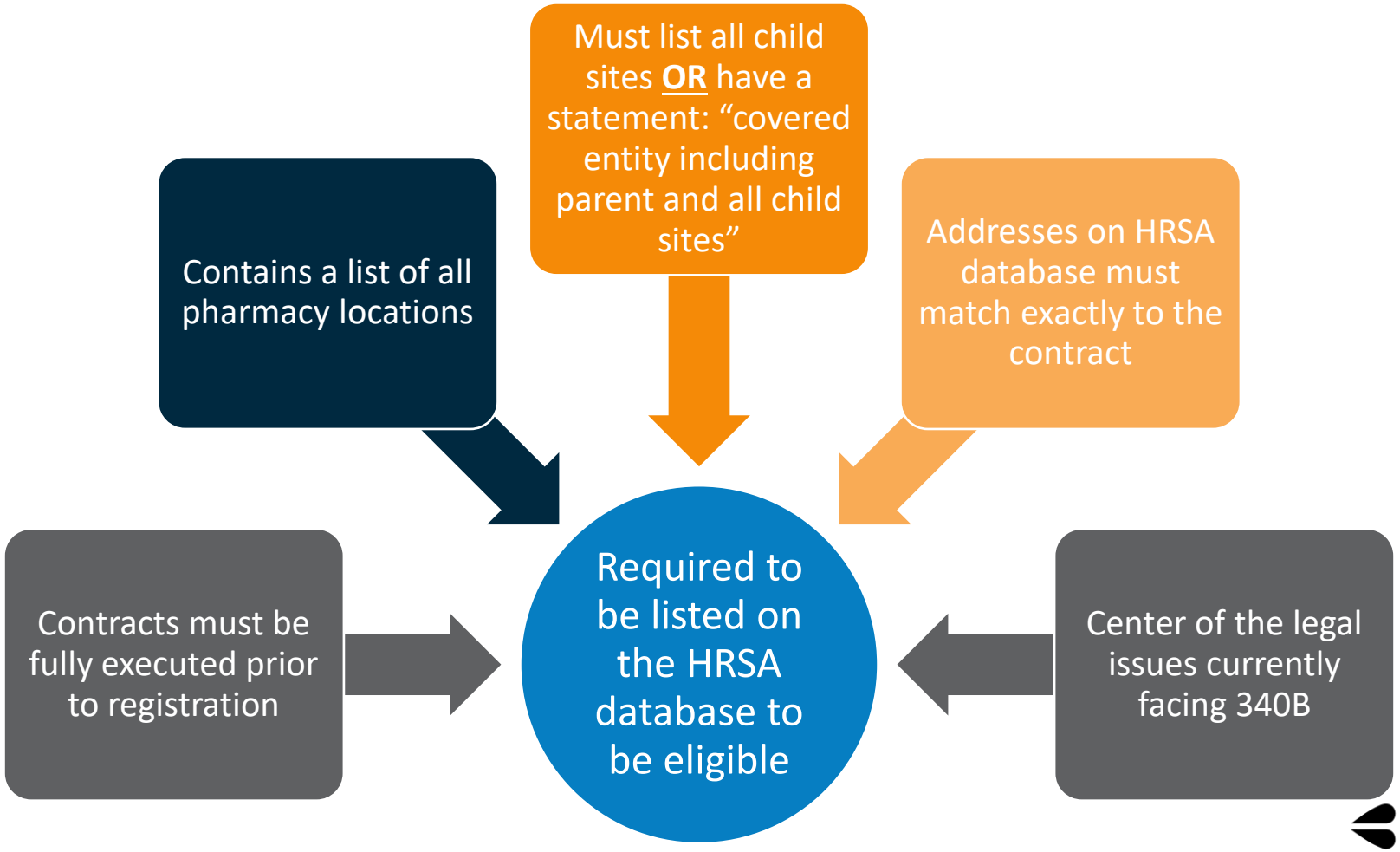
340B Basics: Child Sites

- Must be a fully integrated, reimbursable outpatient department of the hospital.
  - Can be outpatient clinics or rural health clinics

- If the department is outside of the hospital's four walls, then it must be registered with HRSA.
  - Information needed to register a child site:
    - Cost report trial balance with reimbursable expense/revenue
    - Cost Report: Worksheet A – Expenses > 0
    - Cost Report: Worksheet C – Revenue > 0
    - Outpatient service lines 50-117

blue
PHARMACY CONSULTING GROUP

340B Basics: Contract Pharmacy



blue
PHARMACY CONSULTING GROUP

Guidance vs. Regulation

- Since 1992, the 340B Program has been governed by federal guidance, rather than regulations.
- Until the Affordable Care Act (ACA), every aspect of the program was **interpreted** through guidance.
- The ACA expanded:
  - The program into rural and cancer hospitals.
  - Orphan drug discount restrictions.
  - Stronger drug pricing enforcement mechanisms.
  - Gave Health Resources and Services Administration (HRSA) some ability to issue regulations.

blue
PHARMACY CONSULTING GROUP

Guidance vs. Regulation

- HRSA repeatedly requested that Congress give it broad regulatory authority, which would allow its Office of Pharmacy Affairs (OPAIS) to issue regulations on every aspect of the 340B Program.

- HRSA's lack of authority to enforce its 340B guidance, specifically its 1996 and 2010 contract pharmacy guidance, is central to the current debates.

- Based on this, drug manufacturers argue they are not required to offer price discounts because they believe HRSA's guidance is not enforceable.

blue
PHARMACY CONSULTING GROUP

The Bad

blue
PHARMACY CONSULTING GROUP

HRSA Audits

Conducted in most cases by the Bizzell Group

- HRSA contracted vendor
- Prior hospital experience
- Many are pharmacists
- Experienced
- Subject matter experts
- Typically, one to two days either onsite or virtually
- Seen recent audits conducted by HRSA employees

blue
PHARMACY CONSULTING GROUP

Audits-Compliance

Areas of Focus

- Eligibility
- Registration and Database Issues
- **Drug Diversion**
- **Duplicate Discount** (out of state Medicaid)
- GPO Violations (DSH, PEDS, CAN)
- Other

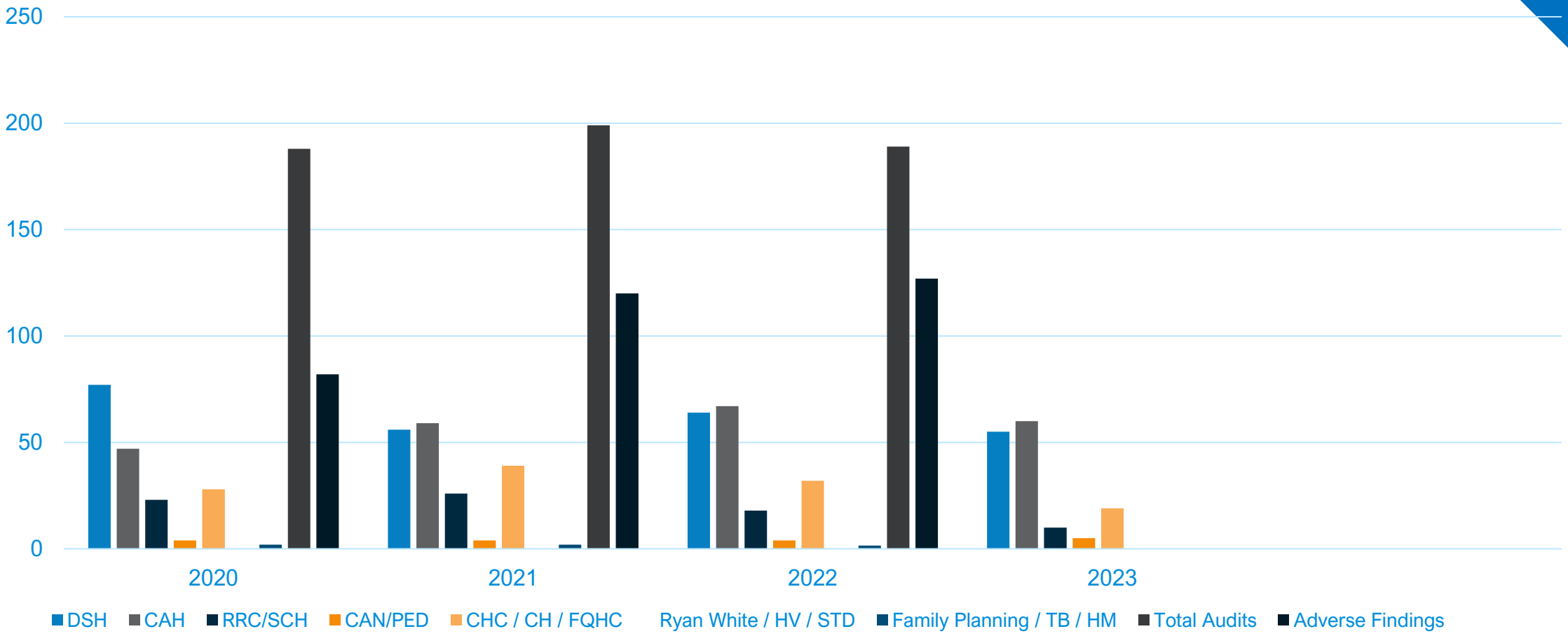
blue
PHARMACY CONSULTING GROUP

FY24 Data Request List (DRL)

Data Request – Covered Entity (CE)

1. **Provide policies and procedures on the topics listed below:**
   - A. Description of CE's registration and recertification process
   - B. Process for ensuring that the 340B Office of Pharmacy Affairs Information System (OPAIS) record is up-to-date and accurate for the parent, applicable off-site facility(ies), and contract pharmacy(ies) (including regular review and timely update of 340B OPAIS records)
   - C. Process for determining what sites are eligible; address whether each service area in which 340B drugs are purchased, ordered, or provided is reimbursable on the CE's most recently filed Medicare cost report (MCR) (for hospitals) or included on the grant (for grantees)
   - D. Description of procurement process (including all pharmacy(ies), if applicable)
   - E. Prevention of GPO violations (applies only to *Disproportionate Share Hospitals, Children's Hospitals, and Free Standing Cancer Hospitals)*
   - F. Definition for any exclusions to the definition of covered outpatient drugs (i.e., bundled drugs, orphan drugs, or inpatient drugs)
   - G. CE's process for conducting oversight of its contract pharmacy(ies) including:
     - Internal audits
     - Independent audits
   - H. How the CE accounts for 340B inventory (physical inventory and virtual inventory replenishment)
   - I. Prevention of diversion at **CE** – Process for confirming the following:
     - Site eligibility location
     - Referral or responsibility of care remained with CE
     - Medical or patient health record
     - Patient eligibility (including patient status change for hospitals)
     - Provider eligibility (relationship)
     - Service in the scope of the grant (applies to grantees)
     - Documenting and accounting for wastage of a drug not dispensed or administered to a patient
   - J. Prevention of diversion at **all pharmacy(ies)** – Process for confirming the following:
     - Site eligibility location
     - Referral or responsibility of care remained with CE
     - Medical or patient health record
     - Patient eligibility
     - Provider eligibility (relationship)
     - Service in the scope of the grant (applies to grantees)
   - K. Mechanism to prevent duplicate discounts at **CE** and off-site facility(ies) for:
     - Physician administrations
     - Outpatient prescriptions
     - Billing multiple state Medicaid agencies, if applicable
   - L. Mechanism to prevent duplicate discounts at **all pharmacy(ies)** for outpatient prescriptions
   - M. When and how CE would self-disclose and CE's definition of non-compliance or material breach
   - N. Definition of an eligible site when the location is not on the MCR (for hospitals) or grant (for grantees) for special circumstances (e.g., COVID-19, flooding, etc.)

blue
PHARMACY CONSULTING GROUP



blue
PHARMACY CONSULTING GROUP

HRSA Audit Findings

2024 Results

- DSH – 52 (findings – 29) with 16 resulting in repayment or terminations
- CAH – 44 (findings – 26) with 10 resulting in repayment or terminations
- FQHC – 21 (findings – 11) with 7 resulting in repayment or terminations
- SCH/RRC – 15 (findings – 10) with 1 resulting in repayment or terminations
- Ryan White / STD – 8 (findings – 2) with 1 resulting in repayment or terminations
- Pediatrics – 3 (findings – 1) with 0 repayments or terminations

blue
PHARMACY CONSULTING GROUP

Ohio HRSA Audit Results

- **2022** – 7 results posted
  - 2 DSH, 1 CAH, 1 SCH, 1 RRC, 1 PED, 1 CHC
  - 5 results had finding but 0 had repayment requirements
- **2023** – 10 results posted
  - 3 RRC, 2 DSH, 1 DSH, 1 PED, 3 CHC
  - 7 results had finding with 4 resulting in repayment or terminations
- **2024** – 7 results posted
  - 3 DSH, 2 CAH, 1 RRC, 1 CHC
  - 4 results had finding with 1 resulting in repayment
- Findings did not all result in payback (incorrect OPAIS record or suspected Medicaid duplicate discounts)

blue
PHARMACY CONSULTING GROUP

HRSA Audit Findings

Remedies

- Corrective Action Plans – some CAPs satisfied findings
  - Responsibility of covered entity to determine full scope of finding(s)
- Possible repayment to manufacturers
  - Responsibility of covered entity to determine amounts
- Some resulted in termination of child site clinics and/or contract pharmacies
- Removal from program – does not appear to have happened in 2023

blue
PHARMACY CONSULTING GROUP

Contract Pharmacy Challenges

blue
PHARMACY CONSULTING GROUP

Companies include, but not limited to, **then…**

Companies include, but not limited to, **now…**

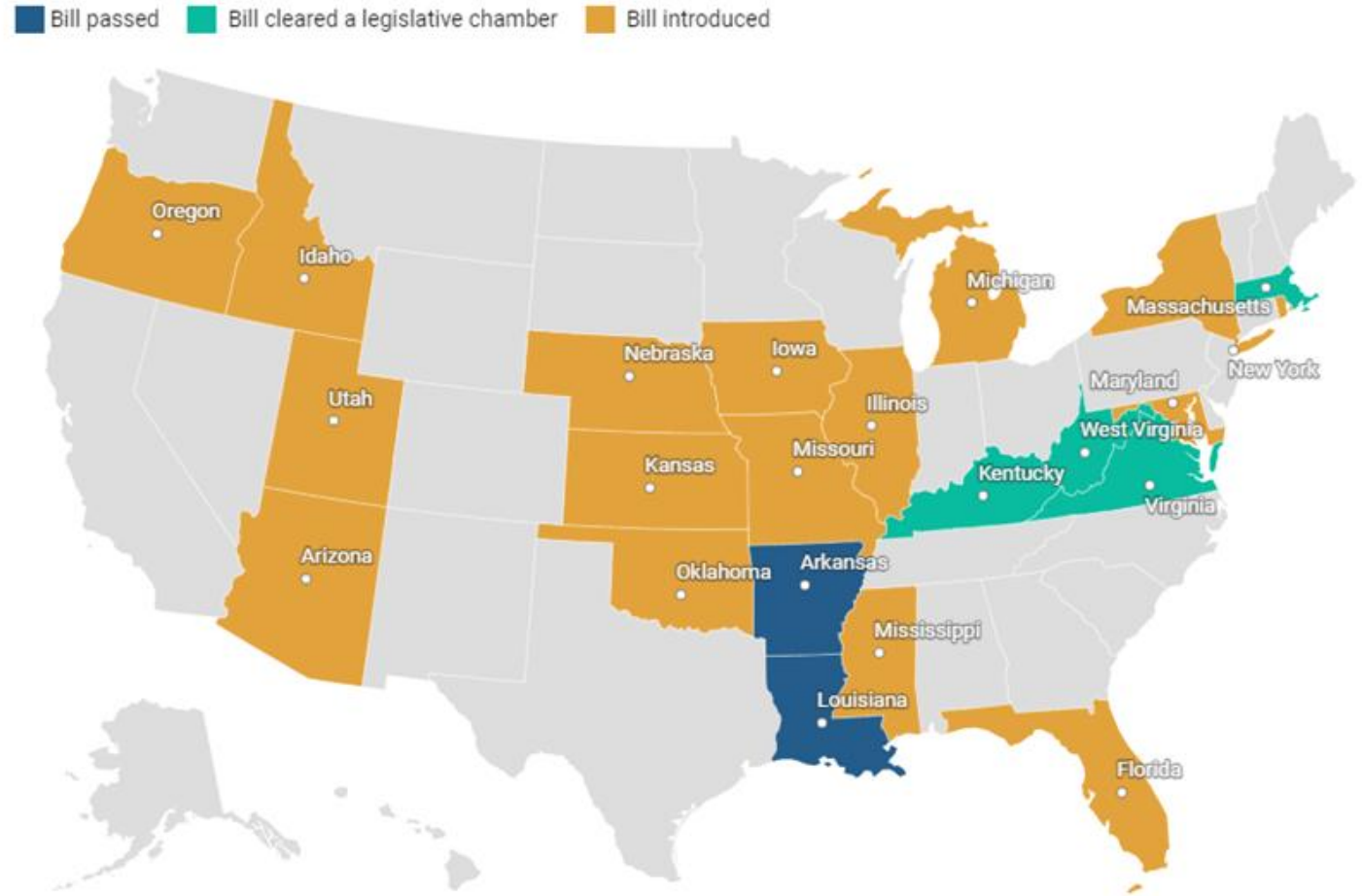
Manufacturer	Entity Types	Contract Pharmacy Designation	NDC First Five	Pricing Logic
Abbvie	Federal Grantees Exempt	Without Entity-Owned pharmacy, designate 1 CP within 40 miles and must submit claim data for designated CP. Limited distribution products (Duopa & Imbruvica) can also designate one CP if in-house pharmacy is not within LDD network.	00032, 00051, 00074	Pricing is restored using chain logic
EMD Serono				
Amgen	Federal Grantees Exempt	Without an entity-owned pharmacy, CE may designate 1 contract pharmacy if it is within 40 miles. With an entity-owned pharmacy, CE may designate 1 additional contract pharmacy if it is within 40 miles and the CE submits claims data for entity-owned and contract pharmacy (4-11-23)	55513, 58406, 72511	Pricing is restored using chain logic
Astellis	Federl Grantees Exempt; 9/1/23	Without an entity-owned pharmacy, CE may designate 1 contract pharmacy		
AstraZeneca	All (ESP use new as of 8/1/23)	Single contract pharmacy designation ESP if CE does not have in-house pharmacy	00186, 00310	
Bausch	All	Multiple contract pharmacies allowed with data submission to 340B ESP	00095, 00187, 00884, 13548, 16781, 24208, 25010, 57782, 65649, 66490, 68012, 68682, 70194, 99207	Claims must be uploaded on a store-by-store basis; pricing is only restored for individual locations when a claim has been uploaded to 340B ESP
Bayer	Federal Grantees Exempt ; Started 5/18/23	Multiple contract pharmacies allowed with data submission to 340B ESP; Single contract pharmacy (within 45 miles) allowed if CE doesn not have in-hourse pharmacy	50419	
Biogen	Federal Grantees Exempt	Single contract pharmacy designation through ESP	64406	
BOEHRINGER INGELHEIM	All as of 8/1/23	One contract pharmacy (within 40 miles) and one specialty pharmacy (BI network specialty pharm) through ESP (Data submission is not necessary)	00597	
Bristol Myers Squibb	Federal Grantees Exempt for non-IMiD products(Federal Grantees included for IMiD products)	2 designated contract pharmacies through 340B ESP (1 for IMiD products and one for all other NDCs) Single contract pharmacy designation for Federal Grantees for IMiD products	00003, 00056	
Eli Lilly	All	Multiple contract pharmacies allowed with data submission to 340B ESP	00002, 00777, 66733	Claims must be uploaded on a store-by-store basis; pricing is only restored for individual locations when a claim has been uploaded to 340B ESP
Exelixis	Federal Grantees Exempt	Multiple contract pharmacies allowed with data submission to 340B ESP, single CP with no data submission	42388	Pricing is restored using chain logic
Gilead	All	Multiple contract pharmacies allowed with data submission to 340B ESP	61958	Pricing is restored using chain logic
GlaxoSmithKline	All	Without in-house pharmacy, one CP can be designated. For specialty/oncology products, the single CP designation must be part of GSK's limited pharmacy network listed in memo.	00173	Pricing is restored using chain logic
Johnson & Johnson	Federal Grantees Exempt	Without an entity-owned pharmacy, CE may designate 1 contract pharmacy if it is within 40 miles. With an entity-owned pharmacy, CE may designate 1 additional contract pharmacy if it is within 40 miles and the CE submits claims data for entity-owned and contract pharmacy.	50458, 57894, 59676, 66215	Pricing is restored using chain logic
Merck	Hospitals & CH; All other Federal Grantees Exempt Starts 6/12/23	Must designate one contract pharmacy within 40 miles, if they do not have entity owned.	00006	Pricing is restored for all pharmacy locations when a single claim is submitted
Novartis	DSH, CAH, RRC, SCH, PEDS, CAN, all other entity types exempt	Without entity-owned pharmacy, designate one CP. CP must be within a 40-mile radius of the parent facility allowed	00065, 00078, 00998	
Novo Nordisk	DSH, CAH, RRC, SCH, PEDS, CAN, all other entity types exempt (Starts 7/1/23)	Hospitals restriced to one CP and one Specialty CP. Unlimited wholly owned contract pharmacies allowed with data submission to 340B ESP	00169, 73070, 71090	
Pfizer	Federal Grantees Exempt	In-house entity owned pharmacies protected. Without entity-onwed pharmacy, may designate one CP for Xelijanz through ESP	00069, 70255	Claims must be uploaded on a store-by-store basis; pricing is only restored for individual locations when a claim has
Sanofi	CH, DSH, CAH, RRC, SCH. Excluded are PED, CAN, RW, FQHC LookALike, STD, FP	Hospitals can only designate 1 contract pharmacy, only. CH can use mltiple contract pharmacies allowed with data submission to 340B ESP	00024, 00039, 00075, 00088, 00955, 58468, 72733	Pricing is restored for all pharmacy locations when a single claim is submitted
Teva	Federal Grantees Exempt	May designate 1 contract pharmacy if within 40 miles and if data is submitted to ESP.		
UCB	Federal Grantees Exempt	Single contrat pharmacy designation through 340B ESP		
United Therapeutics	All	Single contract pharmacy designation through United Therapeutics	66302	

State Efforts

- Drug manufacturers restrictions loosened in Arkansas and somewhat in Louisiana.
- Arkansas pursued enforcement actions to strengthen their case.
- Arkansas decision upheld in federal appeals court (March 2024).
  - Process started in May 2021.
  - Drug companies fought the Arkansas Insurance Department (AID) at every step.
  - AID published rule AR Rule 1103 (effective 9/30/22).
  - PhRMA files appeal in December 2022.
  - AID announces start of enforcement for Act 1103 in August 2023.
    - Sent enforcement letter to Novo Nordisk in September 2023.
    - Novo Nordisk sued AID for enforcing ACT 1103 without statutory basis.
  - Today, almost every drug manufacturer has removed restrictions in Arkansas.

blue
PHARMACY CONSULTING GROUP

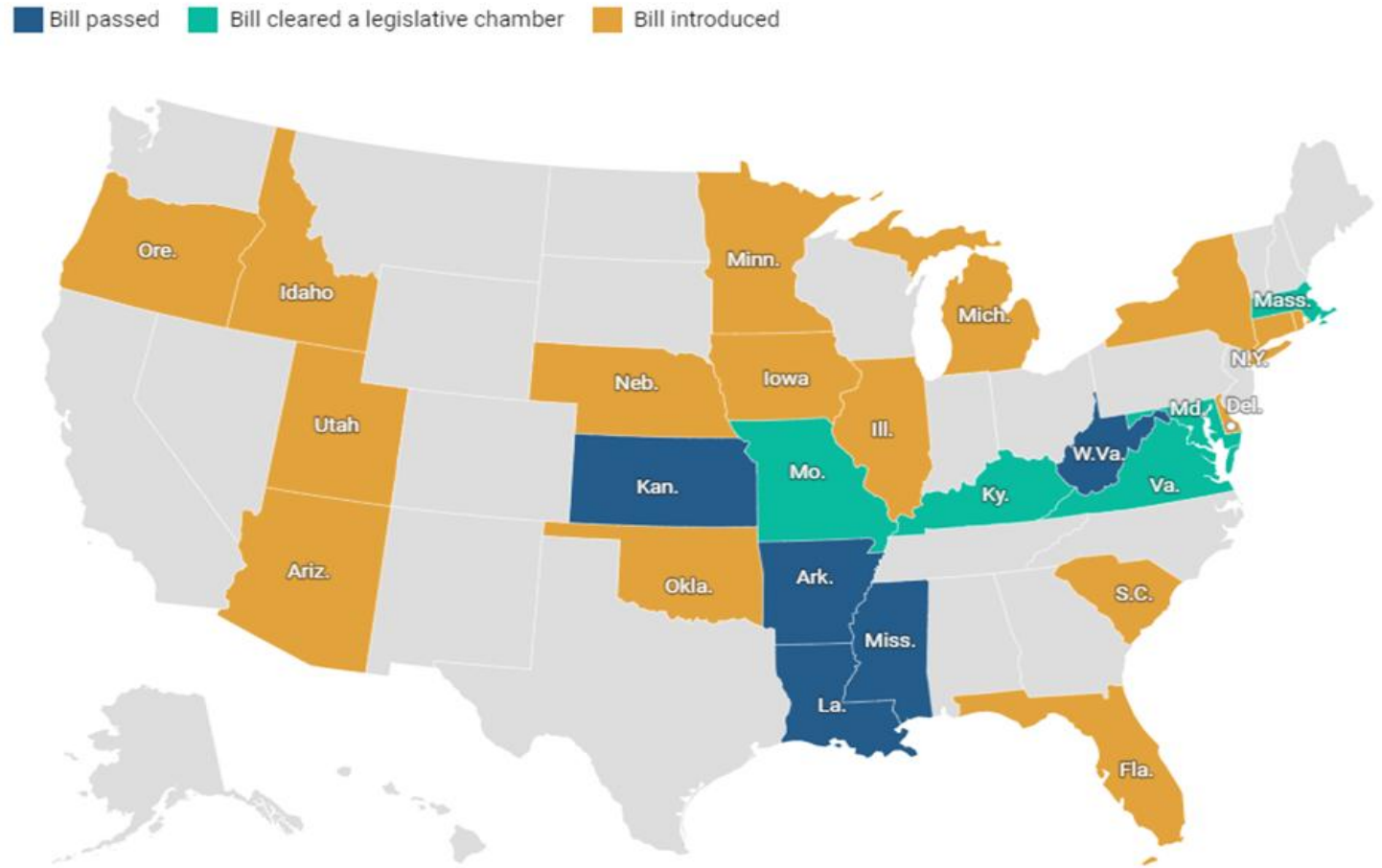
Legislation Tracker: 2023-2024 State Bills and Laws that Prohibit Drugmaker 340B Contract Pharmacy Restrictions



Map: updated as of March 8, 2024 • Created with Datawrapper

PHARMACY CONSULTING GROUP

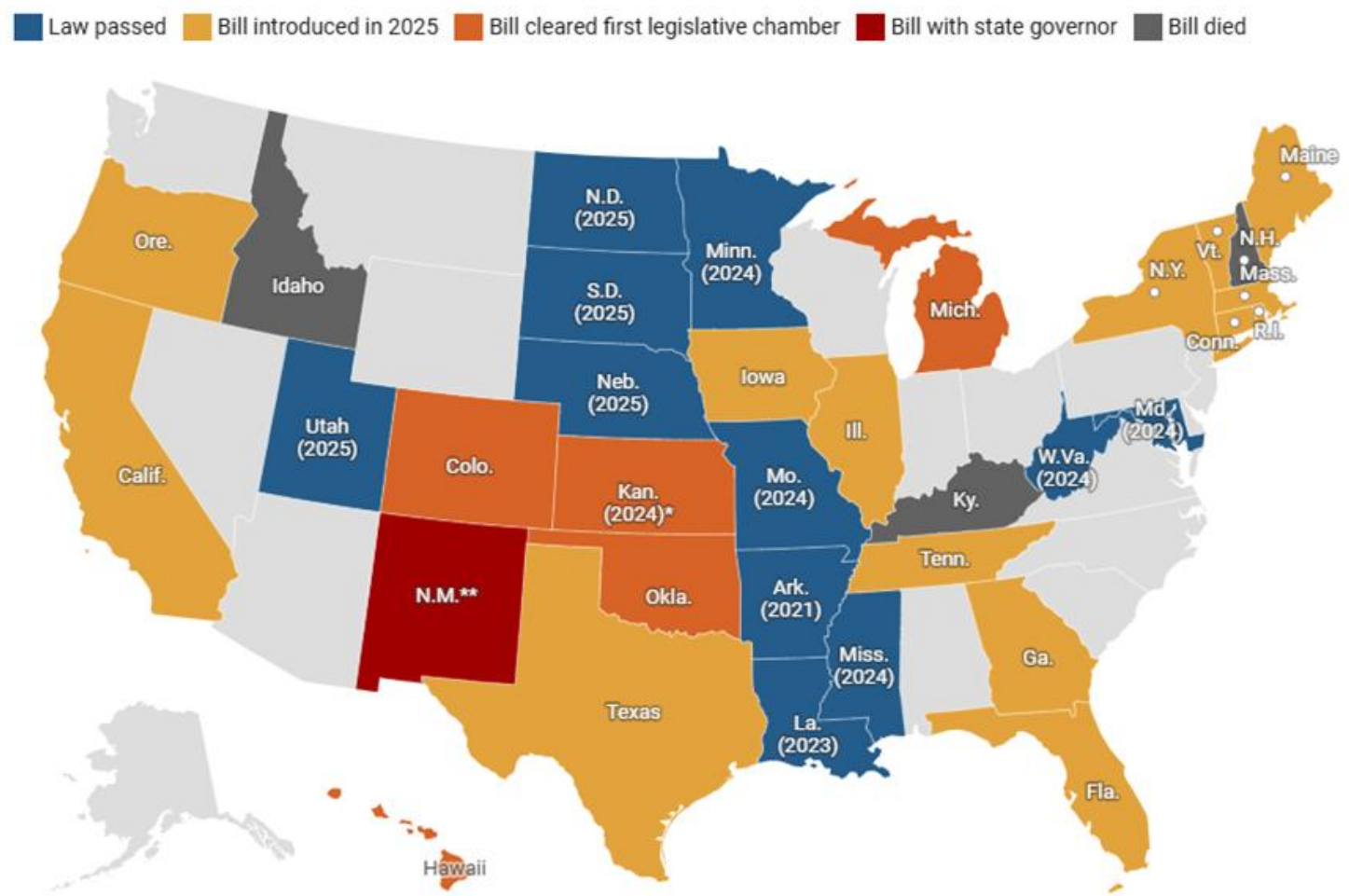
Legislation Tracker: 2023-2024 State Bills and Laws that Prohibit Drugmaker 340B Contract Pharmacy Restrictions



Map: updated as of May 3, 2024 • Created with Datawrapper

blue
PHARMACY CONSULTING GROUP

340B REPORT 2025 State Legislation Tracker: Contract Pharmacy Access Bills and Laws



** Kansas enacted 340B contract pharmacy access provisions in 2024, but the state attorney general argued in federal court that the law is unenforceable and does not "prohibit or forbid anything."*

*** New Mexico's bill only applies to community health centers.*

blue
PHARMACY CONSULTING GROUP

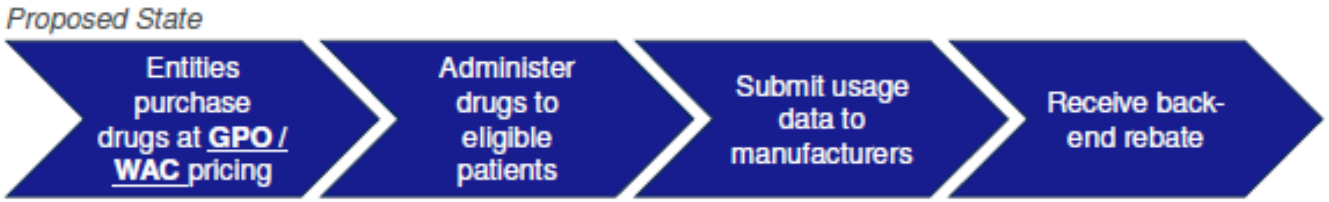
The Reality

blue
PHARMACY CONSULTING GROUP

Threats

Rebate Model versus current model

- Four manufacturers (J&J, BMS, Eli Lilly, Sanofi) attempt to change to rebate model
- HRSA/HHS strongly opposed such models with termination from Medicare & Medicaid
- Current administration hinted to uphold stance



blue
PHARMACY CONSULTING GROUP

Threats

Inflation Reduction Act

- Drug price negotiation program
  - Drug selection – Part D drug for 2026 & 2027
  - Maximum Fair Price (MFP)
- Rebates are paid by drug manufacturers on Part B & Part D drugs
- Changes to both parts expected
- Part B reimbursement reduction

Important Dates

- January 1, 2026 – Drug negotiation take effect on 10 Part D drugs
- January 1, 2028 – Part B drugs to be included in negotiation

Impact

- Slow rate of price increases may change reimbursement and reduce payment to 340B entities

blue
PHARMACY CONSULTING GROUP

Threats

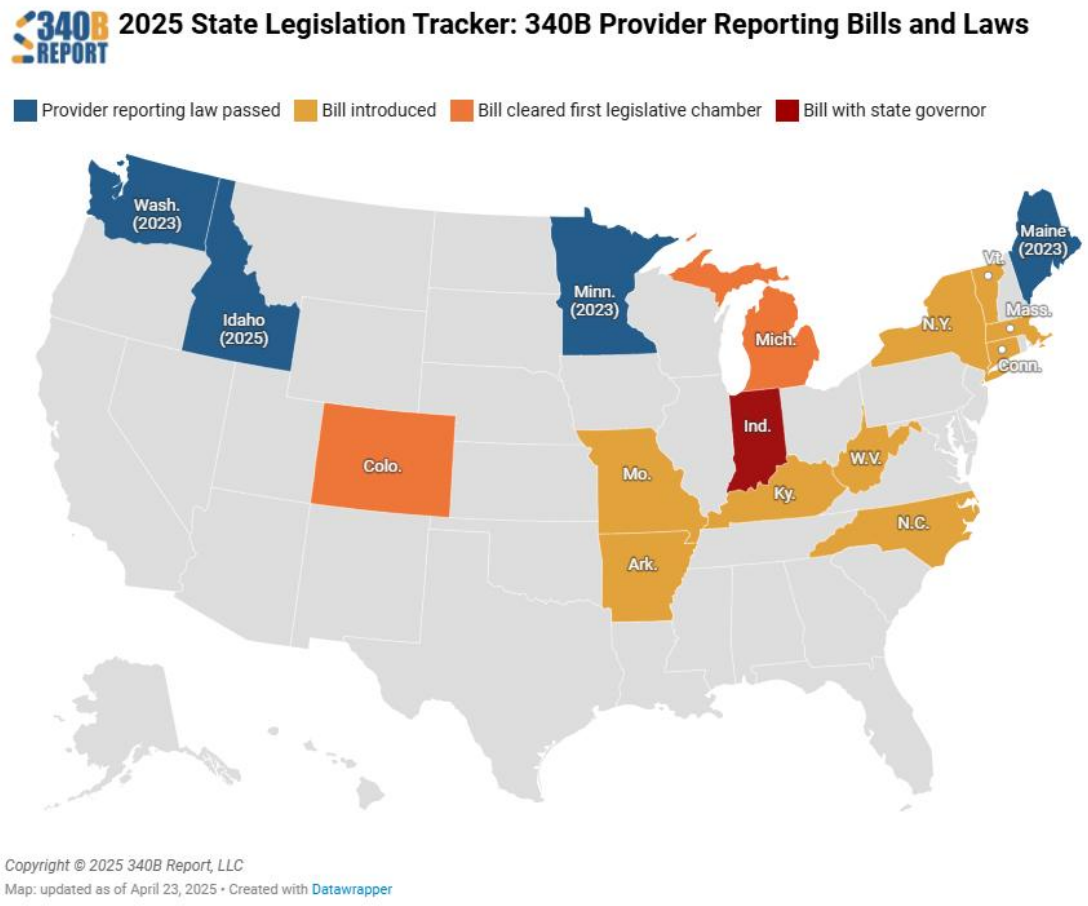
Site Neutrality Proposal

- Policies expanded site-neutral payments and low-cost care delivery models are supported by current administration.
- Part B drug pricing reduction potential
  - Similar to 2018
  - Reduction from ASP + 6% to ASP – 22.5%
  - Millions lost by 340B hospitals
  - Overturned by Supreme Court 2023
  - Medicare repayment required
  - Struggle to recoup money from Medicare advantage plans
  - May affect more 340B entities than in 2018
    - TB claim modifiers on certain Part B drugs

blue
PHARMACY CONSULTING GROUP

Threats

Reporting requirements are closer to a reality than not starting with the states in blue below



blue
PHARMACY CONSULTING GROUP

Threats

In April 2024, Indiana SB 118 cleared the Senate 48-0 and House 89-2 votes

- Hospitals affected
  - DSH, Childrens, CAH, RRCs
  - Submit report to the State (Dept of Health) by April 1st each year
- The report must include:
  - The total acquisition cost and payment received for 340B drugs, sorted by payer type;
  - The total payments made to contract pharmacies and third-party administrators;
  - Descriptions of how 340B savings are used to support charity care or community benefits;
  - The percentage of low-income patients who receive discounted or free medications.
- The Indiana Department of Health will publish an aggregated report by November 15 each year.
- Hospitals that fail to report would face a $1,000 daily fine until the information is submitted.

blue
PHARMACY CONSULTING GROUP

340B Future

- What should a covered entity do?
  - So many questions/concerns still exist about what will happen.
    - Will drug manufacturers continue to deny 340B pricing through contract pharmacy relationships or obtain access to the desired data?
    - Which States will work to protect 340B Hospitals?
    - How much time should I take following all of the legal proceedings?
    - Will 340B become a rebate model?
    - Will reimbursement be less in the future?
    - Will 340B look the same in five years?
  - Regardless, actions **YOU** take today can protect the much-needed revenue streams until Washington, HHS, HRSA, OPAIS or individual States act**!**

blue
PHARMACY CONSULTING GROUP

Monitor KPI

Please consider monitoring these KPI for program success

- Savings, revenue, reimbursement
- 340B purchases versus total
- Provider productivity and leakage
- Capture and participation rates
- Specialty prescriptions versus traditional retail
- Patient adherence due to program
- Patient benefits

blue
PHARMACY CONSULTING GROUP

340B Future

- Please consider some of the following actions if you have not already done so:

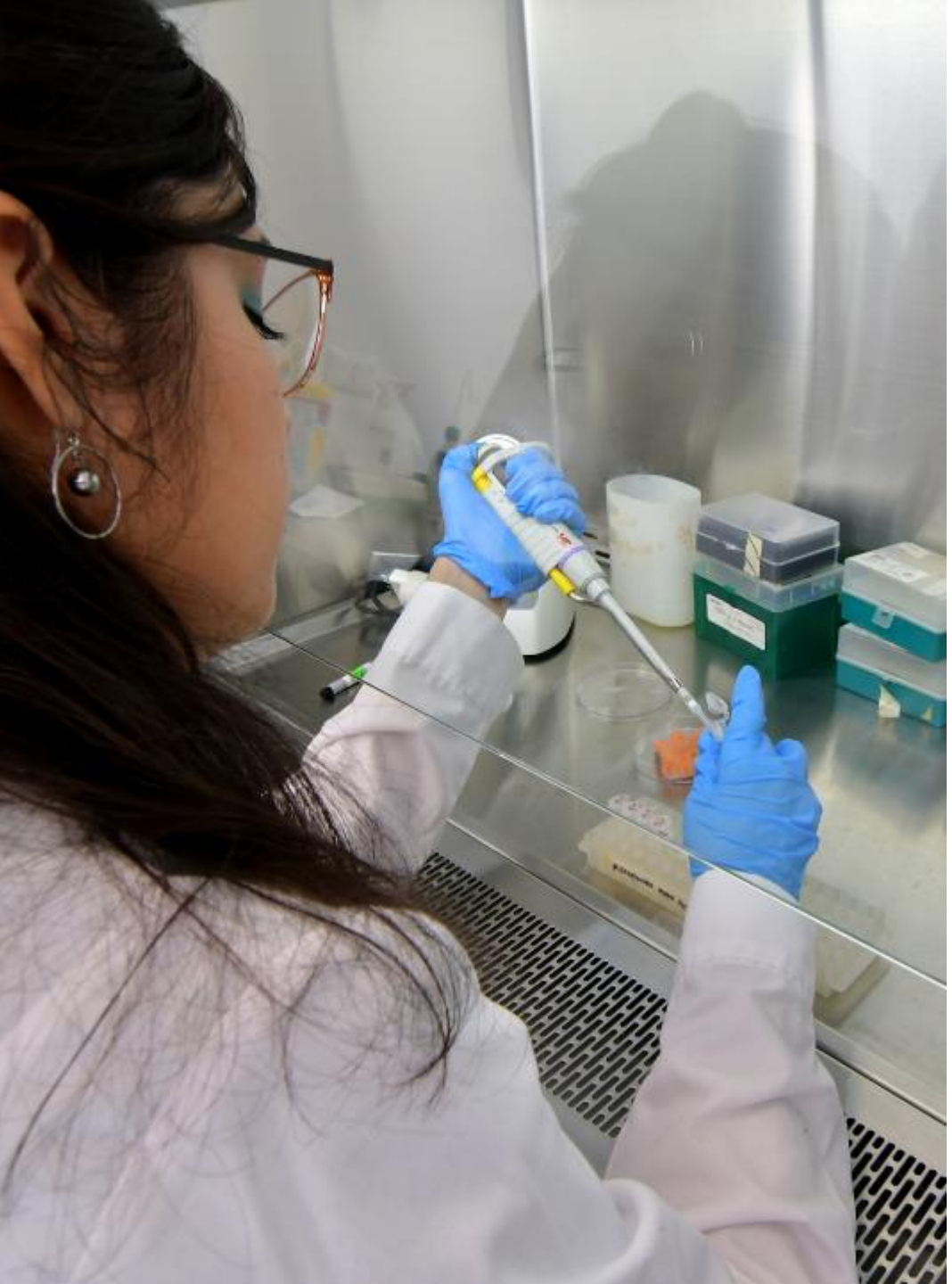
Protect your revenue streams now	Maintain a well run, compliant program	Update your policies and procedures
Consider additional contract pharmacies	When possible, set up a designated contract pharmacy when allowed by drug manufacturers that restrict 340B pricing	Consider referral prescription capture & MTM programs
Evaluate an entity-owned retail and specialty pharmacy	Consider alertnative distribution model to bypass restrictions	ESP data submission

blue
PHARMACY CONSULTING GROUP

Medication Therapy Management Program

- Alternative to referral prescription capture
- Expanding the definition of a “patient”
- Use of clinical pharmacist visit as potential qualifying encounter
- Memorandum of Understanding (MOU)
- Increase in specialty prescription capture
- Can be used to reduce self-funded employer insurance costs
- Must be set up properly to avoid compliance risks

blue
PHARMACY CONSULTING GROUP



Entity-Owned Retail & Specialty Pharmacy

- Multiple advantages exist for a covered entity to own and operate its own retail pharmacy
  - Potential for continued 340B pricing from some or all manufacturers
  - New revenue streams for covered entities
  - Less reliance on big box store pharmacy partners
  - More control over patient care and pharmacy access
  - Access to less expensive drugs for patients
  - Specialty pharmacy opportunities equate to better care
  - Potential savings available for self-funded health plans and employees

blue
PHARMACY CONSULTING GROUP

Summary

1. The 340B Program currently has many uncertainties.
2. Drug manufacturers are not caving into the legal and political pressures.
3. This battle could last for some time.
4. Covered entities should protect its current revenue streams.
5. Consider additional revenue opportunities and program maximization efforts.
6. Support all local, state, and national advocacy efforts.
7. Do your due diligence on the ESP portal and claims submission process.
8. Be HRSA audit ready!!!

blue
PHARMACY CONSULTING GROUP

Questions?

Thank you for attending!

If you have any additional questions, please contact today's presenters or your local Blue & Co. advisor.

Jason Prokopik, Pharm.D. 340B ACE
Blue & Co., LLC
317.713.7916
jprokopik@blueandco.com

Alyssa Kramer, Pharm.D. 340B ACE
Blue & Co., LLC
317.2757404
akramer@blueandco.com