



Medication Access in the US
Payers, PBMs, Prices, & Patients

Who Really Pays?

How Formularies & Utilization Management Tools
Increase Prices & Harm Patients

Coalition of State Rheumatology Organizations

Fellows Meeting

March 1-2, 2024 Austin, TX

Madelaine T. Feldman MD, FACR.

**Coalition of State Rheumatology Organizations- V. President Advocacy and Gov't Affairs
Clinical Instructor/Assis. Prof. of Medicine – Tulane Medical School**

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Rheum Fellow View of Health Insurance



Health Insurance Companies = Payers?

A Person Or Entity, Or Safety.

A Person Or Entity,
Person Named In A Bill Who Has Holder

**Money Dealer
Money Handler**

Fortune 500 Ranking 2024

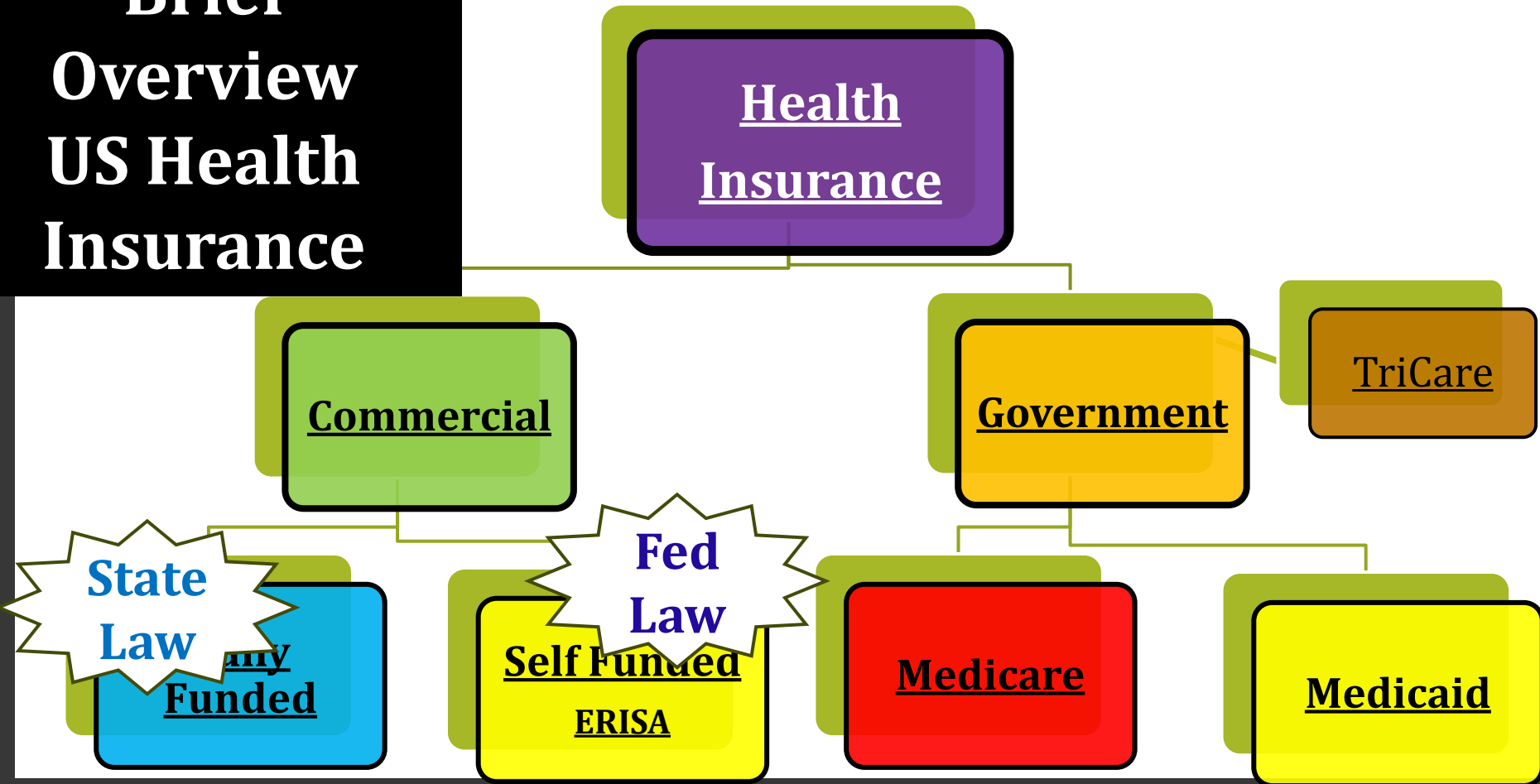
**#5 UnitedHealth Group – Revenue
\$324.326 Billion**

**#6 CVS Health – Revenue
\$322.467 Billion**

**#15 Cigna- Revenue
\$180.364 Billion**

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

Brief Overview US Health Insurance



Health

D/ALS

Part C

Medicare

Advantage

Private Insurance

Pay Premium

Part A

Hospital Care

Generally

No Premium

Covers 100%

First 60 days of hospital charges

Part D

Covers

pharmacy drugs

Private Insurance

Pay Premium

Medicare Part B

- Premium ex. -\$165/mo, Deductible \$226, then 20% Copay
- Supplemental insurance available
- Physician admin.drugs
- No copay cards allowed

Medicare Part D

- Private insurance companies
- Variable premiums formularies
- Self-administered drugs
- No copay cards allowed

Medicare Part C/Medicare Advantage

- Rep
- Cap
- Phy
- No
- Incr

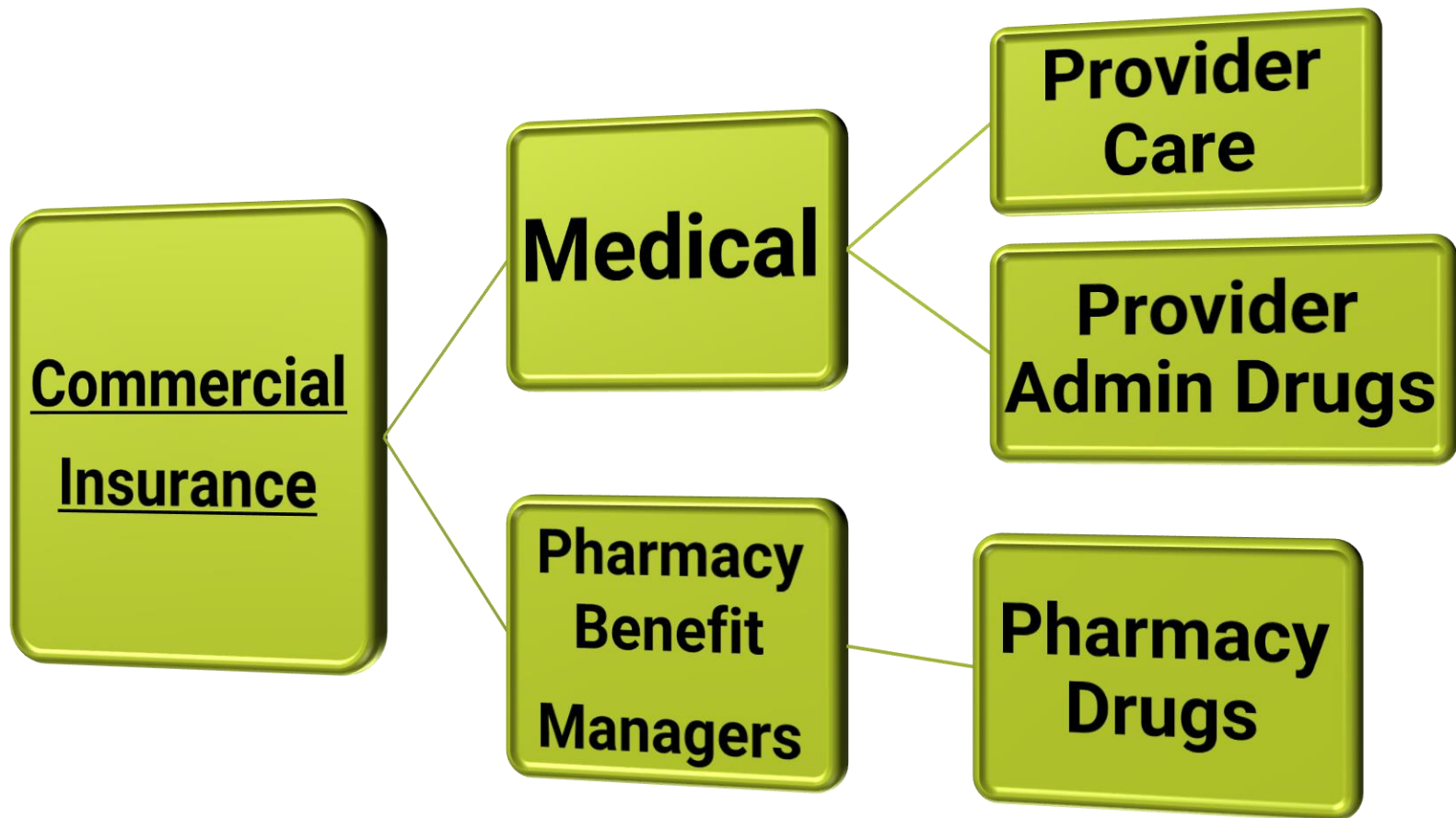
**Increasingly Profitable
For Insurance
Companies**

Medicaid Qualifications in Louisiana

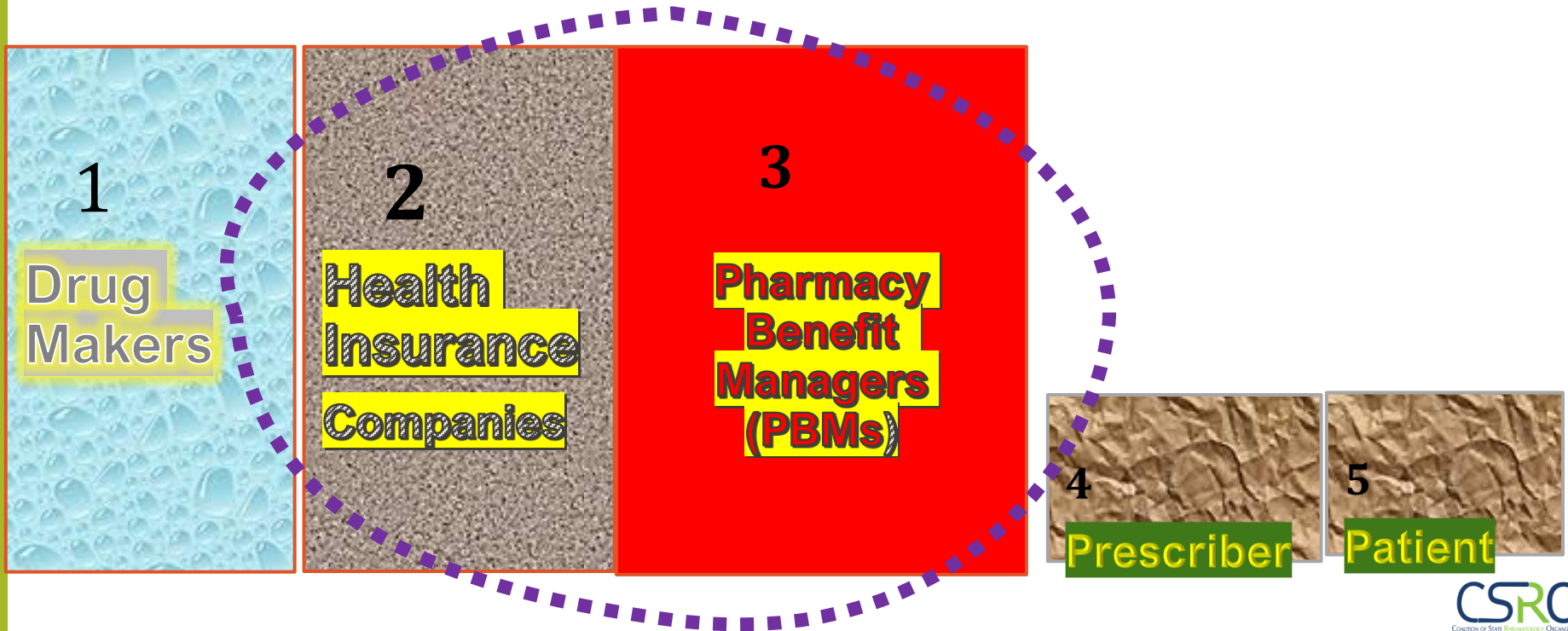
- Receive Supplemental Security Income (SSI) from the Social Security Administration (SSA)
- Are disabled according to the Social Security Administration's [definition](#)
- Have corrected vision no better than 20/200
- Are a low-income parent of children under age 19
- Are a child under age 19
- Are pregnant
- Have no insurance & need treatment for breast and/or cervical cancer
- Receive Medicare coverage and are low-income
- Are aged 19 to 64 years old, have a household income less than 138% of the federal poverty level, and meet citizenship requirement
- Get financial help from the Office of Family Support (OFS) through the [Family Independence Temporary Assistance Program](#) (FITAP)

Mandatory medical services included under Medicaid are:

- Inpatient And Outpatient Hospital Services;
- Physician Services;
- Laboratory And X-ray Services;
- Long-term Care Facilities;
- Family Planning;
- Services For Early Periodic Screening, Diagnosis And Treatment Of Those Under Age 21.
-



Who are some of the Players in the Drug Distribution System?



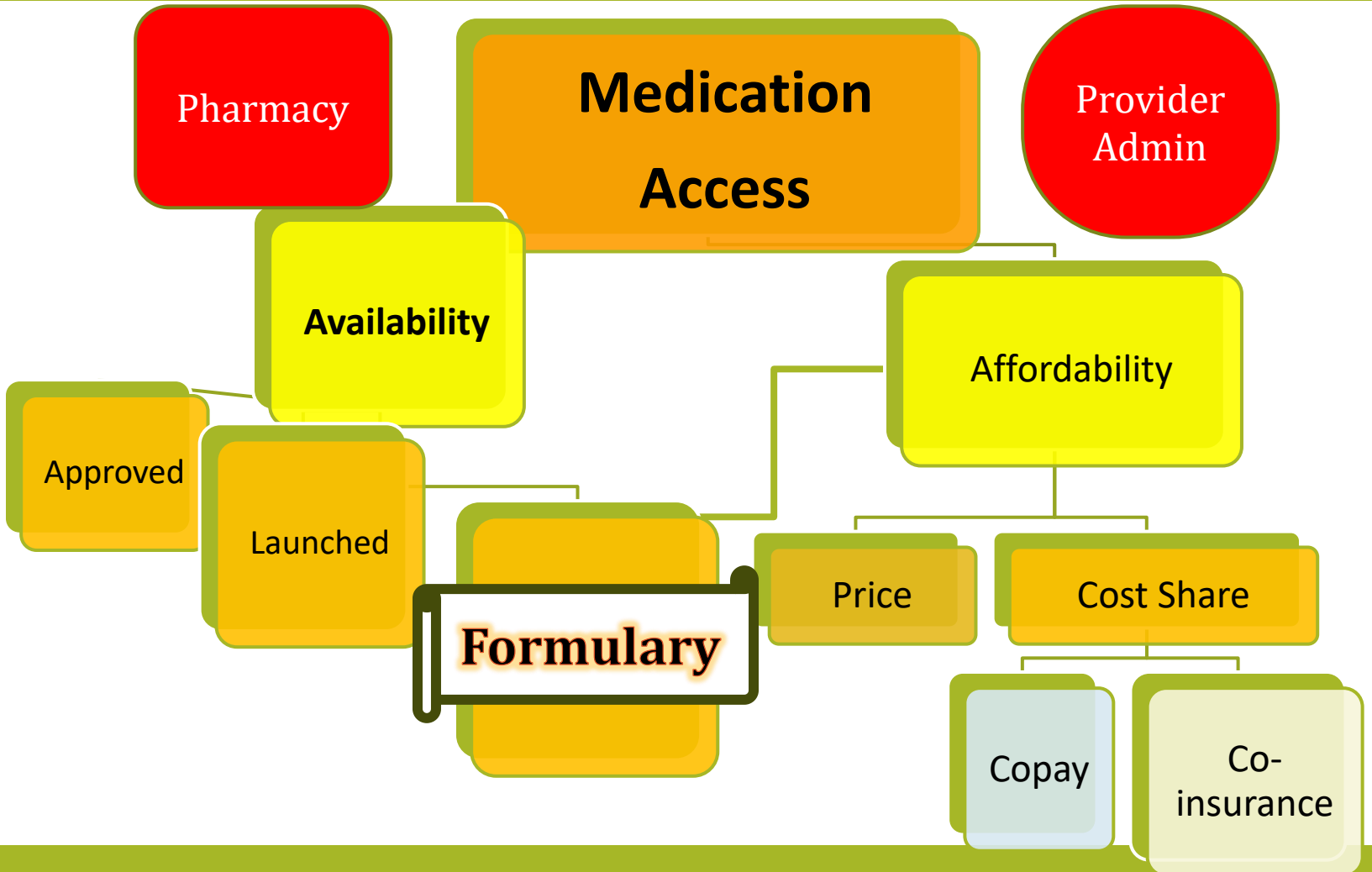
2019

Vertical Integration-PBMs/Insurance Companies

Let's Get Vertical: Insurer + PBM + Specialty Pharmacy + Provider



1. Cigna partners with providers via its [Cigna Collaborative Care](#) program. However, Cigna does not directly own healthcare providers.
2. AllianceRx Walgreens Prime is jointly owned by Prime Therapeutics and Walgreens Boots Alliance.
Source: Drug Channels Institute research; [The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers](#), Chapter 5.



A collection of wooden blocks, some with checkmarks and one with a red X. The blocks are scattered across the frame, with a prominent red X block in the center-right. The background is a solid light green color.

If An Expensive Drug
Is Not On The Formulary...
No Matter How Great It Is...

No One Takes It.

Who Constructs The Pharmacy Drug Formulary?

Pharmacy Benefit Managers

What Maintains The Formulary?

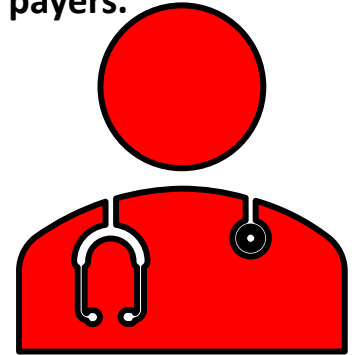
(profitability)

UTILIZATION MANAGEMENT TOOLS

What Do PBMs Do?

“Pharmacy benefit managers, or PBMs, are companies that manage prescription drug benefits on behalf of health insurers, Medicare Part D drug plans, large employers, and other payers.”

- Adjudicate pharmacy claims
- Patient cost share
- Pharmacy network
- SITE of CARE



- **Construct & Maintain Formulary (Utilization Management Tools)**

PBM's Ultimately Determine

What - Constructing the Formulary

When - Step therapy, Non-Med Switch

Where - Pharmacy network, Site of Care

How Much – Copay, Co-insurance

**3 PBM's Control The Formularies For 80% Of
The American People**

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 #: [REDACTED]

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

RE: Prior Authorization Request

Patient Name: [REDACTED]
Patient ID: [REDACTED]
Medication Name: Plaquenil Tab 200mg

Patient DOB: [REDACTED]
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.

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Page 1 of 9

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

- 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

WHAT ABOUT
DRUG PRICES??



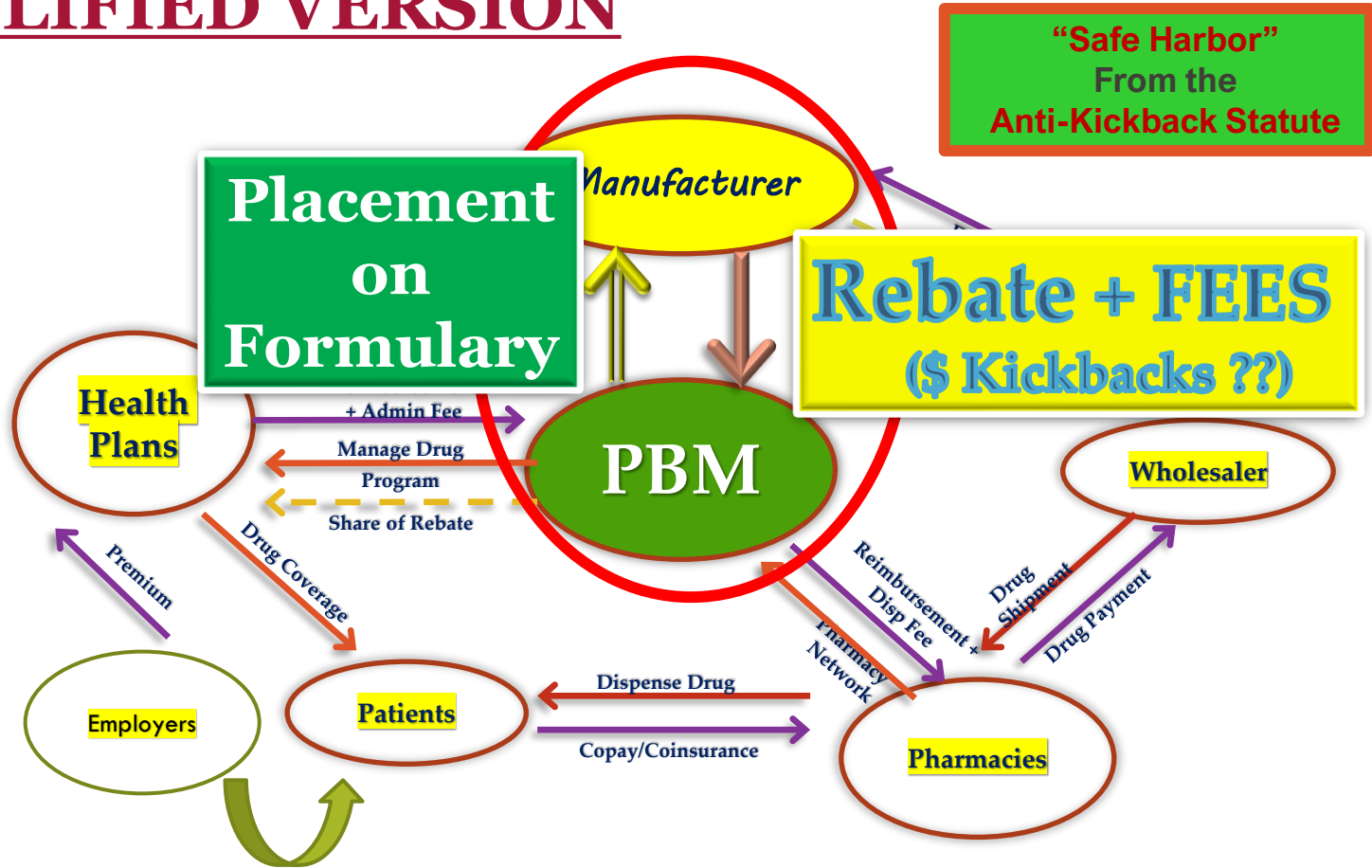
Pharmacy Benefit Managers

Drug Manufacturers



Breaking Down The Drug/Money/Services Flow

SIMPLIFIED VERSION





*What's Even Better is
Preferred Formulary*

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**

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

$$f'(x) = \lim_{h \rightarrow 0} \frac{f(x+h) - f(x)}{h}$$
$$= \lim_{h \rightarrow 0} \frac{x^2 + 2xh + h^2 - x^2}{h}$$

$$= \lim_{h \rightarrow 0} \frac{2xh + h^2}{h}$$

The Equation (Simplified)

FORMULARY REBATE BID =

List Price X % Rebated 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?

Manufacturers COMPETE for the Preferred Spot...



BUILDING A HOUSE

WINNER= Lowest Bidder

COMPETITION
DRIVES
PRICES
DOWN

COMPETITION
DRIVES
PRICES
UP



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?

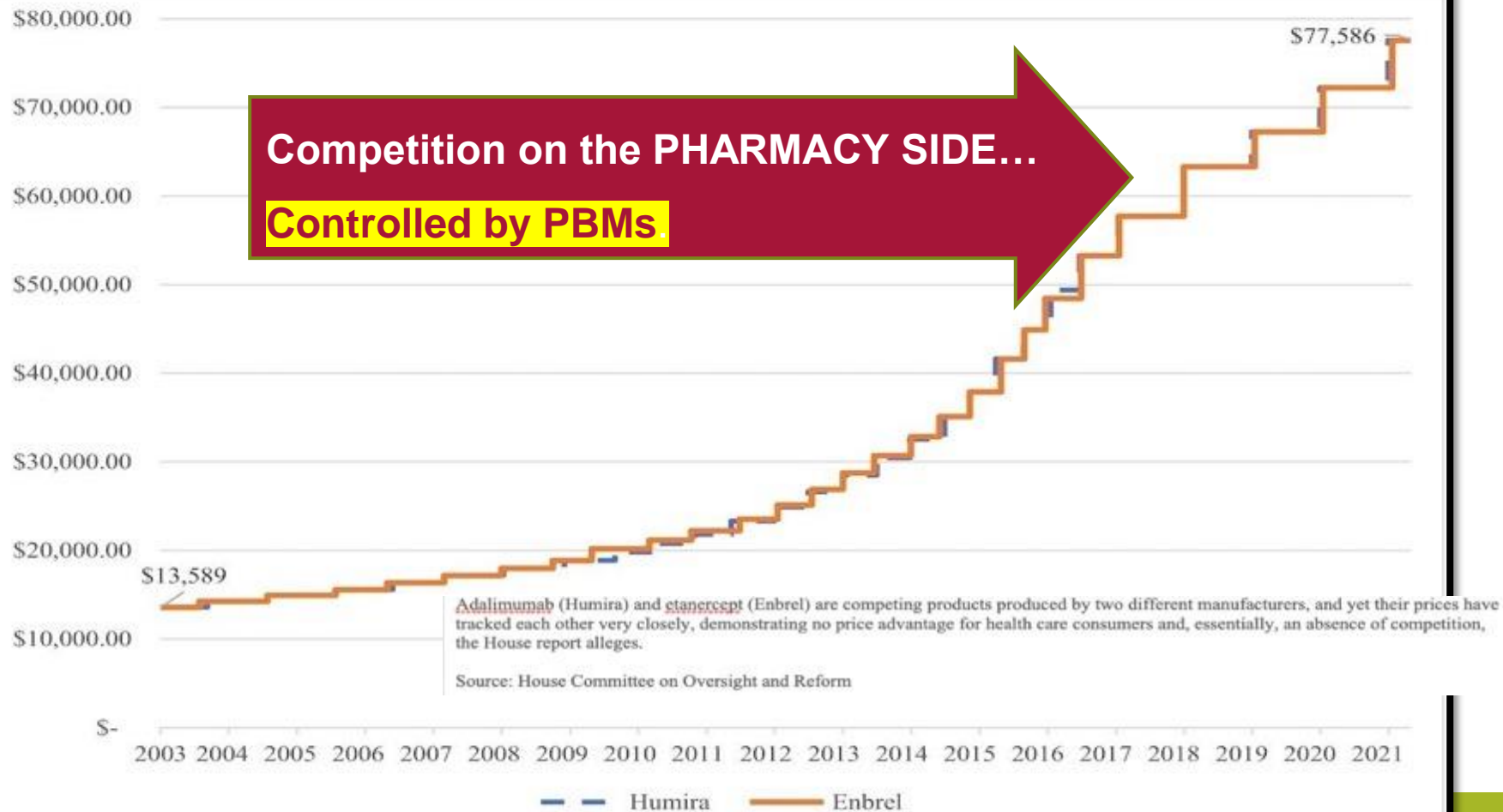
	Drug A	Drug B	Drug C
List Price	~\$30K/yr	~\$70K/yr	~\$80K/yr
Formulary Rebate % (\$ Savings)	50% (\$15,000)	50% (\$32,500)	50% (\$37,500)
Patient-Cost share	\$6000	\$13,000	\$15,000

WINNER! = Drug C

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



Chart. Humira and Enbrel: Price of an Annual Course of Treatment



The Higher the LIST PRICE, The Higher the...

FEEES

FEEES

FEEES

FEEES

FEEES

<u>Invoice Date</u>	<u>Type of Contract</u>	<u>Formulary Rebate</u>	<u>Admin Fee</u>	<u>Price Protection Rebate</u>	<u>Total</u>
Jan-16	Commercial	\$1,612.50	\$24,963.90	\$5,689.26	\$32,265.66
Jan-16	Medicare	\$450	\$2,652.13	\$5,184.14	\$8,286.57

2/1/16 kaleo increase Evzio list price from \$937.50 to \$4,687.50

Apr-16	Commercial	\$7,125.00	\$129,517.29	\$4,951,923.90	\$5,088,566.19
May-16	Commercial	\$9,937.50	\$137,162.51	\$2,266,092.01	\$2,413,192.02
Dec-16	Commercial	\$4,312.50	\$56,395.65	\$977,873.22	\$1,038,581.37
Dec-16	Medicare	\$3,375	\$12,468.56	\$219,218.80	\$235,062.36
	Total	\$26,812.50	\$363,160.04	\$8,425,981.33	\$8,815,954.17

What Is At Stake?

relationship determining
The best of both worlds: quality and affordability.

But instead we are faced with

**Higher List Drug Prices =
Higher Patient Cost Sharing**

- **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**

Copay Cards Are Bad!

**PBMs Thought
"WAIT JUST A MINUTE!"**

Entice Patients, Hook Patients
On Expensive Medications



"Congratulations...your cholesterol
is lower than your copay."

CARTOONSTOCK.com
Search ID: kbrn34 ©
BROWN

“**HOW DO WE MAKE MONEY ON THIS?**”

A **Form Of A Copay Accumulators**

“Deductible Double Dipping”
*(collects deductible amount
from both manufacturer
and patient)*

Disallows Manufacturer **the**

Form Of A Copay Care

Deductible/OOP Costs Of The

Who are Most Affected by Accumulators?

**Stealing Patient
Assistance Money
With Copay Accumulators**

PBMs Claim To *Save Billions For Our Health Care System*

- Designing formularies based on “negotiated discounts”
 - **Secret kickback package – based on list price & market share**
- Utilization Management Tools – “Employers want them”
 - **Keep patients on the most profitable drugs**
 - **Many Employers have no idea what they are signing**
- Encouraging use of generics & affordable brands
 - **Higher priced and brands preferred**

Market Fails On

**Lack of
Transparency**

Restraint of Trade - 3

How Do They Get Away With This?

“Safe Harbor”

From the

Anti-Kickback Statute



Fortune 500 Ranking 2024

**#5 UnitedHealth Group – Revenue
\$324.326 Billion**

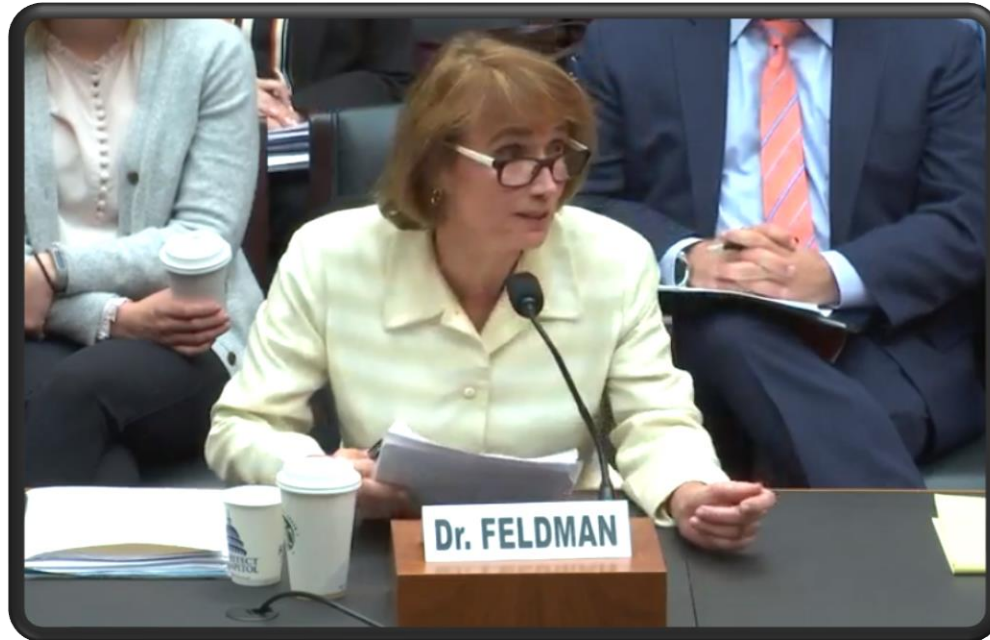
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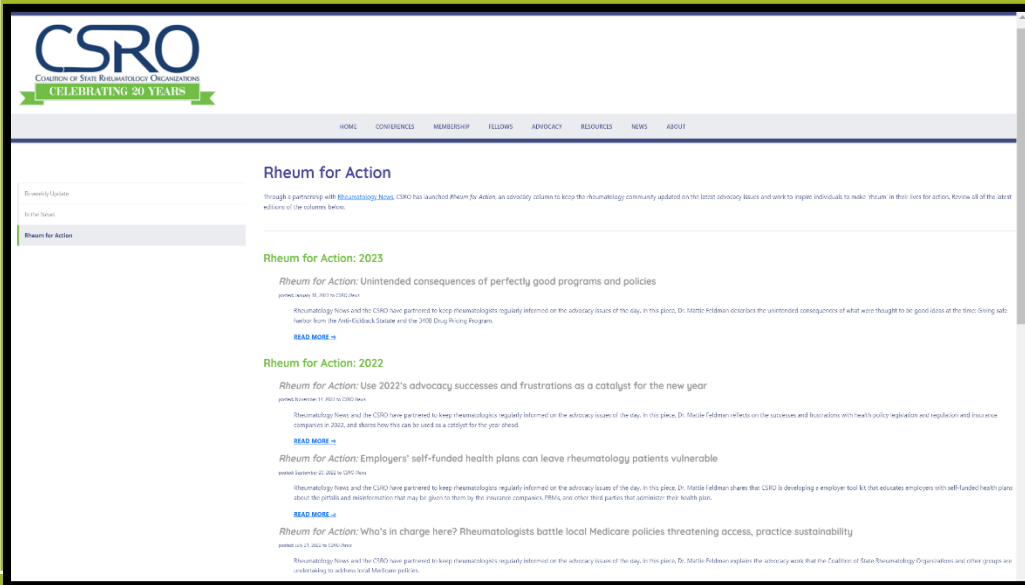
<https://www.50pros.com/fortune500/>

What's a Rheumatologist To Do?

Health Subcommittee – Energy and Commerce 2019



JOIN THE ACTION!



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COLLEGE OF STATE RHEUMATOLOGY ORGANIZATIONS
CELEBRATING 30 YEARS

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Rheum for Action

Through a partnership with [Rheumatology News](#), CSRO has launched Rheum for Action, an advocacy column to keep the rheumatology community updated on the latest advocacy issues and work to inspire individuals to make Rheum in their lives for action. Know all of the latest and best of the columns below.

Rheum for Action: 2023

Rheum for Action: Unintended consequences of perfectly good programs and policies
posted January 10, 2023 by CSRO Staff

Rheumatology News and the CSRO have partnered to keep rheumatologists regularly informed on the advocacy issues of the day. In this piece, Dr. Marie Feldman describes the unintended consequences of what were thought to be good ideas at the time: living safe better from the Anti-Clickback Statute and the 2020 Drug Pricing Program.

[READ MORE →](#)

Rheum for Action: 2022

Rheum for Action: Use 2022's advocacy successes and frustrations as a catalyst for the new year
posted December 14, 2022 by CSRO Staff

Rheumatology News and the CSRO have partnered to keep rheumatologists regularly informed on the advocacy issues of the day. In this piece, Dr. Marie Feldman reflects on the successes and frustrations with health policy legislation and regulation and insurance companies in 2022, and shares how this can be used as a catalyst for the year ahead.

[READ MORE →](#)

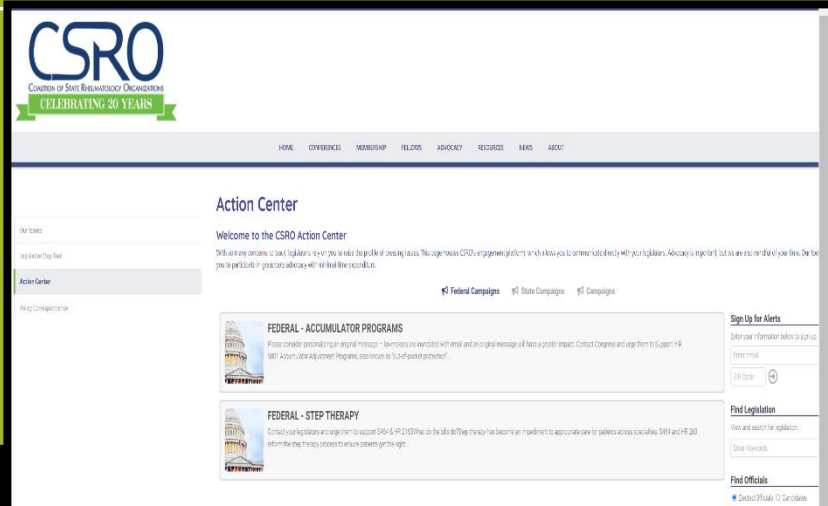
Rheum for Action: Employers' self-funded health plans can leave rheumatology patients vulnerable
posted September 22, 2022 by CSRO Staff

Rheumatology News and the CSRO have partnered to keep rheumatologists regularly informed on the advocacy issues of the day. In this piece, Dr. Marie Feldman shares that CSRO is developing a employer tool kit that educates employers with self-funded health plans about the pitfalls and misstatements that may be given to them by the insurance companies, PBMs, and other third parties that administer their health plan.

[READ MORE →](#)

Rheum for Action: Who's in charge here? Rheumatologists battle local Medicare policies threatening access, practice sustainability
posted on 01/26/2023 by CSRO Staff

Rheumatology News and the CSRO have partnered to keep rheumatologists regularly informed on the advocacy issues of the day. In this piece, Dr. Marie Feldman explains the advocacy work that the Coalition of State Rheumatology Organizations and other groups are undertaking to address local Medicare policies.



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Action Center

Welcome to the CSRO Action Center

With an ever-growing list of legislative, regulatory and policy issues, this page uses CSRO's engagement platform to allow you to communicate directly with your legislators. Advocacy is important, but it is also a matter of your time. Can you participate in greater advocacy when it fits the schedule?

[Federal Campaigns](#) [State Campaigns](#) [Campaigns](#)

FEDERAL - ACCUMULATOR PROGRAMS

Please consider personalizing your message - lawmakers are excited with email and an original message will have a greater impact. Contact Congress and urge them to Support H.R. 5617, Accumulator Adjustment Programs, also known as "Gold Card protection."

FEDERAL - STEP THERAPY

Congress has passed an original message - lawmakers are excited with email and an original message will have a greater impact. Contact Congress and urge them to Support H.R. 5617, Accumulator Adjustment Programs, also known as "Gold Card protection."

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View and search for legislation.
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MISSOURI - WHITE BAGGING

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TEXAS - WHITE BAGGING

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MINNESOTA - WHITE BAGGING

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NORTH DAKOTA - ACCUMULATOR PROGRAMS

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ADVOCACY

Federal Advocacy

State Advocacy

Legislative Map Tool

Action Center

Correspondence

Legislative Map Tool

Welcome to the CSRO Legislative Map

This page houses CSRO's legislative map tool, which will allow you to learn about existing and pending [step therapy](#), [non-medical switching](#), [accumulator adjustment program](#), and [uniform prior authorization](#) laws in your state and at the federal level.

Using the Map

1. SELECT YOUR STATE

For Federal issues click the "DC" icon.

2. SELECT YOUR ISSUE

See what utilization management reform laws are on the books in your state, what their provisions are, how they apply, and what issues are pending in the state legislature.

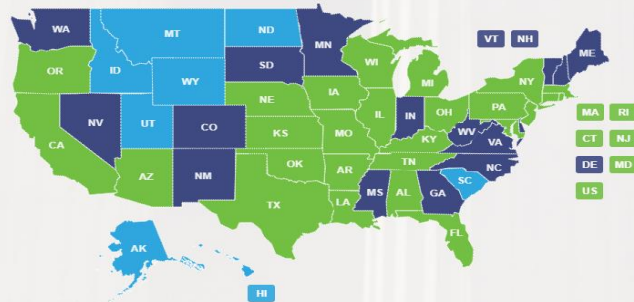
3. NO LEGISLATION?

[Find out how you can get involved](#), and what resources CSRO offers to help you change that.

4. COMMUNICATE WITH US!

We want to hear from you. [Let us know](#) what can be improved, what questions you have, and what issues you would like to see detailed on the map.

■ No Legislation ■ Enacted ■ Active



Leaflet | Legislation data © CSRO

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The state and federal policy environment is constantly changing. Every effort is made to keep the information presented here comprehensive and up to date. Please contact us if you experience any issues, broken links, out of date information, etc.

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**CSRO MAP
TOOL**

**FIND
YOUR
STATE**

CSRO.info/map

**With Sufficient Thrust
Pigs Fly Just Fine!!**



The Transparency Problem



"Let's never forget that the public's desire for transparency has to be balanced by our need for concealment."

*Any
Questions?*

