Who Really Pays?

How Formularies & Utilization Management Tools Increase Prices & Harm Patients

Coalition of State Rheumatology Organizations - Fellows Meeting

February 21-22, 2025, Nashville, TN

Madelaine T. Feldman MD, FACR.

Coalition of State Rheumatology Organizations- V.President Advocacy and Gov’t Affairs
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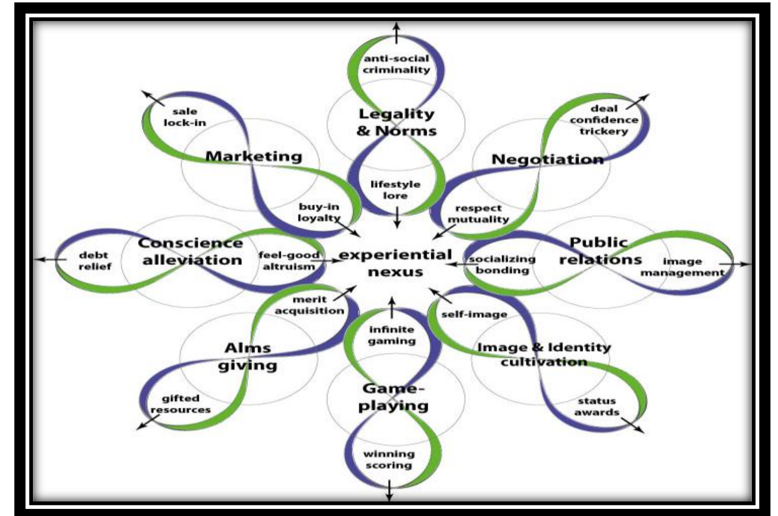


RHEUM FELLOW VIEW OF HEALTH INSURANCE

This Photo by Unknown Author is licensed under CC BY-NC

Health ... urance Companies = Payers?

A M... ...n Or Safety.

A Person Or Entity...

Person Named In A Bill Who Has ... Holder

Money Dealer

Money Handler

Fortune 500 Ranking 2024

#5 UnitedHealth Group – Revenue

$324.326 Billion

#6 CVS Health – Revenue

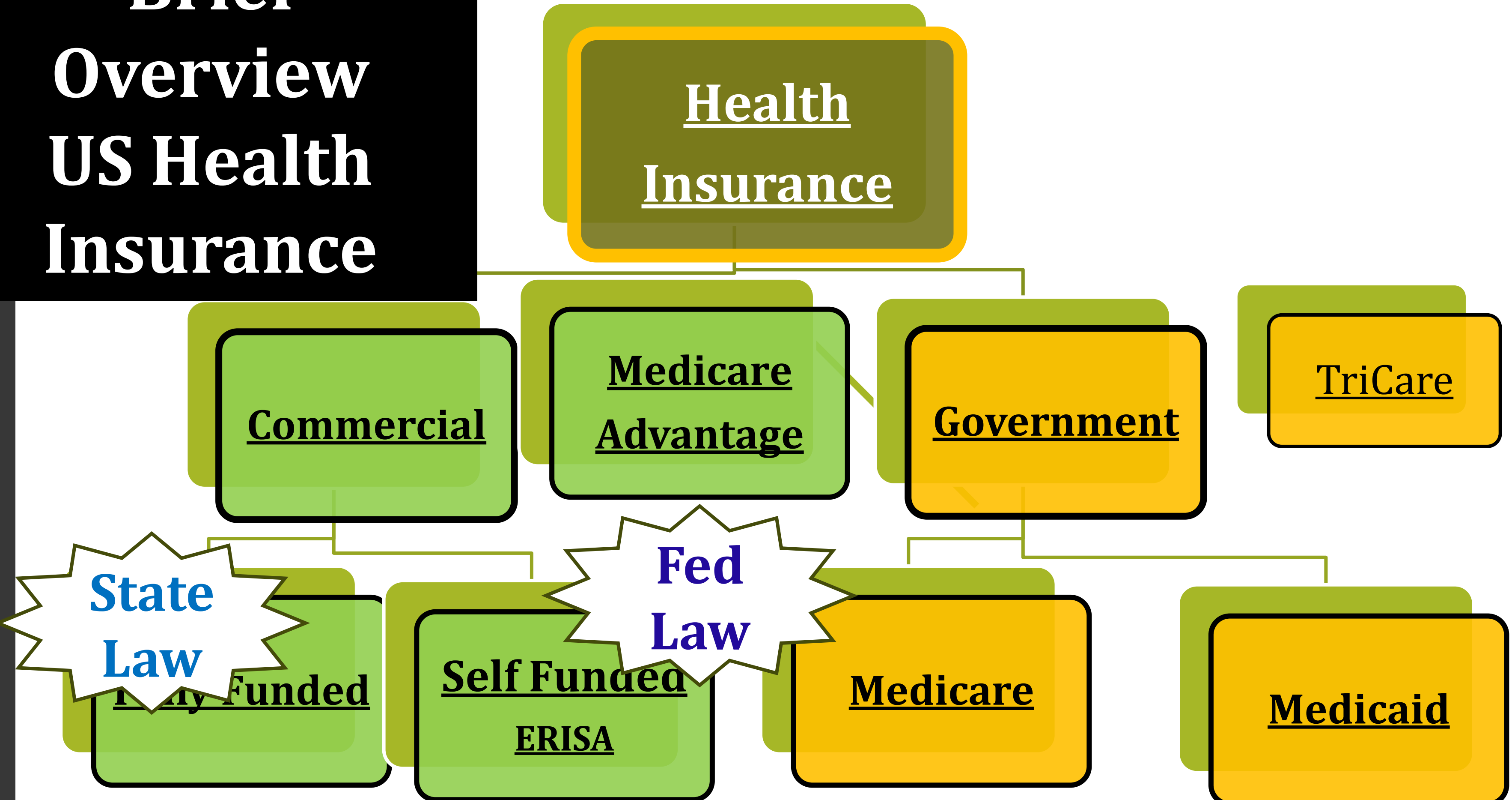
$322.467 Billion

#15 Cigna- Revenue

$180.364 Billion

https://www.50pros.com/fortune500/

Brief Overview US Health Insurance



Part C

MA Plans Increasingly Profitable For Insurance Companies

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Fortune 500 Ranking 2024

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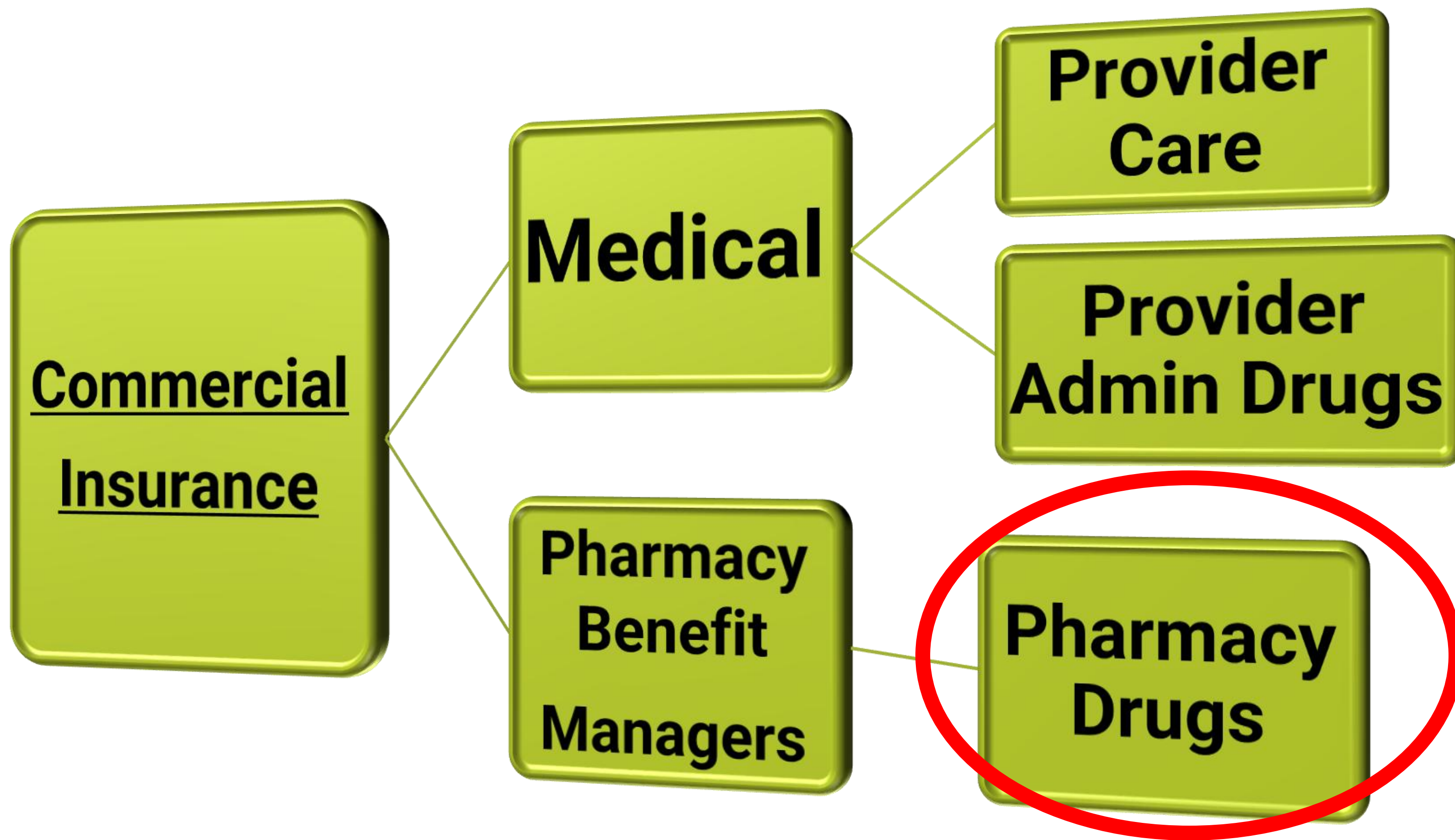
Commercial Insurance
Medical
Provider Care
Provider Admin Drugs
Pharmacy Benefit Managers
Pharmacy Drugs

Medication Access

Pharmacy

Provider Admin

Availability

Approved

Launched

Formulary

Affordability

Price

Cost Share

Copay

Co-insurance

No One Takes It.

Who Constructs

The Pharmacy Drug Formulary?

Pharmacy Benefit Managers (PBMs)

3 Control 80% of presc

2019

Vertical Integration-PBMs/Insurance Companies

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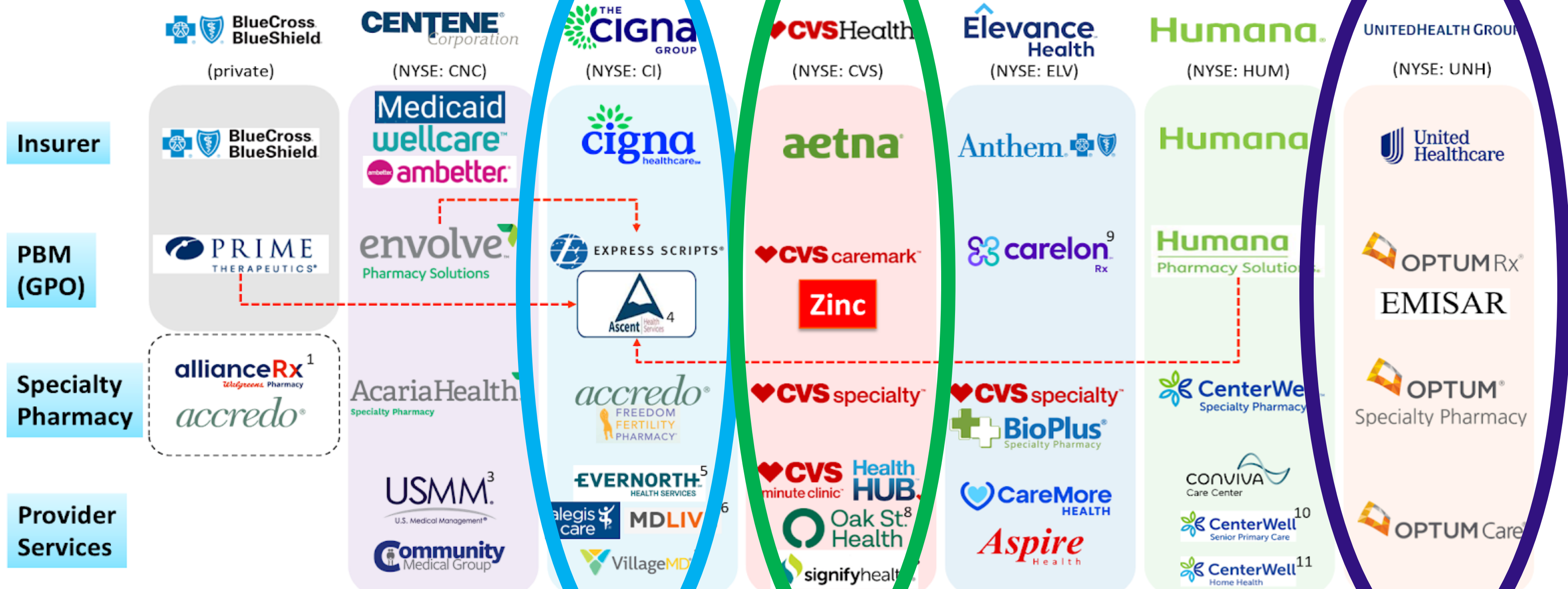
Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2023



1. Since 2021, Prime's Blue Cross and Blue Shield plans have had the option to use Express Scripts or AllianceRx Walgreens Pharmacy for mail/spec[illegible] pharmacy services. [illegible]ec. 2021, Walgreens pu[illegible]sed Prime Therapeu[illegible] 45% ownership interest, so this business had no PBM ownership as of 2022. Effective June 2022, the company was [illegible]anded as AllianceRx Wal[illegible]ns Pharmacy.
2. Centene has announced that it would outsource its PBM operations to Express Scripts in 2024. In 2023, Centene rebranded its pharmacy benefit s[illegible]idiary as Centene [illegible]armacy Sevrices.
3. In 2021, Centene sold a majority stake in its U.S. Medical Management to a group of private equity firms.
4. Since 2020, Prime has sourced formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Serv[illegible]mercial plans.
5. Previously known as Evernorth Care Group and Cigna Medical Group.
6. In 2021, Cigna's Evernorth business acquired MDLive.
7. In 2022, Cigna invested $2.7 billion for an estimated 14% ownership stake in VillageMD. Walgreens owns a majority of VillageMD.
8. In September 2022, CVS Health announced its acquisition of Signify Health. In February 2023, CVS announced its acquisition of Oak Street Health. Both transactions closed in 2023.
9. Previously known as IngenioRx.
10. In 2021, Partners in Primary Care and Family Physicians Group businesses were rebranded as Centerwell Senior Primary Care.
11. In 2022, Kindred at Home was rebranded as CenterWell Home Health. In 2022, Humana announced an agreement to divest its majority interest in Kindred at Home's Hospice and Personal Care Divisions to Clayton, Dubilier & Rice. Humana also announced plans to close a majority of its SeniorBridge

Source: The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Exhibit 234. Companies are listed alphabetically by corporate name.

DRUG CHANNELS INSTITUTE

2023

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What Maintains the Formulary's Profitability?

Utilization Management Tools

Utilization Management Tools

****

"Tools" To Control The Use Of Drugs

Utilize the Drugs That Offer the Most Savings (Profit to the PBM)

Prior Authorizations –Doctors asking permission to have a specific drug covered by insurance

Step Therapy: Requires patients to fail first on a payer-preferred drug

Non-medical Switching: A patient is forced to change to a different medication for a non-medical reason

Accumulator Adjustment Programs
(not a utilization tool but it is a profit tool)

Formularies Can Change Mid Plan Year & Drop Medications Forcing Stable Patients Off Of Their Medication

Recent Example Of Prior Auth Step Therapy Requirements

For Generic Hydroxychloroquine

Must TRY 4 Of The Following

Optum Rx®

Kelly Weselman
4441 Atlanta Rd Se

Smyrna, GA 30080

Hours of Operation:
5 a.m. - 10 p.m. PT, Monday-Friday
6 a.m. - 3 p.m. PT, Saturday

Address:
PO Box 2975
Mission, KS 66201

Date: 02/18/2023

To: Kelly Weselman
Phone: (770)333-2035
Fax: 7703332059
Reference #:

From: Optum Rx
Phone: 1-800-711-4555

RE: Prior Authorization Request

Patient Name:
Patient ID:
Medication Name: Plaquenil Tab 200mg

Patient DOB:
Status of Request: **Deny**
GPI/NDC: 13000020100305

Decision Notes:

Plaquenil is denied because it is not on your plan's Drug List (formulary). Medication authorization requires the following:
(1) You need to try four (4) of these covered drugs:
- (a) Azathioprine 50mg*.
- (b) Dexamethasone.
- (c) Hydrocortisone tablet.
- (d) Methylprednisolone.
- (e) Mycophenolate capsule or mycophenolic acid DR*.
- (f) Prednisolone or prednisolone sodium phosphate (5mg/5ml, 15mg/5ml, 25mg/5ml).
- (g) Prednisone.
- (h) Trexall or methotrexate.

(2) OR your doctor needs to give us specific medical reasons why four (4) of the covered drug(s) are not appropriate for you.

This document and others if attached contain information from Optum Rx that is proprietary, confidential and/or may contain protected health information (PHI). We are required to safeguard PHI by applicable law. The information in this document is for the sole use of the person(s) or company named above. If you received this document by mistake, please know that sharing, copying, distributing or using information in this document is against the law. If you are not the intended recipient, please notify the sender immediately and return the document(s) by mail to Optum Rx P.O. Box 2749, Shawnee Mission, KS 66201.

CSRO

The Impact of Step Therapy on Patients

Authors:

Jennifer Snow, MPH;
Madelaine A. Feldman, MD, FACR;
Jenna Kappel, MPH, MA

https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/impact-of-step-therapy-on-patients_final_1019.pdf

- Resulted In **More Missed Work, More Out-of-pocket Expenses**, And **More Of A Decrease In Quality Of Life**—both Physically And Emotionally
- Pay **More Out Of Their Own Pockets**, Leading To **Increased Rates Of Nonadherence**
- The **Significant Variation Among Payer Formulary Protocols**, Among And Within Plans, Calls Into **Question The Clinical Rationale For Step Therapy**
- Potential For **Disease Flares, Negative Immune Responses, Adverse Effects, And Complete Loss Of Response.**

Consequences of Non-Medical Switching

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Coalition of State Rheumatology Organizations

- Rheumatoid arthritis **(RA) patients** found those forcibly switched to a different medication experienced

  42 percent more ER visits and 12 percent more outpatient visits within the first 6 months.1

- People with **epilepsy** showed switching caused **breakthrough seizures** requiring more inpatient and emergency room care. **2, 3**

- Nonmedical switching can **limit future treatment options**. Practice causes some patients to become less responsive to treatment, even if they are returned to the original medication. **4**

- Nonmedical switching actually **increases health care costs**. forced to switch treatments **37 percent higher medical costs** (including ER visits, hospitalizations, and physician care) and **26 percent higher overall costs than patients continuing on a successful medication. 5**

1 Signorovitch J et al. Switching from adalimumab to other disease-modifying antirheumatic drugs in rheumatoid arthritis without apparent medical reasons: Impact on health care service use. Ann Rheum Dis. 2012:17(Suppl 3):717

2 Epilepsy Foundation. 2009. In Their Own Words: Epilepsy Patients' Experiences Changing the Formulation of the Drugs They Use to Prevent Seizures.: https://www.epilepsy.com/sites/core/files/atoms/files/In-Their-Own-Words.pdf

3 Zachary III WM, Doan QD, Clewell JD, et al. Case-control analysis of ambulance, emergency room or inpatient hospital events for epilepsy and antiepileptic drug formulation changes. Epilepsia 2009 Mar;50(3):493-500

4 Global Alliance for Patient Access. Non-Medical Switching: Fast Facts. January 2017. Accessible at: http://gafpa.org/wp-content/uploads/GAfPA_Fast-Facts_Non-Medical-Switching_January-2017-1.pdf

5 Chao J, Lin J, Liu Y, et al. Impact of nonmedical switching on healthcare costs: a claims database analysis. Value in Health 2015;18 (Issue 3); pp A252

PBMs Ultimately Determine

What - Constructing the Formulary

When - Step therapy, Non-Med Switch

Where - Pharmacy network, Site of Care

How Much – Copay, Co-insurance

3 PBMs Control The Formularies For 80% Of The American People

What About Drug Prices??

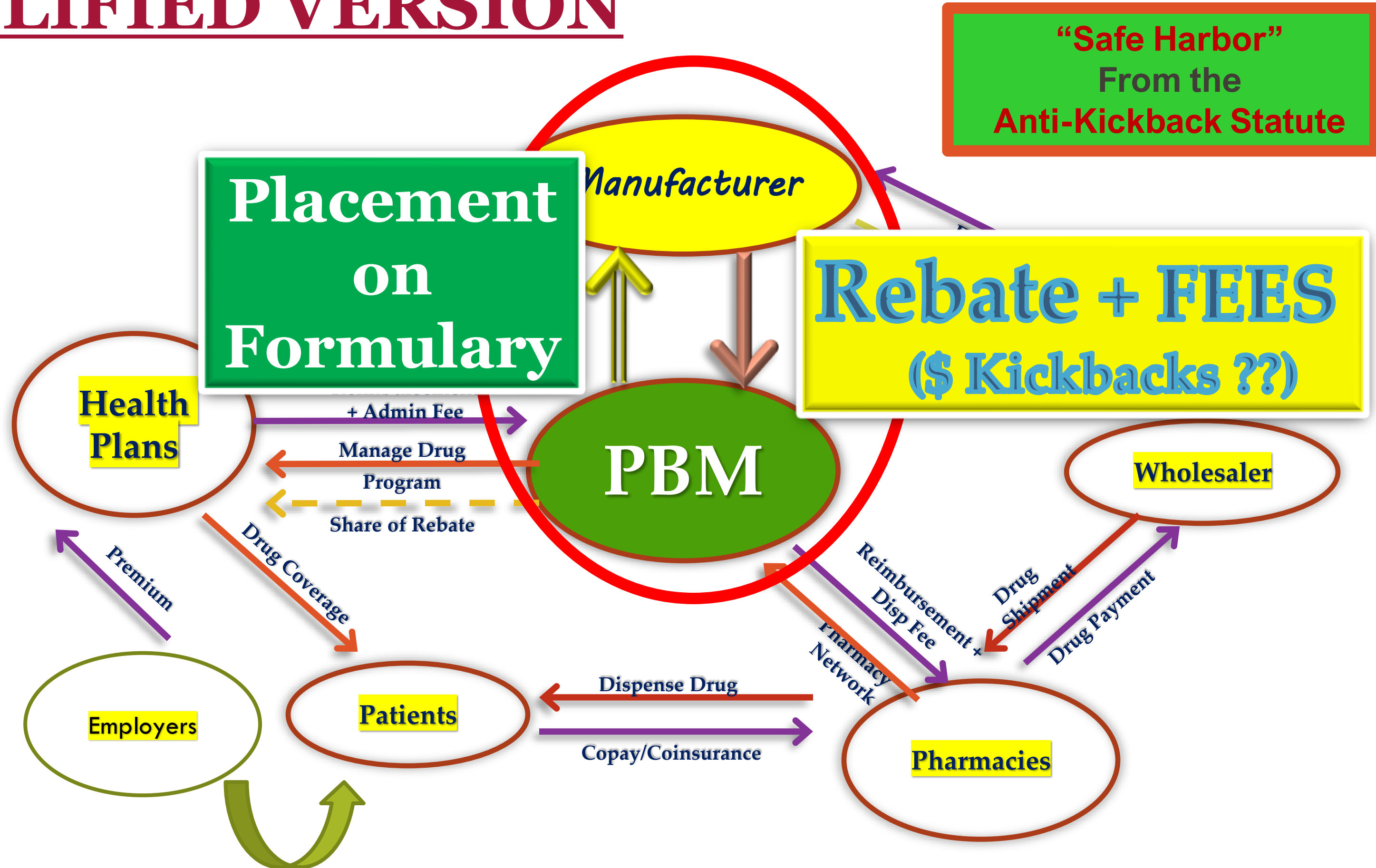
"It's a major breakthrough. But we're still years away from being able to justify the outrageous cost per pill."

Pharmacy Benefit Managers

Drug Manufacturers

Breaking Down The Drug/Money/Services Flow

SIMPLIFIED VERSION



No One Takes It.

Benefits Of Preferred Placement For Drug Makers

- Step Therapy - Fail *Your* Drug First
- Non Medical Switching - Switch To *Your* Drug
- Excludes Competitors To *Your* Drug
  - Exclusionary Contracts
  - Performance Contracts

https://www.insidesources.com/preferred-placement-and-rebate-walls/

What Determines Preferred Placement?

Efficacy?

Safety?

Lowest List Price?

Guess again…..

Can't Forget About The Fees !

How it Works:

"BIDDING WAR" for the Preferred Place on Formulary…

Drug Makers

PBMs

THE EQUATION

The Equation (Simplified)

FORMULARY REBATE BID =

List Price X % Rebates/Fees X # Scripts Filled

1. **List Price Of The Drug**
2. **% Rebate Promised**
3. **# Scripts Filled (*Market Share*)**

An Increase In Any One Of These Variables

Better Chance At Preferred Placement

But What About COMPETITION?

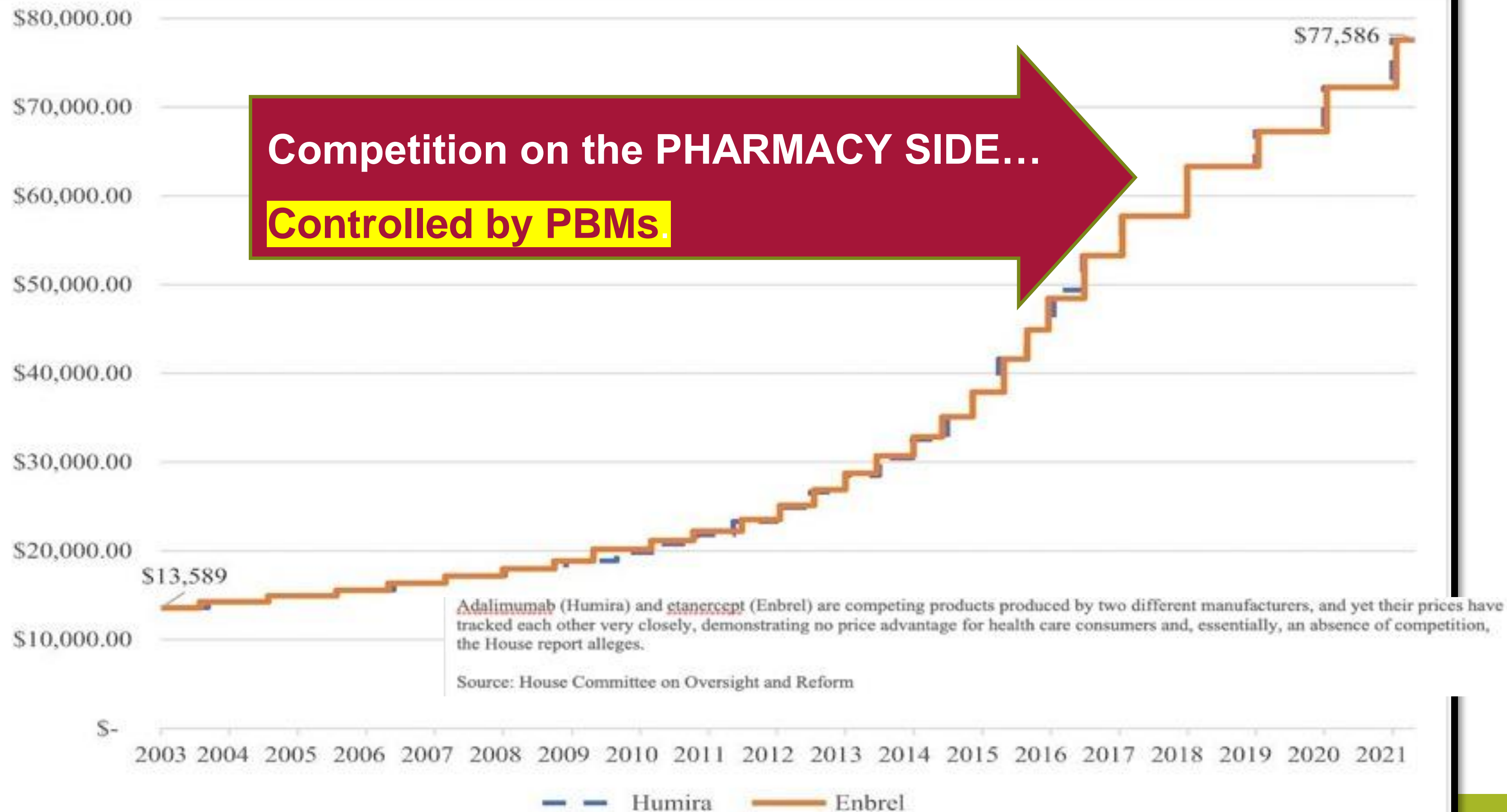


Chart. Humira and Enbrel: Price of an Annual Course of Treatment
$80,000.00
$70,000.00
$60,000.00
$50,000.00
$40,000.00
$30,000.00
$20,000.00
$10,000.00
$-
$77,586
$13,589
Competition on the PHARMACY SIDE…
Controlled by PBMs
Adalimumab (Humira) and etanercept (Enbrel) are competing products produced by two different manufacturers, and yet their prices have tracked each other very closely, demonstrating no price advantage for health care consumers and, essentially, an absence of competition, the House report alleges.
Source: House Committee on Oversight and Reform
2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021
Humira
Enbrel

Manufacturers COMPETE for the Preferred Spot…

COMPETITION DRIVES PRICES DOWN

BUILDING A HOUSE

WINNER= Lowest Bidder

SELLING A HOUSE

WINNER= Highest Bidder

OUR DRUG DISTRIBUTION SYSTEM

- Rebate/fee bids based on a % of the list price of the medicine.
- These price concessions can be well over 50% of the list price.
- **This creates a perverse incentive for HIGHER PRICED MEDICINES, not lower, because the HIGHER PRICED MEDICINE can provide the larger rebate /fee package.**

Which Drug Has the Best Bid?

	Drug A	Drug B	Drug C
List Price	~$30K/yr	~$70K/yr	~$80K/yr
Formulary Rebate % ($ Savings)	50% ($15,000)	50% ($32,500)	50% ($37,500)
Patient-Cost share	$6000	$13,000	$15,000

WINNER! = Drug C

HIGHEST SAVINGS to PBM, but also **HIGHEST COST** to patient

The Higher the LIST PRICE, The Higher the…

FEES

FEES

FEES

FEES

FEES

FROM EXPRESS SCRIPTS CONTRACT (Axios.com)

For sake of clarity, Rebates do not include, for example,

- **Manufacturer Administrative Fees**;
- **Inflation payments**;
- **Product discounts or fees related to the procurement** of prescription **drug inventories** by ESI Specialty Pharmacy or the Mail Service Pharmacy;
- **Fees** received by ESI from pharmaceutical manufacturers for **care management/ services** provided with the **dispensing** of products;
- **Other fee-for-service arrangements** whereby pharmaceutical manufacturers generally report the fees paid to ESI or its wholly-owned subsidies for services rendered as **"bona fide service fees"**

Such laws and regulations, as well as ESI's contracts with pharmaceutical manufacturers, generally prohibit ESI from sharing any such "bona fide service fees" earned by ESI, whether wholly or in part, with any ESI client.

https://www.axios.com/drug-pricing-contract-express-scripts-d536e8a9-a8a3-4bc9-8028-05453e617326.html

...hat Is At Stake?

...ionship determining

The best t... ...nd affordability.

Higher List Drug Prices =
Higher Patient Cost Sharing

But instead we are faced ...

- Formulary Restrictions
  - Step-therapy
  - Non-medical switching
  - Exclusions
  - Prior authorizations

Because Co-insurance Based on List Price…

- **Copay Cards From the Manufacturer Are Needed To Help Patient Pay**
- **20% -List Prices $Thousands/month or More**
- **Helps Patients with Chronic Diseases *Also* By Reducing Deductible**

PBMs Thought
"WAIT JUST A MINUTE!"

“ HOW CAN WE MAKE MONEY ON THIS?”

Accumulator Adjustment Program-Copay Accumulators

A Utilization Management Tool

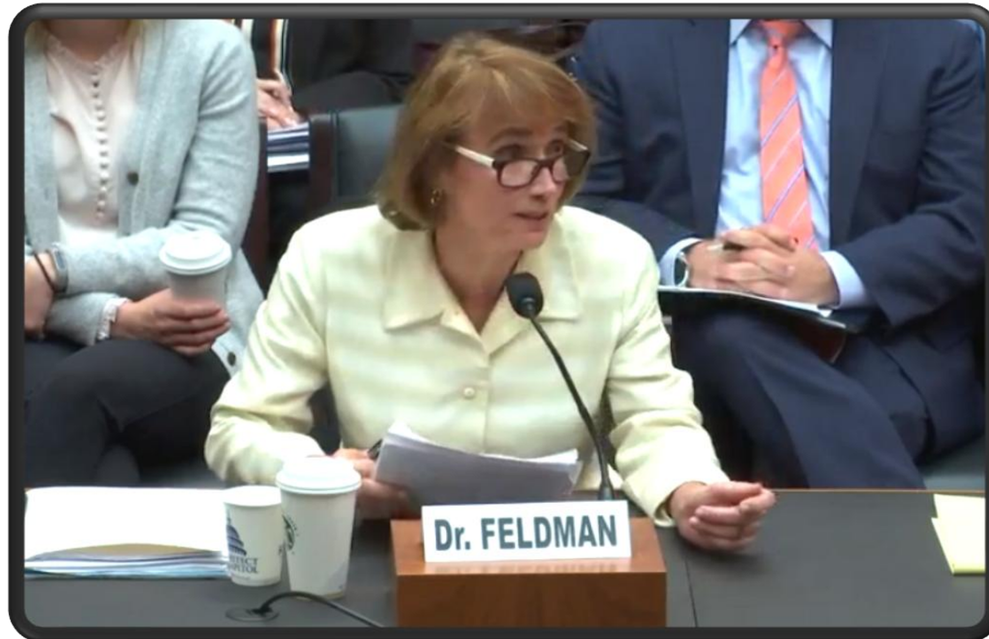
Disallows Money Paid By A Drug Manufacturer In The Form Of A Copay Card To Count Toward The Deductible/OOP Costs Of The Patient.

Essentially Stealing Patient Assistance Money With Copay Accumulators

Over 20 States Have Passed Bans On Accumulator Programs

What's a Rheumatologist To Do?

Health Subcommittee –
Energy and Commerce 2019



CSRO
Coalition of State Rheumatology Organizations

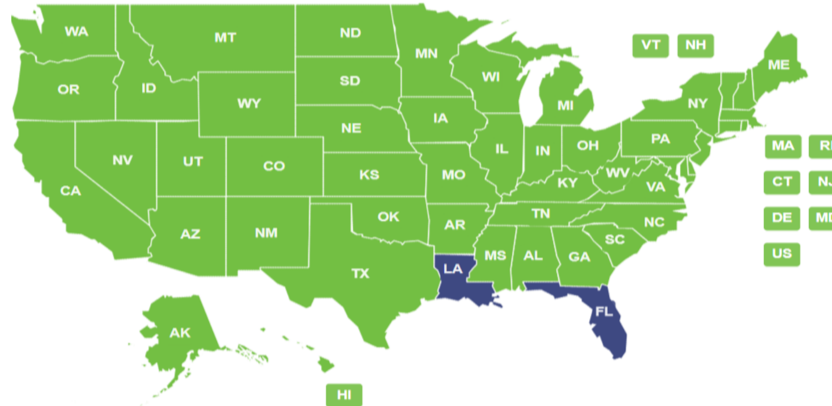
Legislative Map Tool

CSRO's legislative map tool allows the rheumatology community to easily learn about existing and pending legislation in their state and at the federal level that pertains to CSRO's utilization management and drug pricing reform priority issue areas. Information on state-specific legislation and regulation regarding in-office dispensing for rheumatology is available here.

Using the Map

1. Find Your State

Click on your state to view a listing of current or proposed legislation in your area. To review Federal issues, click the "US" Icon.



LOUISIANA

ACCUMULATOR ADJUSTMENT PROGRAMS

ENACTED LEGISLATION R.S. 22:976.1

KNOW THE LAW | FILE A COMPLAINT

NON-MEDICAL SWITCHING

ENACTED LEGISLATION

KNOW THE LAW | FILE A COMPLAINT

PBM REGULATION

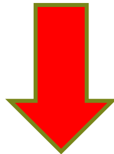
ENACTED LEGISLATION LRS 22:1657

KNOW THE LAW

PRIOR AUTHORIZATION

ENACTED LEGISLATION RS 22:1006.1 & 46:460.33

KNOW THE LAW | FILE A COMPLAINT



STEP THERAPY

ENACTED LEGISLATION (COMMERCIAL & STATE EMPLOYEE) RS 22:1053

KNOW THE LAW | APPEALS | OFFICE HANDOUT | COVER SHEET

Supporting Information for Step Therapy Exception Request

Pursuant to Louisiana Revised Statutes §22:1053

Determination required within:

- ☐ 24 hours (exigent circumstances)
- ☐ 72 hours

Pursuant to §22:1053 of the Louisiana Revised Statutes the patient qualifies for an exception to the step therapy protocol because any **one** of the following conditions has been met:

- ☐ The patient has tried the required drug, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and the drug was discontinued due to a lack of efficacy effectiveness, diminished effect, or an adverse event.
- ☐ The required drug is expected to be ineffective.
- ☐ The required drug is contraindicated or will likely cause an adverse reaction or physical or mental harm.
- ☐ The patient is currently receiving a positive therapeutic outcome on a drug for the medical condition under consideration.
- ☐ The required drug is not in the best interest of the patient based on medical necessity.

Rationale for Request

Signature:	**Date:**

Attn: Department of Insurance

Fax: 225.342.5900/Complaint:

https://www.ldi.la.gov/onlineservices/ConsumerComplaintForm

Legislative Map Tool

CSRO's legislative map tool allows the rheumatology community to easily learn about existing and pending legislation in their state and at the federal level that pertains to CSRO's utilization management and drug pricing reform priority issue areas. Information on state-specific legislation and regulation regarding in-office dispensing for rheumatology is available here.

Are there issues you would like to see on the map or have other suggestions? Let us know! Email info@csro.info with your feedback.

Underwriting support provided by: AMGEN

Using the Map

1. Find Your State
Click on your state to view a listing of current or proposed legislation in your area. To review Federal issues, click the "US" Icon.

2. Select an Issue
Learn about the utilization management reform laws in your state and find resources to help you better understand the policy.

3. Get Involved
Contact CSRO for additional resources and to learn about ways you can take action to make an impact on legislation in your state.

No Legislation | Enacted | Active

FEDERAL GOVERNMENT

MEDICARE PHYSICIAN FEE SCHEDULE

ACTIVE LEGISLATION HR 879

READ THE BILL

GET UPDATES FOR US

Support CSRO's Work

Directly impact CSRO's advocacy efforts by making an online donation today - click here to give now.

Action Center

Welcome to the CSRO Action Center

With so many concerns to track, legislators rely on you to raise the profile of pressing issues. This page houses CSRO's engagement platform, which allows you to communicate directly with your legislators. Advocacy is important, but we are also mindful of your time. Our tool allows you to participate in grassroots advocacy with minimal time expenditure.

Federal – Eliminate the 2.83% Cut to the Medicare Physician Fee Schedule

Contact your members of Congress and urge them to cosponsor and support the Medicare Patient Access and Practice Stabilization Act (H.R. 879), which would eliminate the 2.83% cut to the Medicare Physician Fee Schedule, which went into effect on January 1. It would...

New Jersey – Support Step Therapy Reform

Contact your state legislators and urge them to support A.1825/S.3533, which would protect patients from excessive step therapy by creating an exceptions process that would allow patients to appeal step therapy protocols in cases where they are clearly inappropriate...

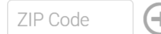
View Your Election Center

Enter your address to view voting resources and your officials & candidates

Sign Up for Alerts

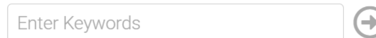
Enter your information below to sign up.

Enter Email



Find Legislation

View and search for legislation.



Scorecard

View how your officials voted on key actions!

View scorecard

RHEUM FOR ACTION (Now in Medscape and Rheumatology News)

Rheum for Action

Through a partnership with Rheumatology News, CSRO publishes a bi-monthly advocacy column authored by Vice President of Advocacy & Government Affairs, Madelaine Feldman, MD.

Titled *Rheum for Action*, the column inspires individuals to make 'rheum' in their lives for action and keeps the rheumatology community updated on the latest advocacy issues affecting their work. Review all of the latest editions of the columns below.

Rheum for Action: 2025

Rheum for Action: Patients Before Monopolies Act: A Game Changer for Patients, Pharmacists, and Prices?

posted: January 24, 2025 to *CSRO News*

READ COLUMN ⇒ | VIEW PDF ⇒

Rheum for Action: 2024

Rheum for Action: Abuse of the Safety-Net 340B Drug Pricing Program: Why Should Physicians Care?

posted: November 18, 2024 to *CSRO News*

Rheumatology News and the CSRO have partnered to keep rheumatologists regularly informed on the advocacy issues of the day. In this piece, Dr. Mattie Feldman discusses the 340B Drug Pricing Program.

READ MORE ⇒

Rheum for Action: 'Reform School' for Pharmacy Benefit Managers: How Might Legislation Help Patients?

posted: September 17, 2024 to *CSRO News*

Rheumatology News and the CSRO have partnered to keep rheumatologists regularly informed on the advocacy issues of the day. In this piece, Dr. Mattie Feldman discusses reforms that would improve patient's access to available and affordable medications.

READ MORE ⇒

Rheum for Action: Fed Worker Health Plans Ban Maximizers and Copay Accumulators: Why Not for the Rest of the US?

posted: July 29, 2024 to *CSRO News*

Rheumatology News and the CSRO have partnered to keep rheumatologists regularly informed on the advocacy issues of the day. In this piece, Dr. Mattie Feldman discusses healthcare affordability and the need for policies to prioritize the health and well-being of patients.

READ MORE ⇒

Rheum for Action: Specialists Are 'Underwater' With Some Insurance-Preferred Biosimilars

posted: May 16, 2024 to *CSRO News*

Rheumatology News and the CSRO have partnered to keep rheumatologists regularly informed on the advocacy issues of the day. In this piece, Dr. Mattie Feldman discusses the financial challenges posed by certain biosimilars for which acquisition costs exceed reimbursement levels.

READ MORE ⇒

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COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS

With Sufficient Thrust Pigs Fly Just Fine!!

Any Questions?