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Legal Update: Pharmacy Benefit Industry and Emerging Trends

Presented by: Candida Ruesga and Leah Tinney

Candida Ruesga

Candida is a Partner at The Phoenix Law Group with 25 years in the legal practice, including over a decade dedicated exclusively on the pharmacy benefit management industry.

She represents PBMs, health plans, and pharmacies in all aspects of pharmacy benefit management. As a former commercial litigator, she brings a practical lens to transactional and compliance work, with a focus on contracts and compliance strategies that help clients avoid future disputes, litigation, and regulatory exposure before they arise.

Leah Tinney

Leah Tinney provides regulatory guidance to PBMs and advises on a wide range of legal and compliance matters across the pharmacy industry. Her practice includes licensing, Anti-Kickback Statute compliance, contract negotiation, and adherence to complex state and federal healthcare regulations. Leah partners with cross-functional teams to support compliant innovation across pharmacy and healthcare operations.

Leah brings valuable perspective from her experience as in-house counsel. She embraces collaboration and creative problem-solving, and enjoys helping teams navigate regulatory challenges with clarity and confidence.

Presentation Roadmap

Federal Updates

State Regulation Trends & Enforcement

Key Takeaways

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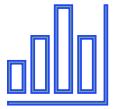
Federal Updates

Consolidated Appropriations Act of 2026

Rebate Pass-Through

Contracting & Audits



Transparency Reporting

Consolidated Appropriations Act of 2026

Rebate Pass-Through Requirements

Effective for plan years beginning Aug 3, 2028

Exception: Unexpired contracts

PBMs must pass through 100% of rebates, fees, alternative discounts, and other remuneration

Note: Subcontractor remuneration also be passed through

Quarterly remittance within 90 days and fully enumerated disclosure

Plans may audit their PBM at least once per year

Plan must notify DOL if PBM does not pay unremitted amounts 90 days after demand

Consolidated Appropriations Act of 2026

PBM Contracting & Auditability

PBM contracts with aggregators/GPOs must be available for plan audit (reasonable confidentiality limits)

Rulemaking forthcoming on remittance processes, audits, and fiduciary disclosures

Consolidated Appropriations Act of 2026

PBM-To-Plan Transparency Reporting

- Due every 6 months (quarterly upon plan request)
- Agency rulemaking will specify format and content
- Statutory format requirements: plain language, machine-readable, HIPAA and civil rights compliant
- A PBM may impose reasonable limits to prevent unauthorized disclosures

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Consolidated Appropriations Act of 2026

- Summary for plan use
- Summary for member use
- Total gross and net spending on covered drugs; total expected/received rebates/fees/discounts per NDC
- If feasible, manufacturer copay assistance per NDC
- Broker/consultant compensation tied to PBM referrals/retention
- Explanation of any steering in the plan design

Universal Data Elements (All Plans)

NOTE: More detailed reporting required for "Specified" Large Employers/Plans

CAA 2026 – Medicare Requirements

Any Willing Pharmacy

- Reasonable and relevant contract terms ***defined***
- Must include dispensing fees

Rebate Pass-Through

- NO remuneration from Part D utilization (PBM+ Affiliates)
- Bona fide service fees (flat $ amount; FMV; actual services)

Reporting and Disclosures

- Detailed Annual Claims Data Reporting
- PBM officer-certified reports to plan summarizing rebate-related formulary placement agreements

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DOL Proposed Rule

Published Prior to CAA 2026

(Published 1/31/2026)

Applies *only* to Self-Insured ERISA

Requires Pre-Service Estimates Reporting

Semi-annual Reporting

(like CAA reporting with a few differences)

Extended comment period due to CAA 2026

(Ended 4/15/2026)

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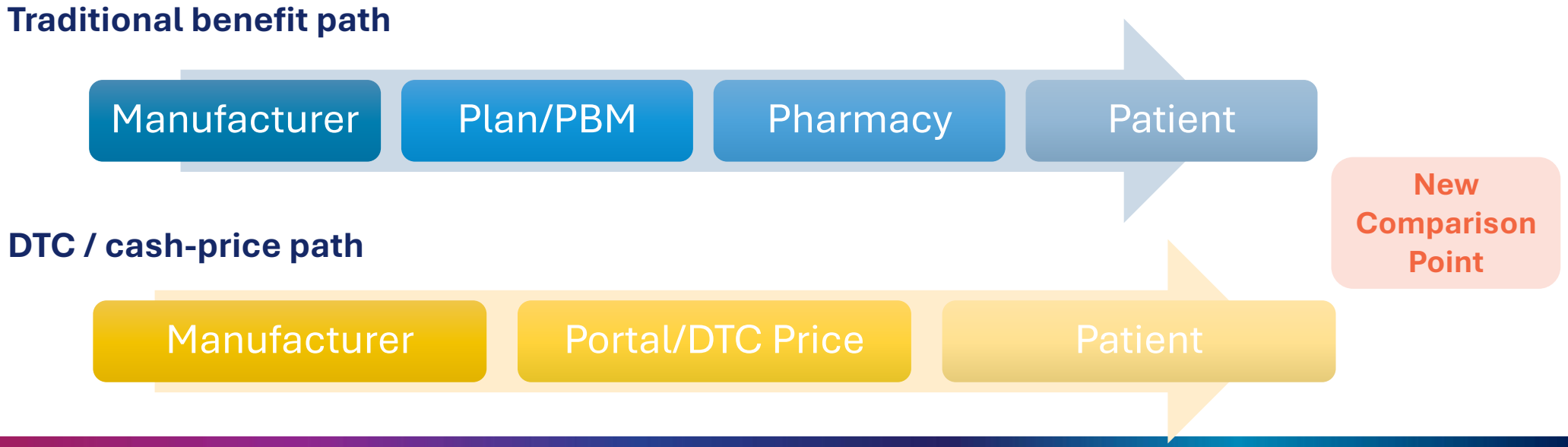
Direct to Consumer Programs (TrumpRx)

- DTC programs may not replace PBMs but they create new price comparisons outside the plan benefit



Direct to Consumer Programs (TrumpRx)

- Issue is less about replacement than price comparison + claims visibility

PBM relevance

May pressure formulary, rebate, network, and "best price" value story

Plan issues

Claims gaps: OOP tracking, deductibles, accumulators, UM visibility

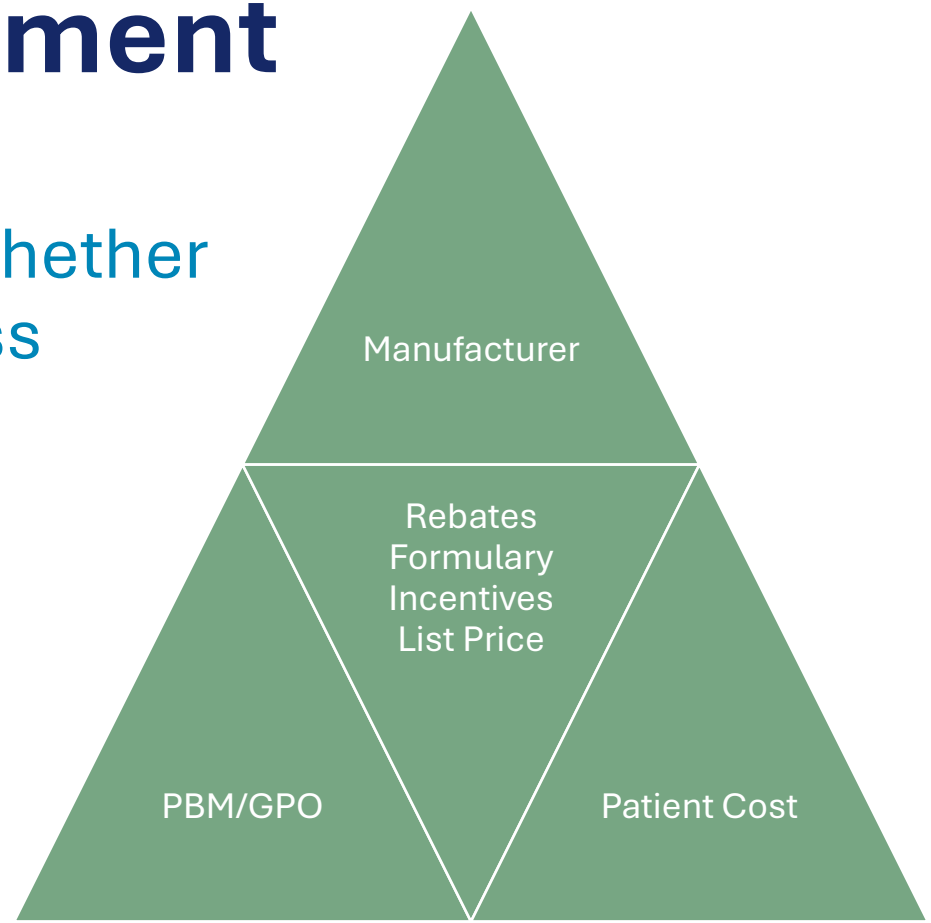
Consumer issues

Clearer cash prices, but possible benefit confusion and fragmented safety data

Takeaway: Watch for whether DTC prices become a real comparator to PBM-administered benefits

FTC Insulin Rebate Enforcement

- FTC scrutiny is moving from disclosure to whether PBM incentives affect drug costs and access
- What Happened
  - FTC announced an Express Scripts settlement over insulin rebate practices
  - Broader case targeted major PBMs and affiliated GPOs
  - Theory centers on rebate-driven formulary incentives and patient cost exposure



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Key Message:

Rebate design is now an antitrust & consumer-protection issue, not just a contracting issue

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FTC Insulin Rebate Enforcement

- Enforcement focus is on incentives, documentation, and patient exposure

- **Rebate preference vs. lower-list-price alternatives**
- **Patient cost-sharing exposure**
- **Manufacturer payment treatment**
- **Formulary placement incentives**
- **Affiliate / GPO economics**
- **Formulary decision documentation**

Practical standard: can the PBM explain and defend why products are preferred?

State Regulation Trends & Enforcement

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Universal. But Not Uniform.

- Regulated in All 50 States
- Broad and Varying Definitions
- Real Consequences

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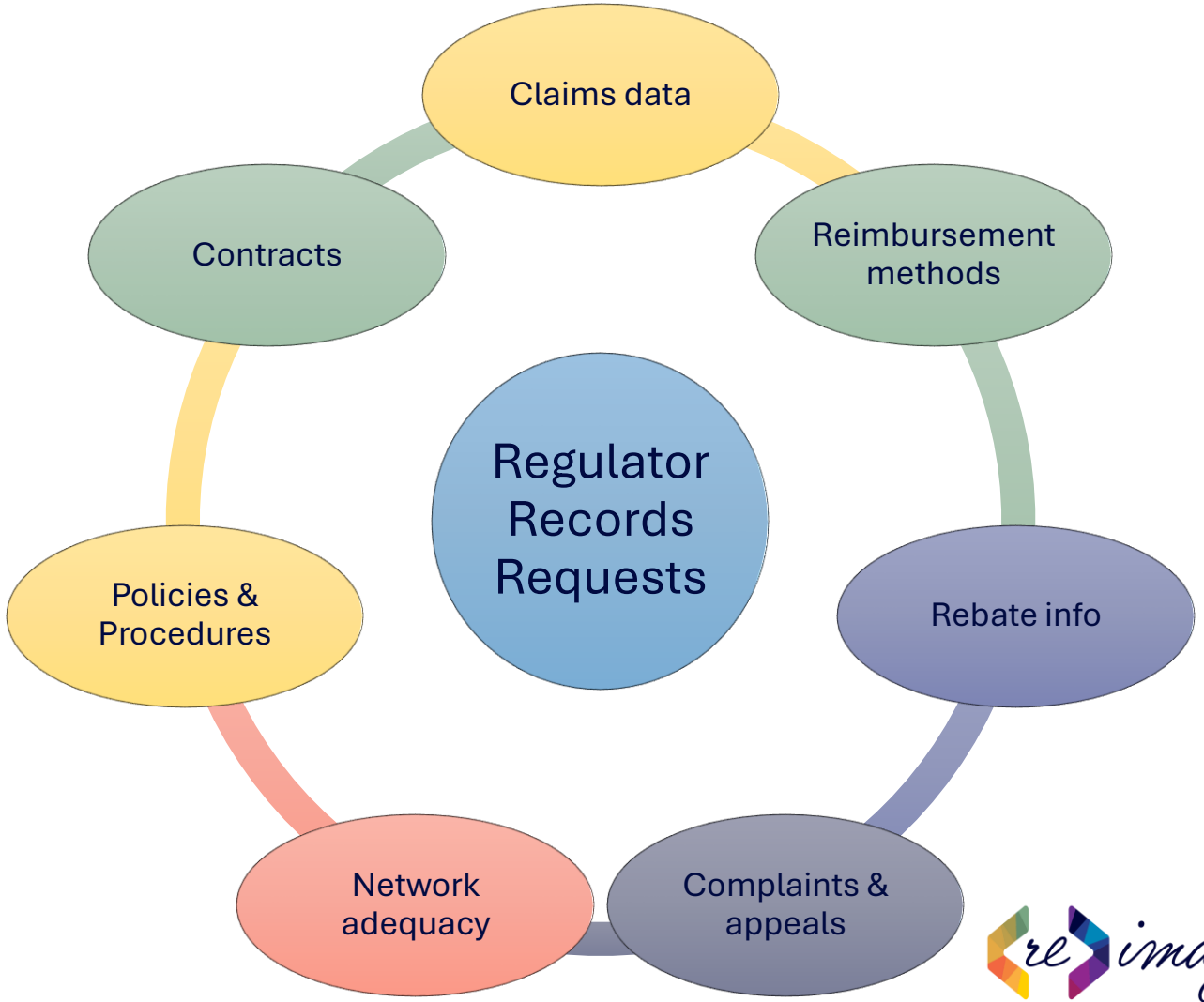
Documentation & Transparency

- The transparency trend is evolving into an examination trend
  - States are moving from broad PBM rules to structured oversight
  - PBM compliance is increasingly document-driven and exam-ready
  - Regulators may expect PBMs to produce contracts, claims data, rebate information, reimbursement methodologies, complaints, appeals, audit records, and policies

Documentation & Transparency

Operation alignment needed

- Legal
- Regulatory
- Finance
- Network
- Claims
- Client service teams



Documentation & Transparency

- Three oversight tools to watch

Licensing	Reporting	Market Conduct Exams
• More detailed registration / renewal requirements • Increased fees and assessments, including per-member fees	• More data to agencies • More disclosures to clients / plan sponsors	• Broader document requests, audits, corrective action plans, and penalties

Key Takeaway: Compliance is becoming more like insurance compliance: recurring filings, auditable records, and regulator-ready operations

Documentation & Transparency

- Three oversight tools to watch

New Market Conduct Exams in FL, TN, WV, VT, IN, IA (limited scope)

- FL currently being challenged by PCMA
  - Failure to engage in sufficient rulemaking
  - Burdensome costs

Market Conduct Exams

- Broader document requests, audits, corrective action plans, and penalties

Business Model Mandates

Moving Beyond Transparency and Oversight

- Rebate Pass-Through
- Minimum/Mandated Pharmacy Reimbursement
- Coverage Mandates
- ***De-Linking PBM Compensation***
- ***Vertical Integration & PBM Owned Pharmacies***

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De-Linking Compensation

Colorado HB1094

(Eff. 1/1/2027)

California SB41

(Eff. 1/1/2026

- PBM compensation **limited** to PBM fee
- PBM fee must be flat $ amount
- Fee disclosed in written agreement
- Must be bona fide value of service
- Cannot be tied to price of drugs, amount of rebates, formulary placement

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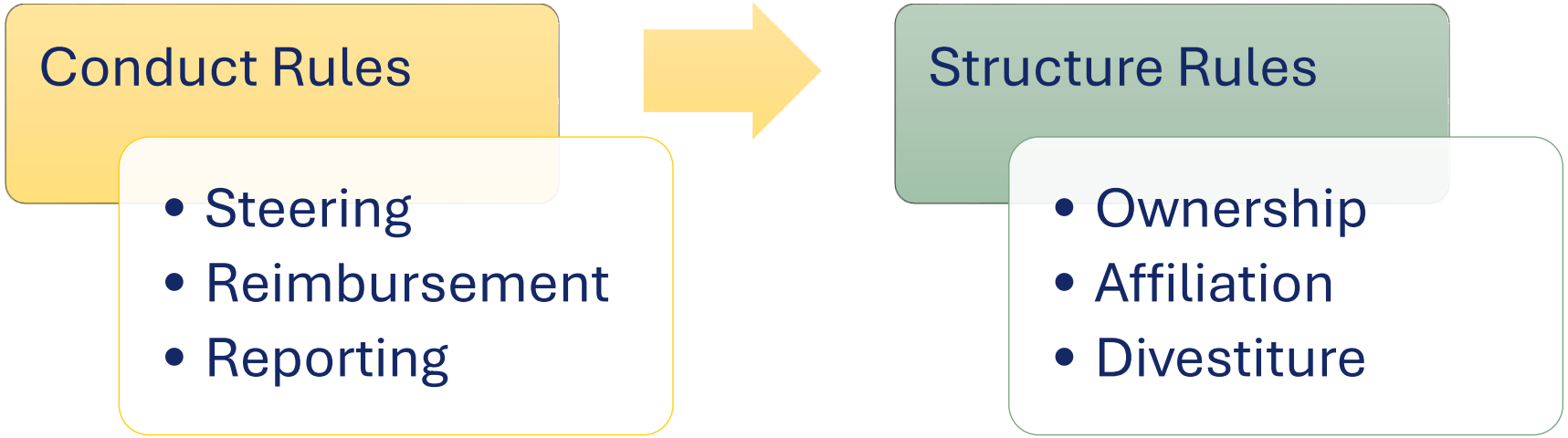
Vertical Integration & PBM-Owned Pharmacies

- States are testing whether PBM regulation can reach corporate structure (not just conduct)



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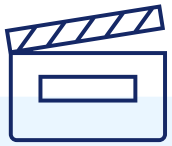
Vertical Integration & PBM-Owned Pharmacies

Arkansas: Test case

- First sweeping PBM-owned pharmacy ban
- Preliminarily blocked before Jan. 1, 2026 effective date



Tennessee: Take Two

- FAIR Rx Act targets PBM pharmacy ownership
- CVS suit followed hours after enactment

Others: Watch list

- Louisiana / Indiana considered similar concepts
- Many proposals stop short of full separation

Litigation themes: dormant Commerce Clause, ERISA / Part D preemption, pharmacy access, mail-order access, local pharmacy protection.

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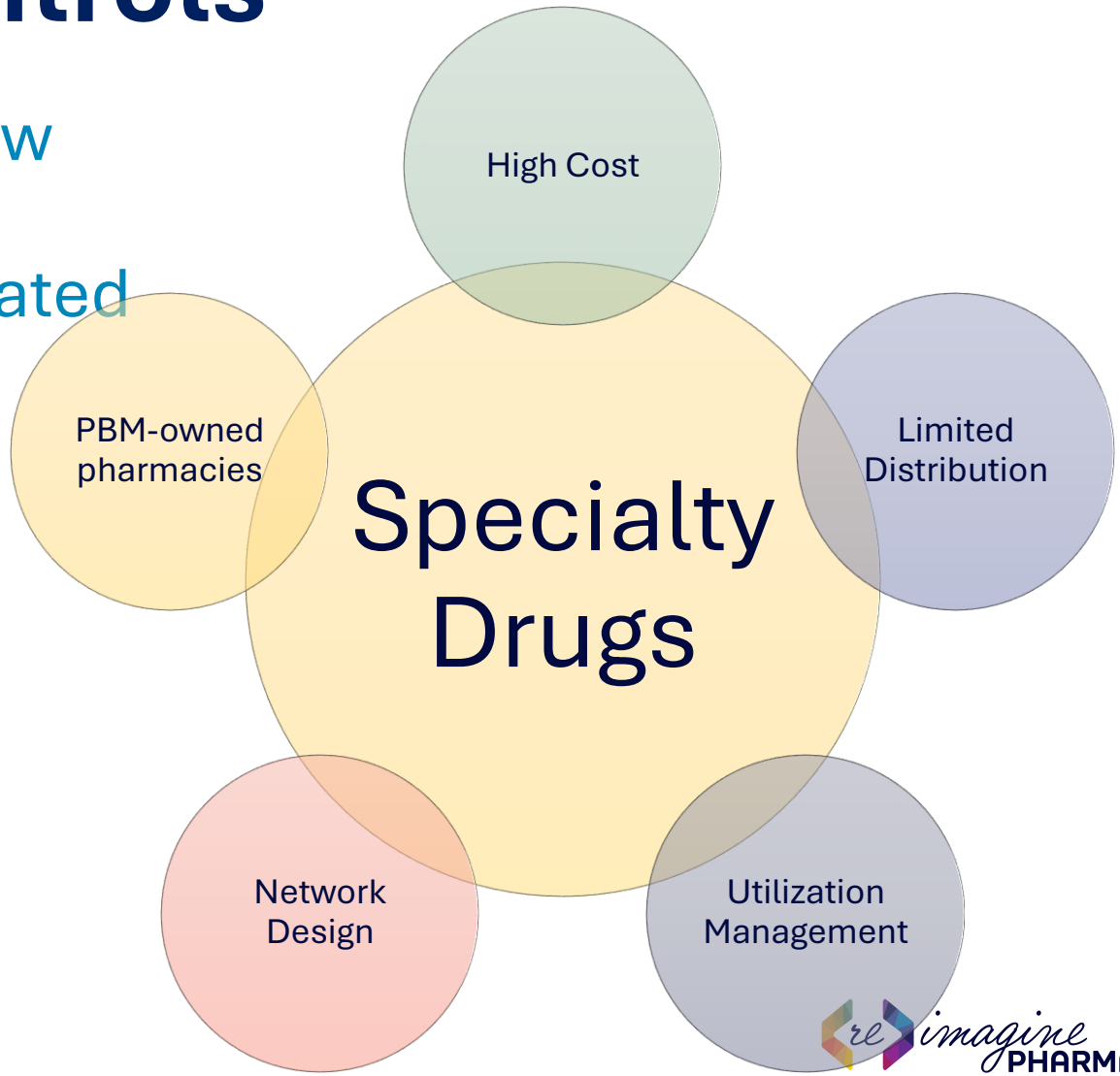
Specialty Pharmacy & Drug Designation Controls

- States are scrutinizing how “specialty” labels affect access, choice, and affiliated pharmacy steering.



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Specialty Pharmacy & Drug Designation Controls

Iowa SF 383: Attempts to target specialty-drug designations used to prevent or limit access through in-network pharmacies.

Regulatory concern: PBMs may use specialty classifications to narrow dispensing channels or steer volume to affiliated pharmacies.

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Specialty Pharmacy & Drug Designation Controls

- **Operational question:** can the PBM justify specialty status with objective criteria — clinical complexity, handling, monitoring, safety, or distribution limits?
- **Takeaway:** Specialty-drug designation is becoming an access and steering issue, not just a clinical or operational classification.

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Key Takeaways

Key Takeaways

Federal reforms are targeting PBM economics and incentives

2026 CAA, DOL fee-disclosure proposal, and FTC insulin rebate action all point toward scrutiny of compensation models, rebates, formulary incentives, GPO arrangements, and plan fiduciary oversight

States are increasingly regulating PBM business models, not just PBM conduct

Newer laws and proposals target delinking, pharmacy reimbursement, rebate treatment, specialty-drug designations, and vertical integration

Key Takeaways

Litigation will define the boundaries of the next phase of PBM regulation

Cases involving ownership bans, specialty pharmacy restrictions, ERISA / Medicare preemption, and market conduct exam authority will shape how far states can go and how PBMs must operationalize compliance

State regulation is universal, but the operational requirements vary widely

Every state now regulates PBMs in some form, but the key compliance question is which lever each state uses: licensure, reporting, reimbursement rules, spread-pricing limits, rebate treatment, steering restrictions, or market conduct exams