Session – Panel Discussion

Transforming Pharmacy Benefits: Embracing the Push for Transparency, Innovation, and the Future of PBM Solutions

Moderator: Hugh Gallagher

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Panelists:

- **Lisa Boyd,** Co-founder and CEO | Liviniti
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- **Rachel Straus,** Founder and CEO | PBM Princess, LLC

Embracing Transparency

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Legislative Oversight

2025: President Trump, RFK Jr., Dr. Oz, Makary




Previously introduced bills which garnered bipartisan support (S1339 and S1542) focused on transparency requirements, prohibition on spread pricing and rebate reform did not pass in December of 2024.

The Health Subcommittee reconvened in February 2025. Lawmakers met to discuss “An Examination of How Reining in PBMS Will Drive Competition and Lower Costs for Patients.”

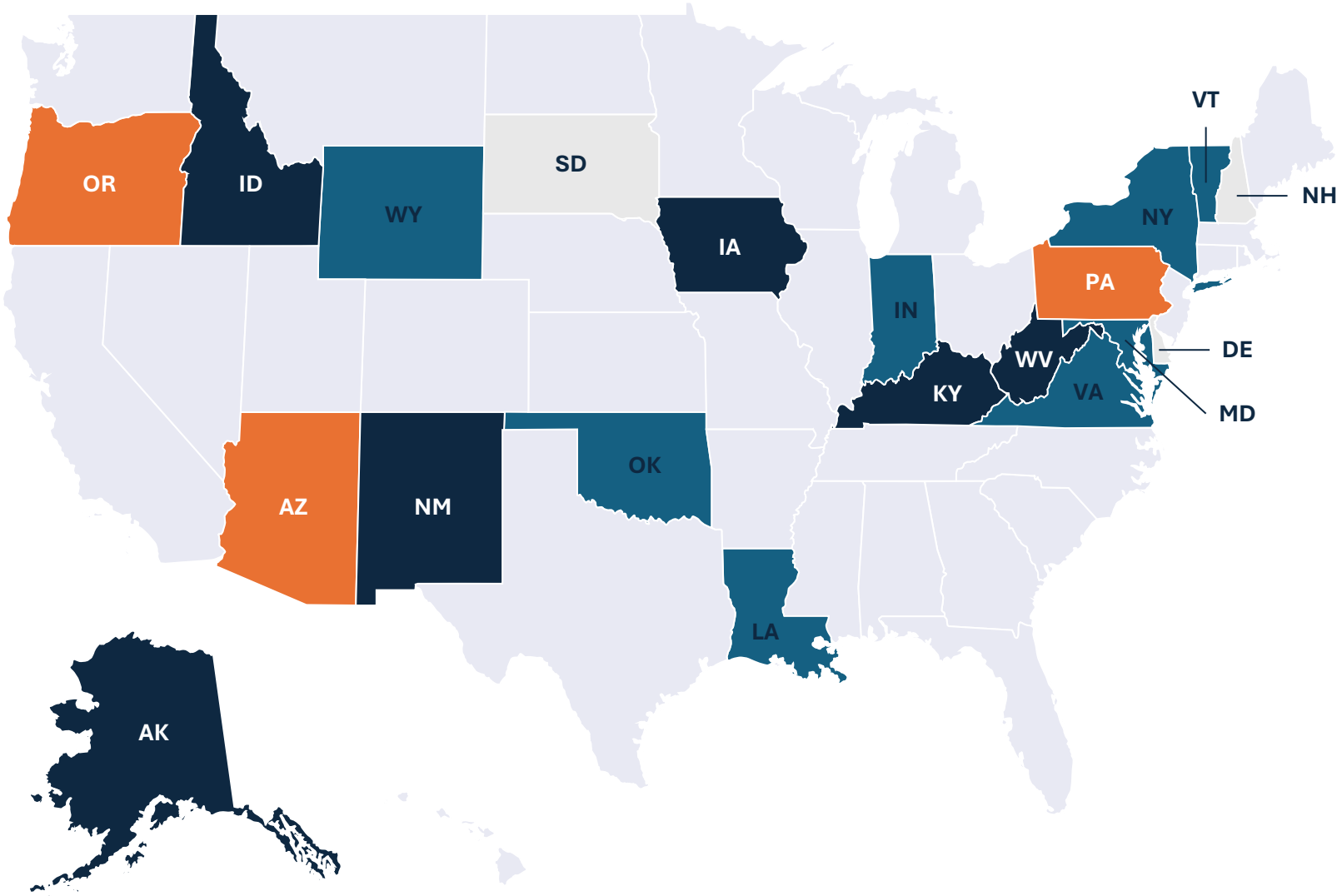
High probability new PBM legislation will be reintroduced in 2025 with focus on promoting transparency within PBM contracting and commercial market practices

Up For Discussion

- Spread Pricing
- Pass Through of Rebates
- Retroactive Fees (DIR)
- Patient Steering
- Audit Practices
- Appeals Processes
- Delinking
- ERISA Preemption

PBM State Law Update

Patient Steering, PBM Reporting Requirements Expanded and Ban on Spread Pricing

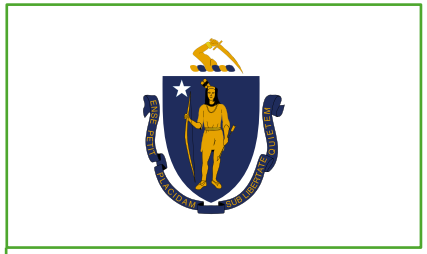


Which states enacted PBM legislation in 2024?

- Pricing transparency
- 340B
- Increased reporting requirements
- Patient steering and affiliate reimbursement

Source: MultiState. Data as of 12/11/2024

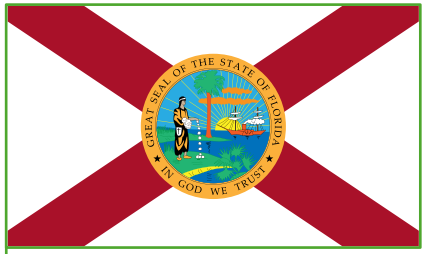
States Focusing on PBM Reform 2025



Massachusetts

Passed

Imposing cost sharing limits, mandatory licensing and regulation of PBMs, reporting requirements.



Florida

Market conduct exams **underway.**

Oklahoma

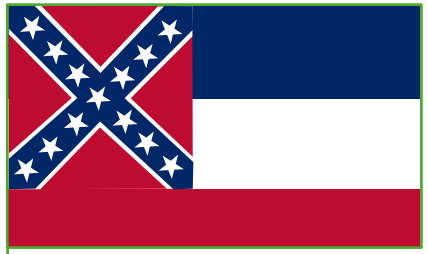
The Patient's Right to Pharmacy Act

It restricts SI Plans on network and formulary choice.

Arkansas

HB 1150 - Passed

Bans PBMs from owning pharmacies within the states, includes operating a mail order only pharmacy.



Mississippi

SB 2677 & HB 1123

Focuses on PBM regulation and oversight.

McKee Foods Corporation v. BFP, Inc.,

- On **March 31, 2025**, the U.S. District Court for the Eastern District of Tennessee ruled that **ERISA supersedes key provisions of Tennessee laws**
  - **Federal Preemption Affirmed**
  - **Plan Design Autonomy Protected**
  - **Incentive Structures Upheld**
  - **Fiduciary Responsibilities Clarified**
  - **Implications for Multi-State Employers**

The court's ruling is a positive development for sponsors of self-insured ERISA plans.

Innovative Payment Models

340B Insights

Hospitals and other Covered Entities are accused of:

Profiting from 340B without necessarily benefiting patients or reinvesting the savings for patients

Pursuing duplicate discounts from 340B pricing and rebates from payers

Growing 340B drug purchases through explosion of contract pharmacies

Drug Manufacturers:

Have restricted contract pharmacy use

Have attempted to move from a discount to rebate model

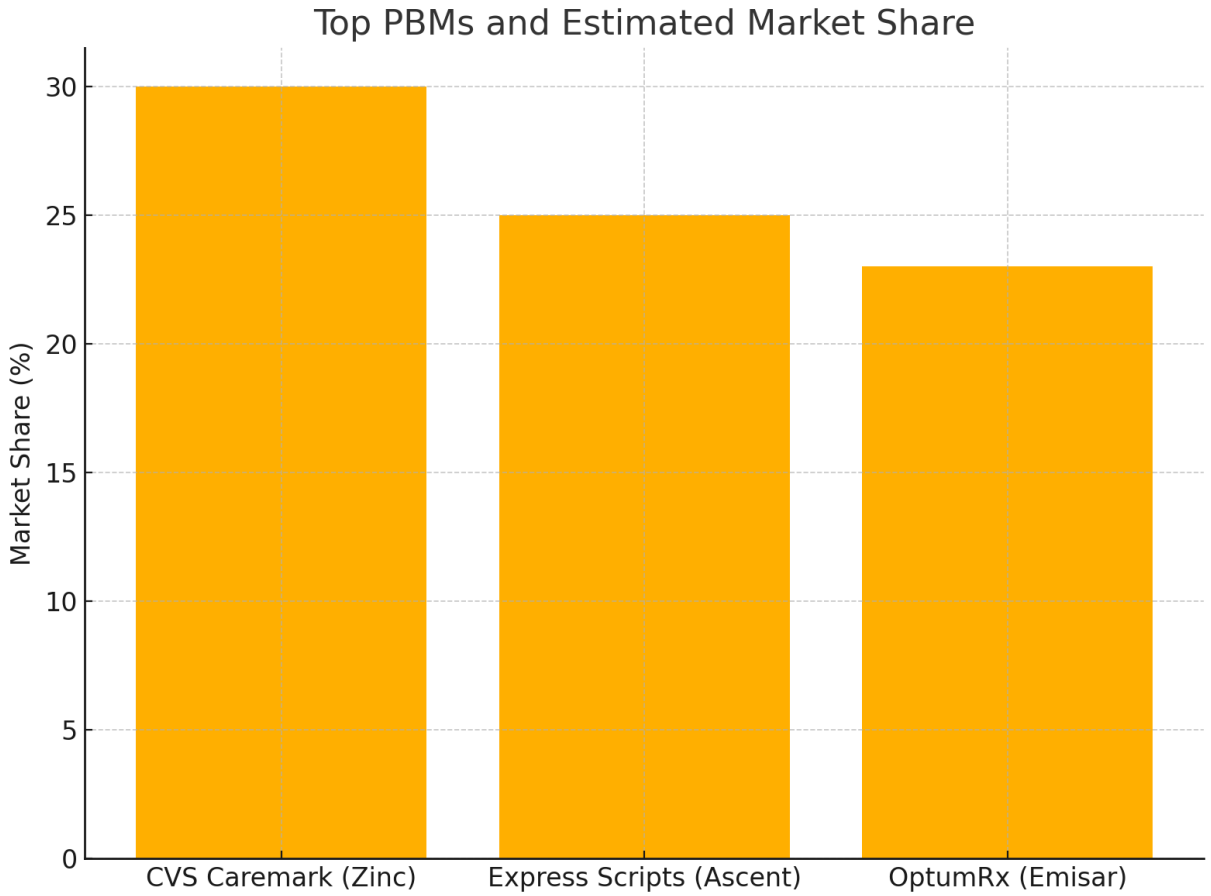
Regulatory:

States are fighting back by enacting laws for contract pharmacies

Federal courts are fighting the proposed rebate model as being unaffordable

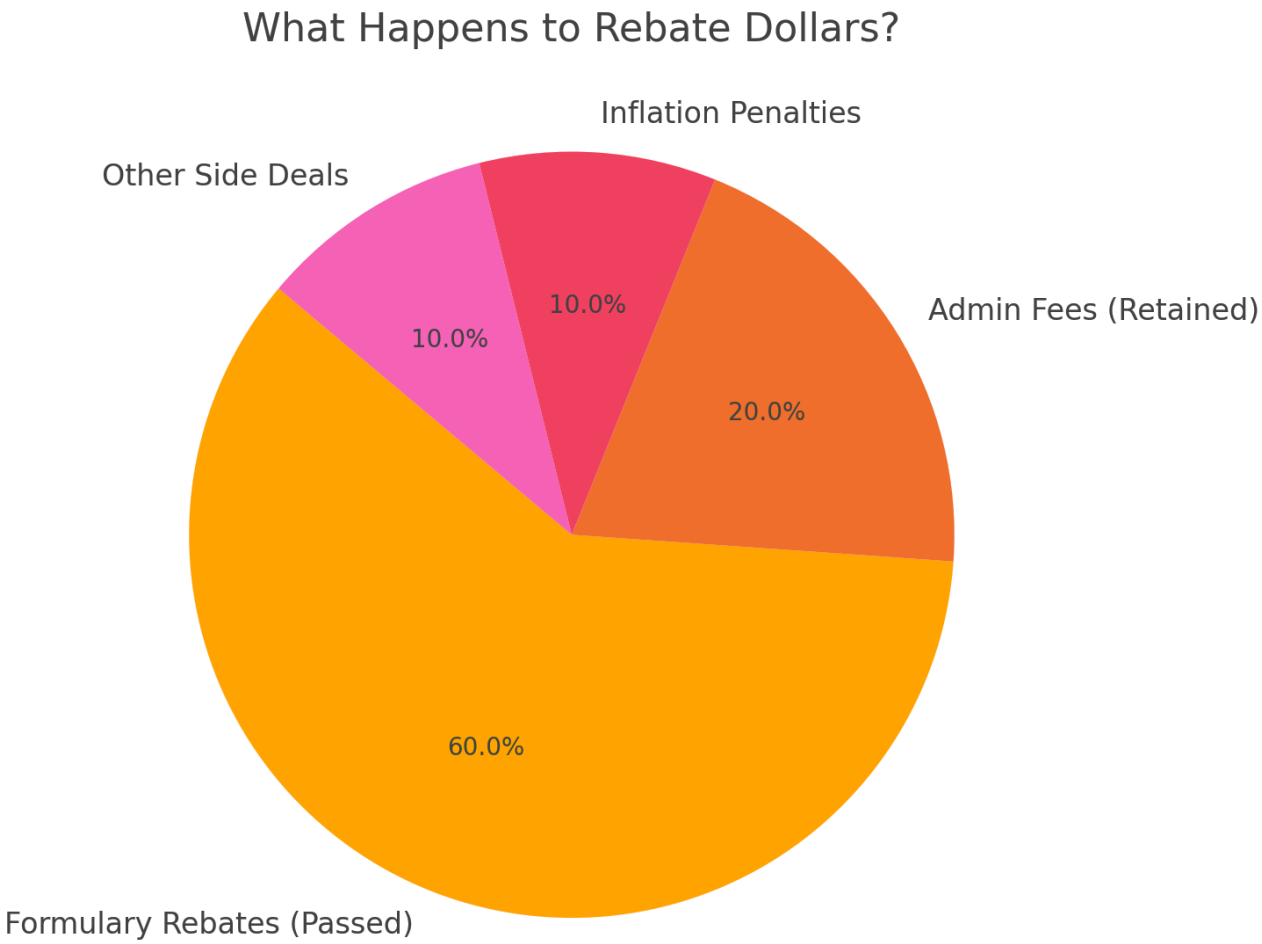
Rebates and the News

- **Dominance of Major PBMs:** CVS Caremark, Express Scripts, and OptumRx process **nearly 80%** of all Rx claims
- **PBMs have their own GPOs for rebates:** Zinc (CVS), Ascent (Express Scripts), Emisar (OptumRx)
- **FTC is investigating** PBM-owned GPOs for **anti-competitive behavior**
- **Rebates** may increase **list prices**, disadvantaging consumers



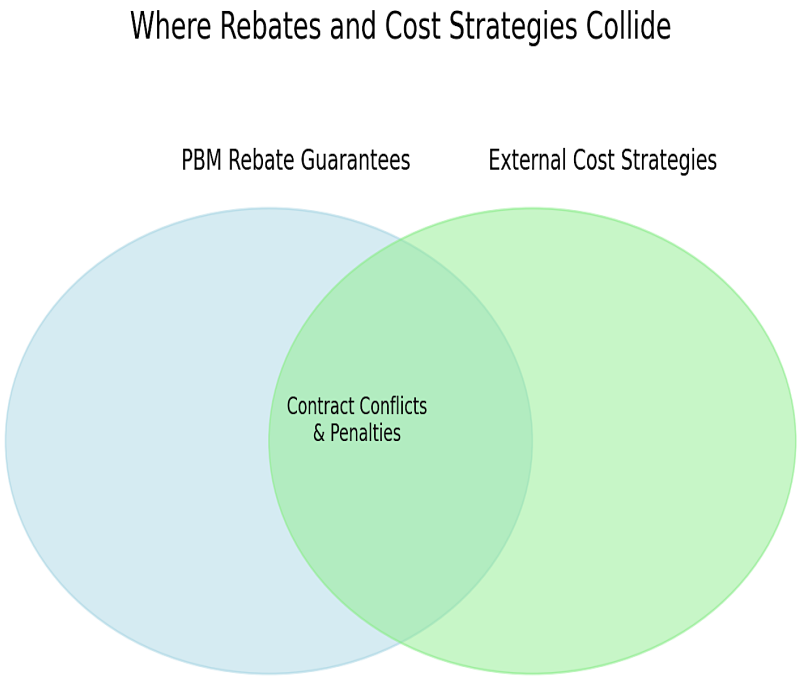
The 100% Pass-Through Illusion

- **‘100% pass-through’** usually means only formulary rebates.
- **Admin fees, inflation penalties,** and other bonuses often excluded.
- **PBM-owned GPOs** may keep dollars outside rebate bucket.
- **Considerations:**
  - What is defined as a rebate?
  - Will cost saving programs (OTC, Specialty, international) impact the contract terms negatively



When Rebates Clash with Cost-Saving Strategies

- **Rebate guarantees** may block programs like PAPs or international sourcing.
- These programs shift **brand/specialty drug volume**, hurting PBM rebate performance.
- Running outside programs may **breach contract** or trigger penalties.
- **Solution:** Carve out rebates via standalone contracts or aggregators.
- **Considerations to ask PBMs:**
  - Can rebates be marketed like the claims to vendors of the client's choice?
  - Will this impact the rates? And why?



Rebate vs. Savings vs. Channel Optimization

- **Rebates** are not the same as **net savings.**
- **Therapeutic changes should always be considered**

- **340B** and **alternative channels can** remove PBM margin (or Rebate margin) and increase value – especially in the case of guarantees (even in a pass-through contract!)

- **Employers** should optimize by drug and site of care.

- **Question:** Are you chasing rebates or actual value?

DRUG NAME	PRICE (net est. Rebate 30%)	340B	Cost	$$ Savings by Percentage
OZEMPIC	$4,257,057.02	$3,396,753.10	$860,303.92	20%
JARDIANCE	$2,622,977.60	$900,039.89	$1,722,937.71	66%
TRULICITY	$1,245,357.84	$580,160.00	$665,197.84	53%
STELARA	$1,187,871.34	$542,650.00	$645,221.34	54%
FARXIGA	$832,724.29	$513,275.83	$319,448.46	38%
ENBREL	$806,890.56	$282,362.20	$524,528.36	65%
RINVOQ	$755,544.65	$417,666.67	$337,877.98	45%
SKYRIZI	$744,236.86	$442,500.00	$301,736.86	41%
JANUVIA	$701,254.78	$441,128.00	$260,126.78	37%
RYBELSUS	$700,417.86	$535,860.00	$164,557.86	23%

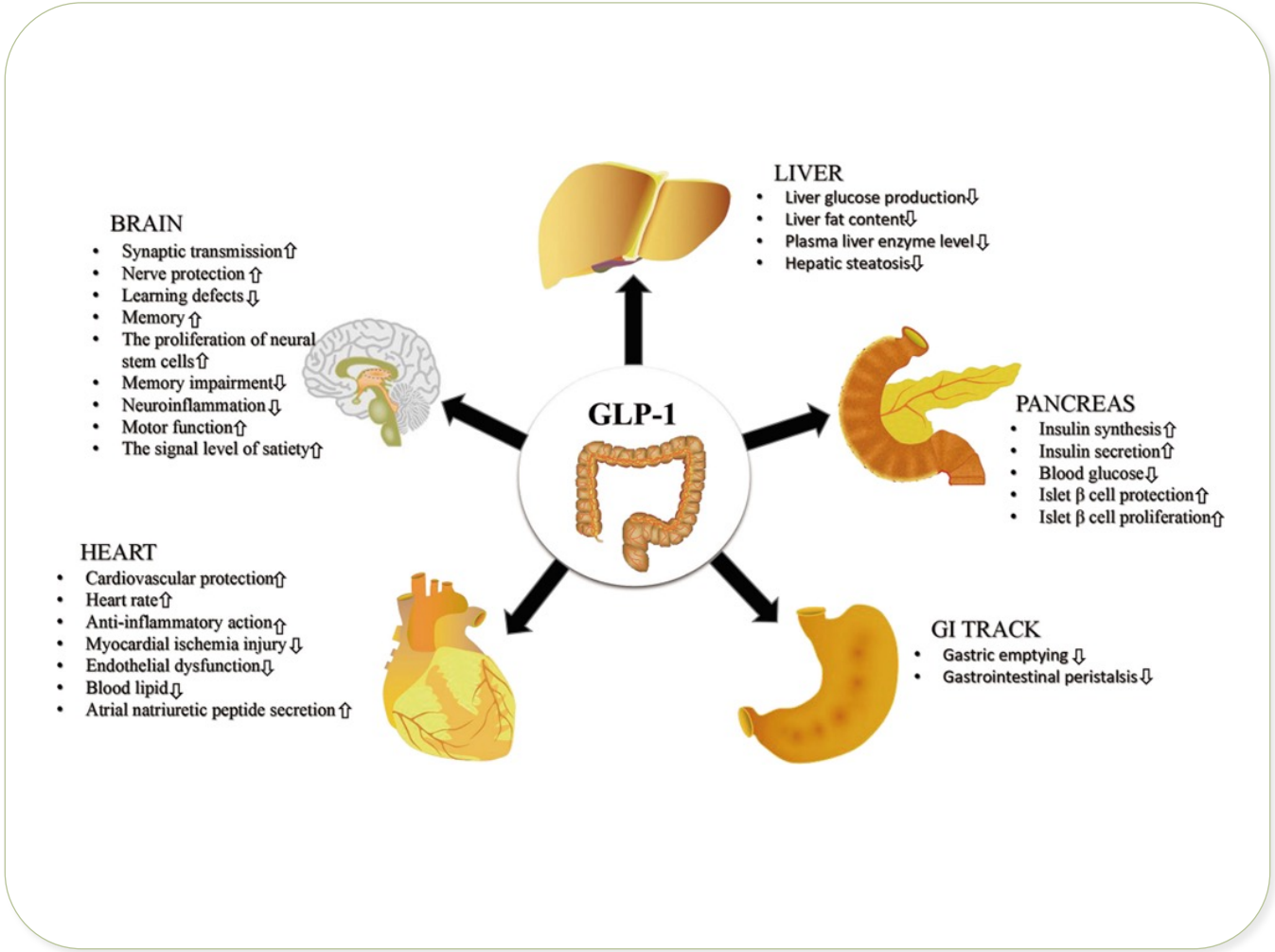
Key Drug Trends

and

The Future of PBM

Uses for GLP-1 Medication

- **FDA Approved Indications:**
  - Diabetes Mellitus – Type 2
  - Weight Loss
  - Sleep Apnea
  - CV Risk Associated with Obesity
- **Current Clinical Trials:**
  - Heart Failure
  - Peripheral Artery Disease (PAD)
  - Diabetic Kidney Disease
  - Alzheimer's Disease
  - Parkinson's Disease
  - NAFLD/NASH



Approved GLP-1/GIP Medications

Generic Name	Brand Name	Approval Date	Indication
Exenatide	Byetta	2005	Type 2 Diabetes
Exanatide extended-release	Bydureon	2012	Type 2 Diabetes
Liraglutide	Victoza	2010	Type 2 Diabetes
	Saxenda	2014	Weight-loss
Dulaglutide	Trulicity	2014	Type 2 Diabetes
Semaglutide	Ozempic	2017	Type 2 Diabetes
	Rybelsus (PO)	2019	Type 2 Diabetes
	Wegovy	2021	Weight-loss
Tirzepatide	Mounjaro	2022	Type 2 Diabetes
	Zepbound	2023	Weight-loss
		2024	Sleep Apnea

FDA Stops Compounds

Tirzepatide and semaglutide are no longer in a shortage

FDA Grace Period End Dates:

- Tirzepatide
  - Pharmacies – Feb 18th
  - Outsourcing Facilities – March 19th
- Semaglutide
  - Pharmacies – April 22nd
  - Outsourcing Facilities – May 22nd

Current Landscape/Pipeline

CagriSema (cagrilintide/semaglutide)

- Type 2 Diabetes (2026)
- Weight Loss (2027)
  - REDEFINE 1 Phase 3 trial
    - 22.7% weight loss vs 16.1% weight loss with semaglutide

Notable future indication expansions:

- Zepbound
  - Heart Failure (3Q2025)
- Wegovy
  - Heart Failure (2H2025)
  - Metabolic dysfunction-associated steatohepatitis (2026)
  - Osteoarthritis of knee with obesity (2026)
- Ozempic
  - PAD with Diabetes (2026)
  - Diabetic retinopathy (2027)
- Rybelsus
  - Alzheimer's Disease (2027)

Coverage Strategy

Prior Authorization must be in place

- No “Smart” Prior Authorizations
- Provider must show documentation of diagnosis (Ex: A1c)

Initial Prior Authorization Criteria – Weight Loss

- At least 3 months of lifestyle modifications which include a reduced calorie diet and increased physical activity
  - Lifestyle modifications are to be continue during weight loss therapy
- BMI $\geq$ 30 (obese)
- BMI $\geq$ 27 with at least ONE weight-related comorbidity

Continuation (at 6 months) – Weight Loss

- Weight reduction $\geq$ 5% from baseline

What is **Biosimilar?**

Biologic:

- Made of sugars, proteins, living cells, or tissues
- Natural or living sources (animal/plant cells, bacteria, yeast)

Biosimilar FDA Definition: A biopharmaceutical product highly similar to the reference product without meaningful differences in safety, purity, and potency.

Reference Product:
Original FDA approved biologic

Requirements to be a biosimilar:

- Made from same type of source
- Provide same clinical benefit
- Same strength, dosage and administration
- Same side effect profile

Biosimilars vs Generics

Similarities:

- Undergo clinical trials to compare with Brand medication
- Brand medication is FDA approved
- Abbreviated FDA review process compared to new medications
- Are as safe and effective as Brand medication
- Generally, less expensive than Brand medication

Differences:

- Biosimilar is made from a natural source, while a generic is made from chemicals
- Biosimilar is “similar” to Brand medication, while a generic is an exact copy
- FDA requires more clinical information from trials for biosimilars
- Biosimilars need additional information/trials to be considered interchangeable while generics can be automatically substituted for the Brand medication

Available Biosimilars

Herceptin (trastuzumab)	Actemra (tocilizumab)
Avastin (bevacizumab)	Procrit, Epogen (epoetin alfa)
Rituxan (rituximab)	Neupogen (filgrastim)
Lantus (insulin glargine)	Neulasta (pegfilgrastim)
Remicade (infliximab)	Lucentis (ranibizumab)
Stelara (stekinumab)	**Humira (adalimumab)**

Humira (adalimumab)

FDA Indications:

- Ankylosing Spondylitis
- Crohn's Disease
- Hidradenitis Suppurativa
- Plaque Psoriasis
- Psoriatic Arthritis
- Rheumatoid Arthritis
- Sarcoidosis
- Ulcerative Colitis
- Uveitis

Approved Biosimilars: 10

Humira WAC price: $6,922

~$1,500-$2,000 net cost

Biosimilar Low WAC Price:
$995 - $1,385

~$700-$1,000 net cost

Stelara (Ustekinumab)

FDA Indications:

- Plaque Psoriasis
- Psoriatic Arthritis
- Crohn's Disease
- Ulcerative Colitis

Approved Biosimilars: 7

Over 90% of Stelara spend is within the pharmacy benefit

Humira WAC price:

$30,000

~$1,500-$2,000 rebate value

$12-16k net cost

Biosimilar Low WAC Price:

$3,000 - $4,200

~$2,200 net cost

Financial Impact

Autoimmune disease category accounts for **1% of commercially insured patients** but over **42% of specialty spend**

Low WAC Stelara biosimilars are **~75% lower** net cost compared to Stelara

Biosimilar market share on average at year 3:

- Fast uptake: **53% market share**
- Slow uptake: **23% market share**

Autoimmune market is generally considered a slow uptake biosimilar market

PBM Strategies

Three primary biosimilar strategies

1.

Stelara/Humira at parity with biosimilars (usual 2-3 biosimilar options)

- Retains rebate value on innovator
- Most common strategy

2.

Stelara/Humira Continuation of Therapy with biosimilar new starts

- Rebate reduction on innovator

3.

Biosimilar new starts

- No rebate value on innovator

PBM Strategies

Each PBM has their own internal strategy on biosimilar switches

Very important when selecting CoT or biosimilar only

Must work with PBM with an aggressive biosimilar switch strategy if moving to a biosimilar only formulary

Can have rebate implications on other medications when electing to remove Humira/Stelara from formulary

Innovative Payment Models:

Alternative Funding Considerations

Sourcing Brand Humira or Stelara may be higher net cost than a biosimilar option

More savings potential getting a member to switch to a biosimilar than to source Brand medication

Careful critique of savings analyses, International Sourcing Savings

Winning Messages

- Transparent PBMs deliver lowest net cost
- Challenge where the carriers won't:
  - Site of Care
  - White Bagging
  - Alternative Funding
  - International Sourcing
  - Specialty Carve Out
- One year contract/term
- Medical Rx Rebates
- Scale driven competitive pricing with preferred PBMs (Stronger Buying Power)
- Independent Prior Authorization (No fox guarding the hen house)
- Leverage Market Experts for pricing review with audited claim data

Thank You.

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