

San Francisco Health Service System Health Service Board

Pharmacy Benefit Trends

Presented by Kelvin Richards, Pharmacist

November 14, 2024

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Agenda

- Pharmacy Market
- Clinical Insights
- PBM Marketplace
- Legislative Update

Aon's Perspective on the Pharmacy Market

GLP-1s continue to evolve health care



- Comparing Jul-Dec '23 v Jan-Jun '24, utilizers of **GLP-1s for diabetes** are flat and gross plan paid is up 3.5% as utilization shifts to Ozempic and Mounjaro.
- Comparing Jul-Dec '23 v Jan-Jun '24, utilizers of **GLP-1s for weight loss** are up 64.7% and gross plan paid is up 55.5%. Saxenda utilizers are down 68.2% as Zepbound has fully moved into the market.
- **Supply** challenges begin to resolve, which will increase utilization for clients.
- 134 **potential GLP-1 therapies** in the development pipeline.

Innovation & New Market Entrants

- **Biosimilar utilization will increase** in 2025 for Humira with revised PBM formulary strategies, which will lower overall specialty costs.
- **Stelara** biosimilar enters the market in 2025. Adoption plans in place with the major PBMs.
- The FDA approved 15 biosimilars during the first half of 2024 in the antiinflammatory, cancer, macular degeneration, and osteoporosis categories.
- FDA approved seven novel **oncology** drugs to date in 2024 with breakthrough therapies anticipated for colorectal cancer, breast cancer.



Forces Shaping the Future of Pharmacy



- Federal and state anti-PBM efforts persist.
- **The FTC** sues the big three PBMs specific to insulin pricing.
- To increase patient access to care, state laws and pharmacy practice acts are changing to allow pharmacists to test, treat and prescribe for minor non-chronic conditions.
- Artificial intelligence is being studied to identify patients at high risk of discontinuing opioid use disorder treatment.
- The DEA has increased production to help reduce **short supply of Vyvanse** for ADHD.

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Clinical Insights

GLP-1 Review

Glucagon-Like Peptide 1 Receptor Antagonist

Medications that mimic the actions of the body's natural hormone GLP-1, which is released after eating.

GLP-1 drugs work by:

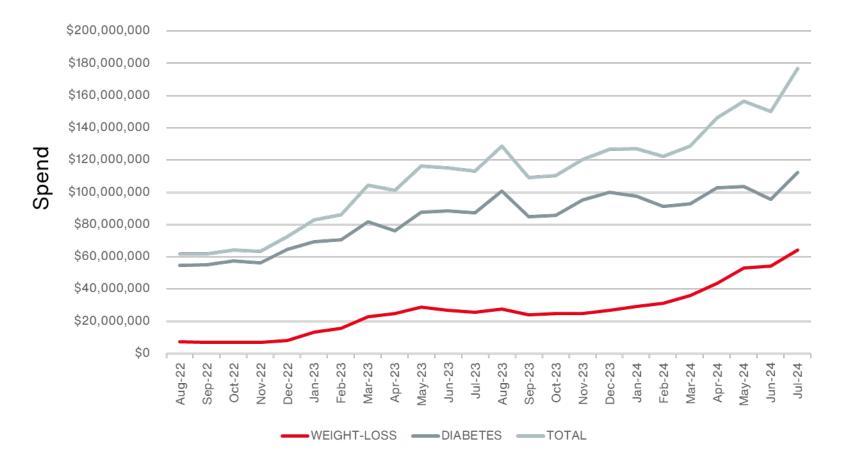
• Reducing appetite

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- Slowing down how quickly food leaves the stomach
- Slightly increasing metabolism
- Helping the pancreas produce more insulin
- Preventing the liver from releasing too much sugar into the bloodstream



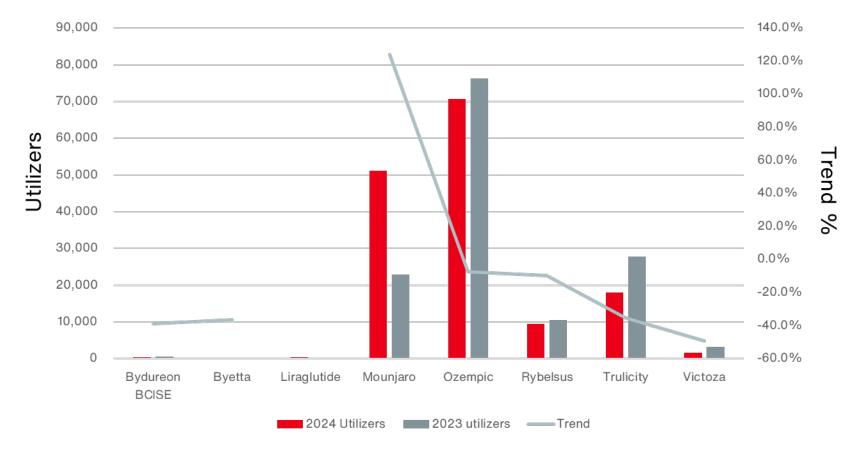
Tracking GLP-1 Spend Over the Past Two Years



Source: Aon pharmacy claims data warehouse

Treatment for Type 2 Diabetes: 2023 v 2024 (Jan –July)

Aon data shows Ozempic uptake in '23 sliding with Mounjaro uptake in '24 increasing



Source: Aon pharmacy claims data warehouse

How Employers are Addressing GLP-1 Coverage for Obesity

Unrestricted	Minimal Restriction	Restrictive	No Coverage
 Fully cover all GLP-1s without restriction 	 Prior auth requirements aligned with FDA approval guidelines 	 Require documentation of prior lifestyle modification treatment/engagement for sustained time frame (ex: 3-6 months) for first prescription fill 	 No coverage for members seeking GLP- 1s for the treatment of obesity
 Members accessing both Ozempic and Wegovy for weight loss use 	 A BMI ≥27 in persons with ≥1 weight-related coexisting condition OR BMI ≥ 30 alone and documentation of lifestyle modification counseling 	 Ongoing engagement in behavior change program for prescription refills Step therapy approach 	• Continue to cover GLP- 1s approved for diabetes for members with a diagnosis of diabetes
 No cost containment — very few employers left in this category 	 Minimal cost containment 	 Mitigates cost, positions member for best outcome 	
No pharmacy rebate loss	No pharmacy rebate loss	 Risk for pharmacy rebate loss 	

Variations exist across the spectrum

GLP-1 Future State

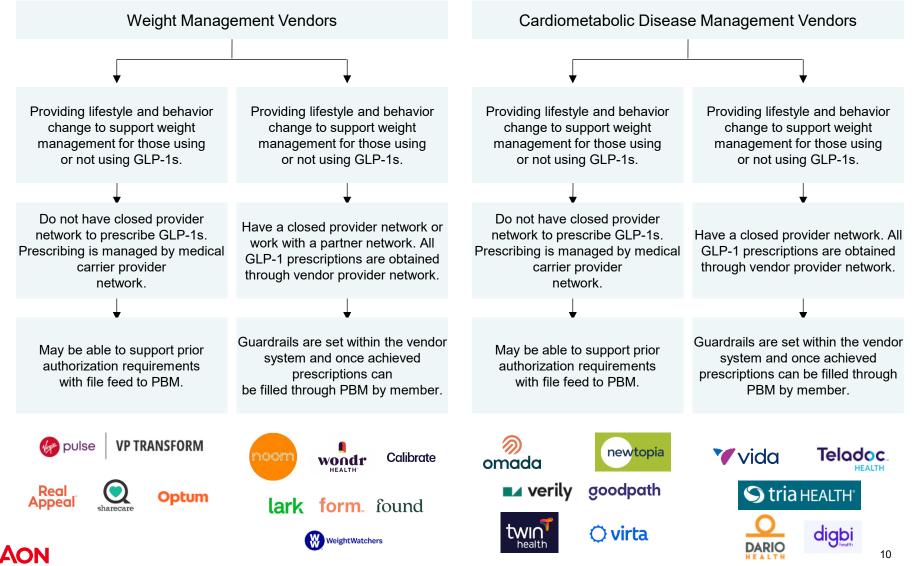
Anti-Obesity and Diabetes GLP-1 Coverage

GLP-1	Route	Frequency	Indication	Generic Launch
Bydureon	Injection	Weekly	Diabetes	2031
Byetta	Injection	Twice daily	Diabetes	2024 into 2025
Mounjaro (tirzepatide)	Injection	Weekly	Diabetes	2039
Ozempic (semaglutide)	Injection	Weekly	Diabetes	2032
Rybelsus (semaglutide)	Oral	Daily	Diabetes	2033
Saxenda (liraglutide)	Injection	Daily	Weight Loss	2026
Trulicity (duraglutide)	Injection	Weekly	Diabetes	Possibly 2024
Victoza (liraglutide)	Injection	Daily	Diabetes	2023 into 2024
Wegovy (semaglutide)	Injection	Weekly	Weight Loss	2032
Zepbound (tirzepatide)	Injection	Weekly	Weight Loss	TBD

Zepbound FDA approved for weight loss on 11/8/2023

A	Overall pipeline:	An oral version of	Competition may	Newer drugs
	 2 products — Phase 3 	Rybelsus at the 25mg	take years to	working in different
ı	 19 products — Phase 2 	and 50mg level is in	reduce costs;	ways that increase
	 32 products — Phase 1 	phase 3 for diabetes	generics for leading	effectiveness
		and weight loss	products not	
			expected before	
			2032	

How the Vendor Market is Responding to GLP-1 Demand



Drug Pipeline

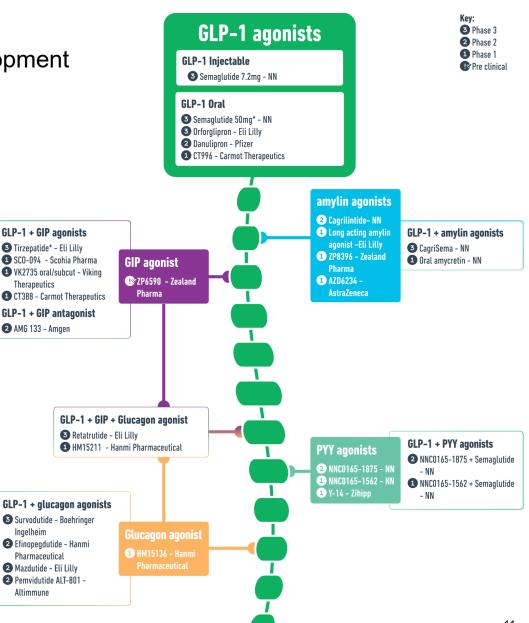
GLP-1 as Backbone of Development

Oral GLP-1 are under development to improve convenience, acceptance, and adherence.

Gastric inhibitory polypeptide (GIP), Amylin, Glucagon, and Peptide YY (PPY) are hormones produced by the body that play a role in food consumption and sugar regulation.

Pharmaceutical manufactures are creating medications the mimic or counter these hormones to improve weight loss or achieve better regulation of blood sugar in diabetic patients.

1. What is the pipeline for future medications for obesity? (Nature)



GLP-1s Reshape Treatment Beyond Diabetes and Weight Loss

An anti-inflammatory effect is speculated as a key mechanism¹









Wegovy anticipated for heart failure with preserved ejection fraction² Ozempic anticipated for chronic kidney disease³ GLP-1s may help reduce alcohol consumption⁴

GLP-1s may reduce sleep apnea symptoms⁵

2. Semaglutide in Patients with Obesity-Related Heart Failure and Type 2 Diabetes | New England Journal of Medicine (nejm.org)

- 3. Diabetes drug Ozempic may delay chronic kidney disease progression (medicalnewstoday.com)
- 4. Semaglutide and Tirzepatide reduce alcohol consumption in individuals with obesity | Scientific Reports (nature.com)

5. Tirzepatide for the Treatment of Obstructive Sleep Apnea and Obesity | New England Journal of Medicine (nejm.org)

Biosimilar Overview

Not a generic...

Biological medications, also known as biologics, are a class of drugs that are made from living organisms or their products; most other medications are created through chemical manipulation.

A biosimilar is a biologic medication that is very similar to an already approved biologic medication, known as the reference product.

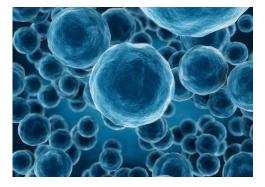
Biosimilars are made from the same types of sources, such as living cells or microorganisms, and are just as safe and effective as their reference products.

A biosimilar medications is not a 'generic' version of the reference product.



A generic version of a nonbiological brand medication is an exact chemical copy of the brand medications; some fillers in the capsule/tablet may differ.

Generic pharmaceutical manufacturers follow an exact recipe to create the product.

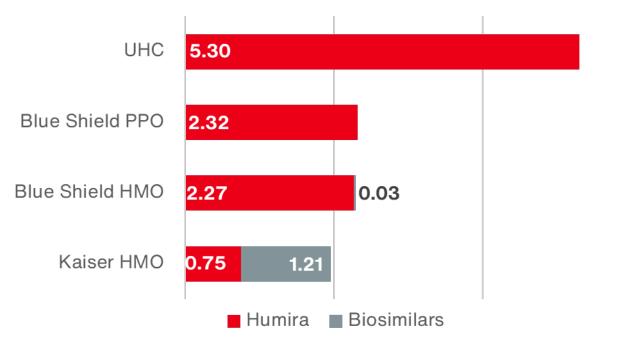


A biosimilar medication is grown in living cells that yield small differences in the end product; testing is required to show similar effectiveness.

Biological pharmaceutical manufacturers may follow a similar process to the brand manufacturer, but the compound is ultimately unique.

Biosimilar Drug Usage for Non-Medicare Population

Kaiser HMO had the highest Biosimilar usage scripts rate among the other plans. Patients in UHC plans and Blue Shield PPO plan focused only on Humira which can be seen in the graphs.

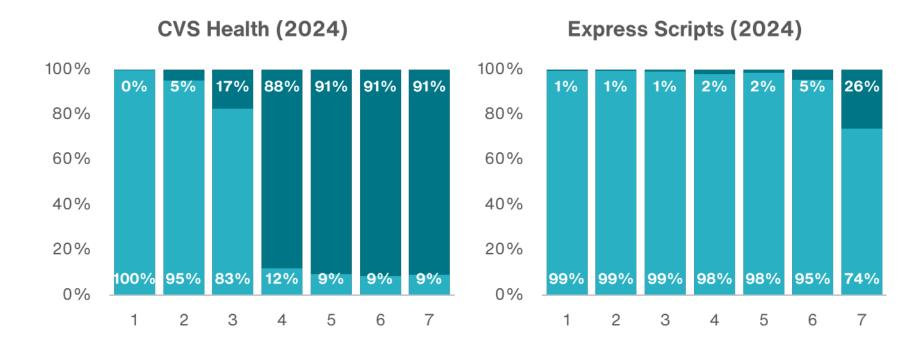


Patients per 1000 Rx Utilization 2023

Source: San Francisco Health Service System All Payer Claim Database

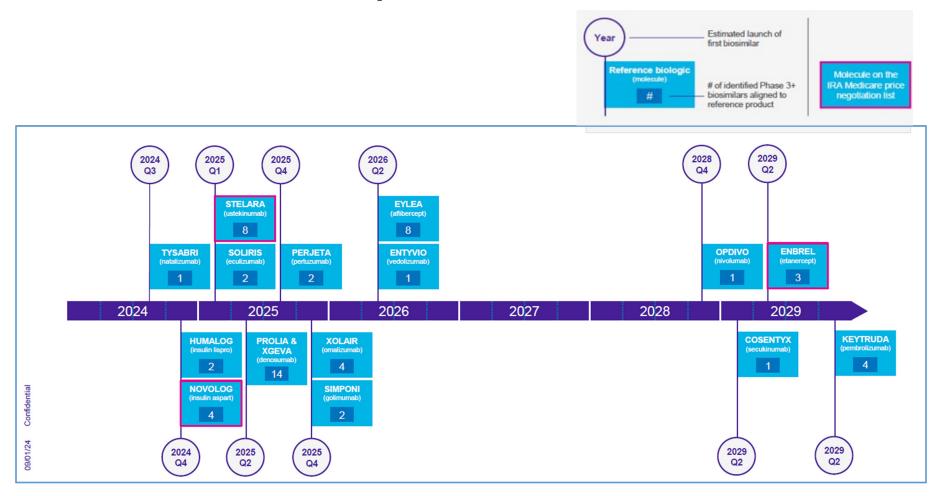
Biosimilar Adoption and the Impact of Formulary Exclusion

Exclusion is the key to affect changes in utilization and unlock savings



Humira Biosimilar

5-Year Biosimilar Pipeline



Source: Cencora PPT Core template (amerisourcebergen.com)

Managing Gene Therapy Risk



Know your risk

2 Know your coverage

Identify all FDA-approved gene & cell therapies as well as those in the near-term pipeline

Understand whether your existing stop loss coverage covers gene & cell therapies under current terms



Know your options

Consider whether to cover gene & cell therapies given their high costs, limited scope and uncertain efficacy

Forecast the potential exposure presented by each therapy based on population data and clinical information

Identify any gaps in coverage such as lasers and exclusions for members with known conditions **Assess** how much risk you can retain based on business objectives and access to capital; ensure proper admin

Perform a clinical review of your health plan population to identify high-risk members who may qualify for therapy

Determine whether your current level of coverage is sufficient or if gaps need to be addressed

Select from the full spectrum of risk management strategies to address any residual gene & cell therapy risk

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Overview of PBM Marketplace



Overview of PBM Landscape and Characteristics

Big 3 PBMs (50M+)	Mid-Sized PBMs (10M+)	Transparent PBMs (1M+)	Emerging/Disrupto	r PBMs
CVS Health	CarelonRx	Abarca	AffirmedRx	Maxor
Express Scripts	MedImpact	Capital Rx	Alluma	Perform Rx
OptumRx	Prime Therapeutics	Navitus	EmpiRx	Rx Preferred Benefits
		Rightway	FliptRx	SmithRx
		WellDyne	Kroger	Vivid Clear Rx
			Liviniti	WithMe Health
Themes				
 Vertical integration Strong purchasing power through GPOs Less flexible than smaller PBMs Experience in all market segments 	 Medium flexibility Emphasis on key market segments (i.e., regulated markets, health plans, or carve- in) May not have the same purchasing power as larger PBMs 	 transparency Additional clinical flexibility More nimble/willing to customize 	 Disruptive financial offering with an emphasis on transparency Additional clinical flexibility More nimble/willing to customize Unproven experience in commercial employer market May be willing to provide limited services and/o provide modular/unique service models 	

Vertical Integration and Carrier-Owned PBMs

The Pharmacy Benefit Landscape is Complicated

Vertically integrated **medical** carriers pay nearly 70% of all commercial insurance claims, pharmacy and medical

80%

of all pharmacy claims in the U.S. are managed by the Big 3 PBMs

90%+

of all rebatable claims **flow through GPOs owned by the Big 3 PBMs** and their integrated medical carriers

Plan Sponsors	SilverScript 	eviCore healthcare Cigna	United Healthcare	Humana	1
PBMs	CAREMARK	() EXPRESS SCRIPTS [.]	Optum Rx°	Humana	PRIME THERAPEUTICS
Rebate Aggregators	EALTH SERVICES	Ascent Health	EMISAR	Ascent Bervices	Ascent Berviews
PBM-Owned Specialty Pharmacies	CVS specialty	accredo [,]	Optum	Specialty Pharmacy	Magellan
PBM-Owned Healthcare Providers	HealthHUB. CVS minute clinic CVS/pharmacy Oak St. Health	-EVERNORTH Care Group [⊶]	Optum	R CenterWell	Source: Frier & Levitt LLC

Emerging and Trending PBM Themes

Clinical-First PBMs are built upon the belief that traditional PBMs have incentives to increase utilization and to approve prior authorizations, especially where they own the mail-order and specialty pharmacies. These PBMs integrate clinicians into their call centers and require use of their clinical programs.



NAVITUS 🕂 rightway ARCHIMEDES

Redefining the Prices by developing or applying different sources for pricing. This includes PBMs, but also discount card programs, and standalone pharmacies with unique dispensing models. For example, CapitalRx is a PBM that uses National Average Drug Acquisition Cost (NADAC) data for claims reimbursement.





Transparency in response to pressure from consumers, legislators and industry advocates to understand the mechanics of PBM profits. All PBMs claim to offer clients transparency. Know that there are different shades of transparency!

Federal Trade Commission

July 2024

In July 2024, the FTC released an interim staff report on PBMs that claims that horizontal consolidation and vertical integration have created financial conflicts of interest and outsized bargaining power for PBMs.

September 2024

The FTC sued Caremark Rx, Express Scripts, and OptumRx, the three largest PBMs, for anticompetitive practices that inflated insulin prices. The FTC claims that the PBMs created a "perverse drug rebate system" that shifted the cost of insulin to patients and blocked access to more affordable options.



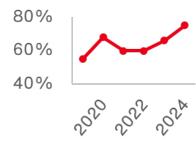
Audit Trends

Errors Increasing

Aon observes an increase in the chance of discovering meaningful errors in a pharmacy audit engagement over time. 55% of audits uncovered errors in 2019, vs. 75% in 2024.

75%±5%

Chance of errors increased annually



Finding Sizes Vary

Aon observes variation in average financial findings per audit. Year over year, the average financial finding per audit is as low as \$15,000, and as high as \$35,000. Outliers removed for this graph.

Most Employers

AutObs serves an average of 55% of clients performing audits annually over the last 5 years. Over 90% of clients perform at least one pharmacy audit in the trailing 3 years.

Not Just Recoveries

While financial recoveries are sometimes a goal, audits help ensure your vendors perform to your standards, and "a clean audit is a good audit."

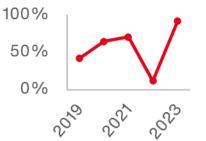
\$25K±\$7K

Average recovery, 3K-10K life client



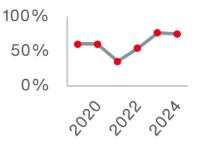
90%

Clients now regularly do audits



65% ROI

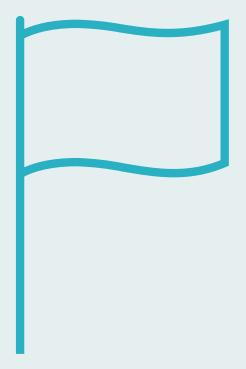
Recovery vs. average engagement cost



Data from Aon Pharmacy Practice. Average client size included: 3,000 – 10,000 lives. Data volume: 1,000 Pharmacy audit engagements per year (average).

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Legislative Updates





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State Legislation

Every year, the 50 states including Washington, DC and Puerto Rico propose hundreds of prescription drug bills.

In 2023, close to 150 bills were signed into law by a governor.

Major topics of these bills were:

- PBM reform
- Decreasing patient cost
- Increasing access
- Reducing high drug prices
- Pharmacy Reimbursement
- Mail and Retail Parity
- Transparency

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California SB966

SB966 went through many amendments before passing both the CA House and Senate. The CA Governor had 30 days to sign or veto this bill. The governor chose the latter and provided the below statement.

My Administration is committed to increasing access and lowering the costs of prescription drugs. As such, I am directing the California Health and Human Services Agency to propose a legislative approach to gather much needed data on PBMs next year, which can be considered in conjunction with data from our entire health care delivery system. There is some existing transparency regarding prescription drug prices provided through the reporting required by SB 17 (Hernandez, Chapter 603, Statutes of 2017) and the establishment of the Healthcare Payments Database. However, we need more granular information to fully understand the cost drivers in the prescription drug market and the role that PMBs play in pricing. Specifically, California should collect comprehensive information from the pharmacy delivery system about the total cost of care for providing individual prescription drug products, including but not limited to wholesale acquisition costs, fees, payments, discounts, and rebates paid to and received by PBMs. These next steps, together with the CalRx program and the Office of Health Care Affordability's work, will offer a multi-pronged approach to improving affordability of prescription drugs in California.

Tracking State Pharmacy Legislative Trends









Florida SB1550/Minnesota SF278/West Virginia HB4112/ Tennessee HB2661/Oklahoma SB737/Oklahoma HB2632 all have proposed/enacted law includes the following changes:

- Requires retail/mail parity
- Prohibits mandatory mail
- Prohibits exclusive specialty

Additional elements of legislation include:

- Prohibits spread pricing
- Prohibits affiliate steering or advertising
- Prohibits white or brown bagging practices
- Requires passing through pricing
- Requires passing through rebates
- Requires NADAC pricing plus dispensing fee
- Requires 60-day continuity of care period for formulary changes



Prescription Drug Affordability Boards (PDABs)

PDABs are generally tasked with one or more of the following duties:

- Determining the affordability of prescription drugs within the state.
- Negotiating with manufacturers for Medicaid supplemental rebates.
- · Recommending ways to reduce spending.
- Setting upper payment limits or UPLs for the amount of money the state can spend on prescription drugs.

The first PDAB was created in Maryland in 2019. Nine other states have created PDABs to review high-cost drugs. Five PDABs have the ability to set upper payment limits (UPLs) for certain prescription drugs. States with established PDAB: Colorado, Maine, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Ohio, Oregon and Washington

Now 13 more states have pending legislation to create prescription drug affordability boards. Those states are: Arizona, Connecticut, Iowa, Kentucky, Michigan, Nebraska, Pennsylvania, South Carolina, Vermont, Virginia, West Virginia and Wisconsin. The HCAI Prescription Drug Cost Transparency Program, CTRx, provides transparency for the cost of prescription drugs in California. Per 127675 – 127686 of the Health and Safety Code, prescription drug manufacturers are required to submit specified reports to HCAI:

- Reports to HCAI of specified wholesale acquisition cost (WAC) increases and related information on a quarterly basis.
- 3-day notices to HCAI of specified new drugs being introduced to the California market
- Reports to HCAI of information related to specified new drugs being introduced to the California market.

2023 and 2024 Federal Bills and Hearings

Both chambers of Congress (House and Senate) took up PBM bills in 2023 and 2024. Many had the same theme — Transparency.

Both chambers had many congressional hearings targeting PBMs and Pharmaceutical companies.

Topics of Congressional bills include the following:

- Ban spread pricing
- Anti-steering
- High costs of drugs
- Delinking PBMs pay a flat fee instead of being paid on the price of a drug. Remove the incentive for PBMs to have higher priced drugs and lower costs for patients who pay a certain percentage of the drug's price regardless of the negotiated discount. Delink compensation from drug prices to align incentives for lower costs.



GOVERNMENT

The Future of Prescription Drug Legislation

Many conversations are taking place across the country around prescription drug policy topics The main focus from many stakeholders is how to decrease drug pricing or lowering costs of prescription drugs to make it more affordable and accessible to millions of Americans.

 The Federal government and states are taking steps to address and even put in measures to decrease prescription drug pricing. We will continue to see more legislation on this topic for both the PBMs and the pharmaceutical industry from states and the federal government. The federal government will need to determine common sense bills that focuses on pricing drug laws for both the PBMs and the pharmaceutical industry.

We are continuing to see snippets of laws being passed by states to decrease the prescription drug costs and increase access to life saving prescription drugs.

• 46 states will convene this year. Montana, Nevada, North Dakota and Texas will not be in session.

The federal government will need to step in and decide on ERISA preemption whether to keep it weak or strengthen it. And this could be done through Congress or the Supreme Court or both.

Healthcare Impact of 2024 Election Results

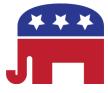
Platform Positions Employers Need to Know



Democrats

- Preserve and expand the Affordable Care Act (ACA)
 - ACA expanded coverage to dependents to age 26, requires employers to offer coverage to full-time employees (FTEs) or incur a penalty, prohibits pre-existing condition exclusions
- Medicaid expansion
- Lower prescription drug costs
- Mental Health Parity
- Protect abortion access
- Enhance Medicare (Medicare for All)

Republicans



- Historically supported the repeal of the ACA
 - Under the Trump Administration, the ACA individual mandate was repealed (the requirement that most Americans maintain health insurance)
- Support state regulation of abortion access
- Support short-term limited duration health plans
- Implemented the Individual Coverage Health Reimbursement Arrangement (ICHRA) which allows for the purchase of individual market coverage with HRA

Prescription Drug Legislation Review

2023 and 2024 in Review

- RxDC submissions unpacking the RxDC reports could potentially help the Three Departments (Department of Health and Human Services, Department of Labor, and Department of Treasury) decide on a pathway to reduce drug costs quicker than the Inflation Reduction Act.
- The Inflation Reduction Act addresses the high cost of prescription drug. However, the IRA targets a small number of drugs over the next 5 years. Over 45 brand drugs and biologics will be targeted. This is probably not going to move fast enough to see lower drug prices. It is a start.
- State Level States are creating Prescription Drug Affordability Boards (PDABs). The first PDAB was
 created in Maryland in 2019. Eight other states have created PDABs to review high-cost drugs. Five
 PDABs have the ability to set upper payment limits (UPLs) for certain prescription drugs. Will setting upper
 payment limits to certain drugs drive up the cost of other drugs that cost less now?
- States with drug price transparency laws can look at the prescription drug cost data and see when drug costs are rising which can drive state legislatures to write bills to lower prescription drug costs.
- The American Rescue Plan (ARP) Act removes the cap on the rebates that drug manufacturers pay to Medicaid effective 1/1/2024. Certain insulin products now have a lower drug price and lower rebates due to the ARP Act. Insulin is not the only product impacted here, the Medicaid Drug Rebate Program currently caps rebates for single source, innovator multiple source, and non-innovator multiple source drugs at 100% of the average manufacturer price. The ARP Act removes the 100% cap for these drugs.
 - More Americans will see a decrease in certain products due to the ARP Act, however, some stakeholders (pharma) fear this and the Inflation Reduction Act could prevent innovation for new prescription drug treatments.

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Wrap Up



Other Market Activity



The Promise of Weight-Loss Drugs Dani Blum

PHARMA

Where these drugs might take us - and what that means for medicine.

Drug shortages hit record high, pharmacists warn

There are at least 323 active shortages, according to a pharmacy trade group.

By <u>Mary Kekatos</u> April 12, 2024, 10:08 AM

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HEALTH NEWS

'Ozempic Babies': How Weight Loss Drugs Can Interfere with Birth Control and Boost Fertility

Nearly a third of independent pharmacies at risk of closure in 2024

The pharmacies are feeling the strains of a CMS rule that went into effect at the start of the year.



What to Do if You're Overpaying for Prescriptions

Reed Abelson

Here's what to know about your pharmacy benefit manager and how to find out if you are being overcharged for medications.