



Medication Access in America

The Multi-Billion Dollar Companies of the Drug Supply Chain

Articularis Healthcare

March 30-31, 2021

Madelaine T. Feldman MD, FACR.

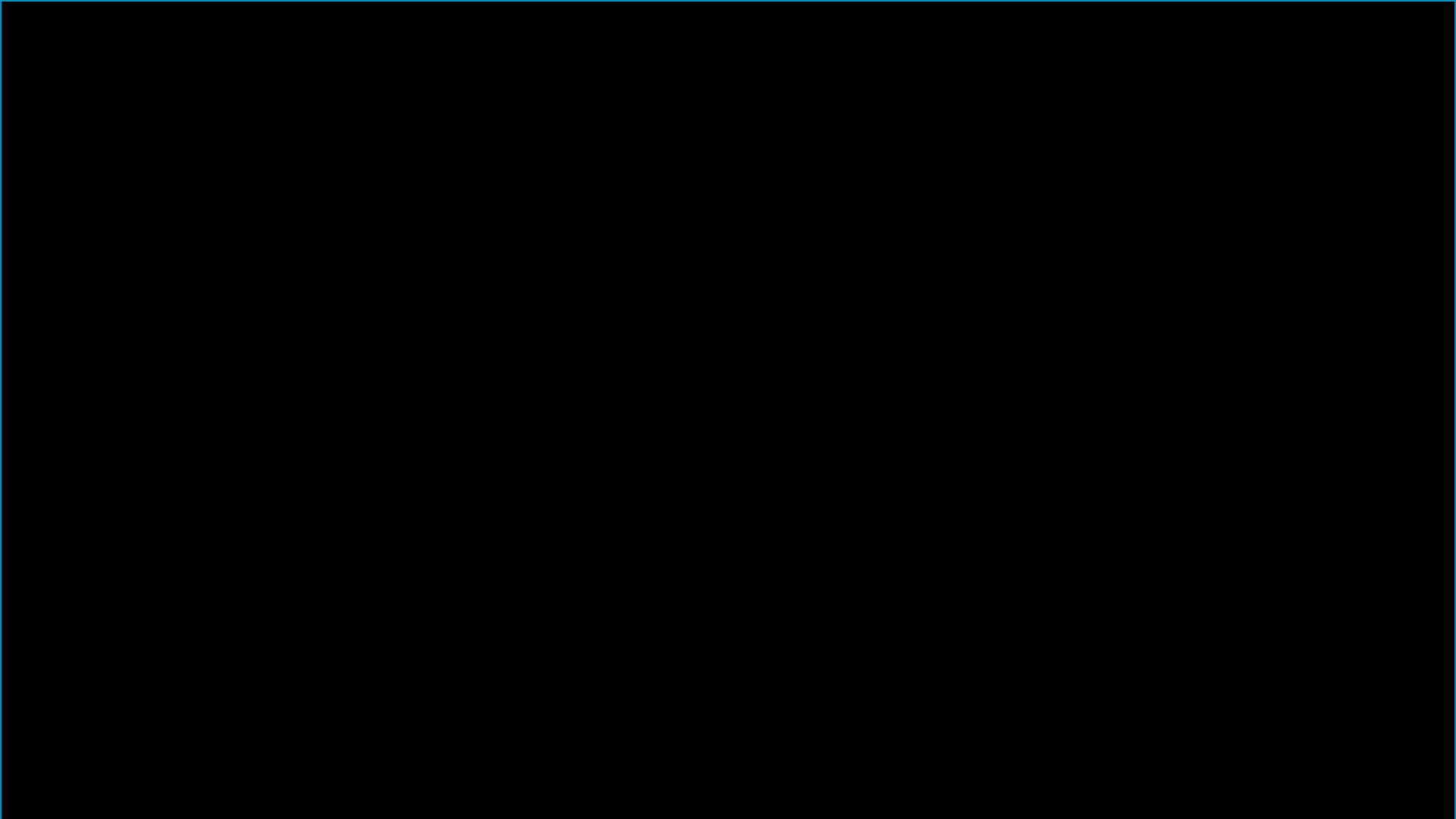
**Coalition of State Rheumatology Organizations- President
Clinical Instructor/Assis. Prof. of Medicine – Tulane Medical School
The Rheumatology Group**

MadelaineFeldman@gmail.com

or

“Waiting for Godot”

Drug Pricing Reform in America



Access

Obstacles to
Access

What Are We
Talking
About?

What Do We
Do About it?

MISC.

Medication Access

Availability

Affordability

Approved

Launched

Formulary

Price

Cost Share

Provider Admin

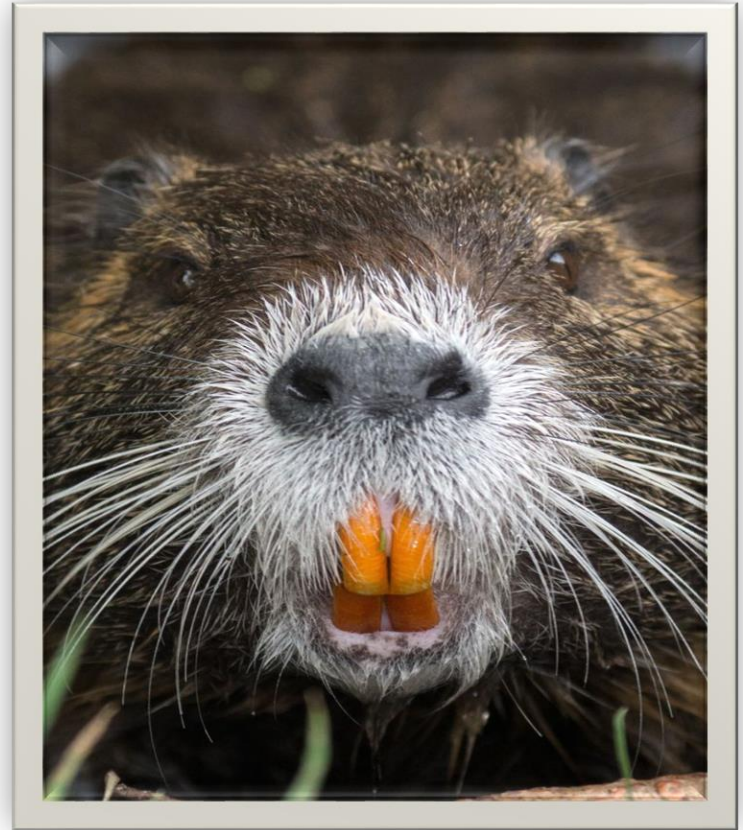
Pharmacy

Copay

Co-insurance



The Bad



For Example...

Martin Shkreli is best known for raising the price of Daraprim, an HIV drug by **5,000 percent** when he was CEO of Turing Pharmaceuticals

***“We raised the price from \$1,700 per bottle to \$75,000,”
Shkreli wrote to a contact in August.
Should be a very handsome investment for all of us.”***



Spent \$2 million on a one-of-a-kind Wu Tang Clan album

Mo Bad...

“Generic Drug Cartel”

“This is most likely the largest cartel in the history of the United States”

- Lawsuits on price-fixing involving at least **sixteen companies and 300 generic drugs**
- **Generic makers blamed –**
 - Industry consolidations,
 - [Federally] mandated plant closures,
 - Elimination of unprofitable generic drug product lines
- The complaint alleges “that the drug companies knew their conduct was illegal and avoided communicating with one another in writing.”

More Bad...

*In 2003 the most widely used self-injectables for RA
were priced around \$1,000/mo*

(Boston Business Journal Dyke Hendrickson Oct 20, 2003)

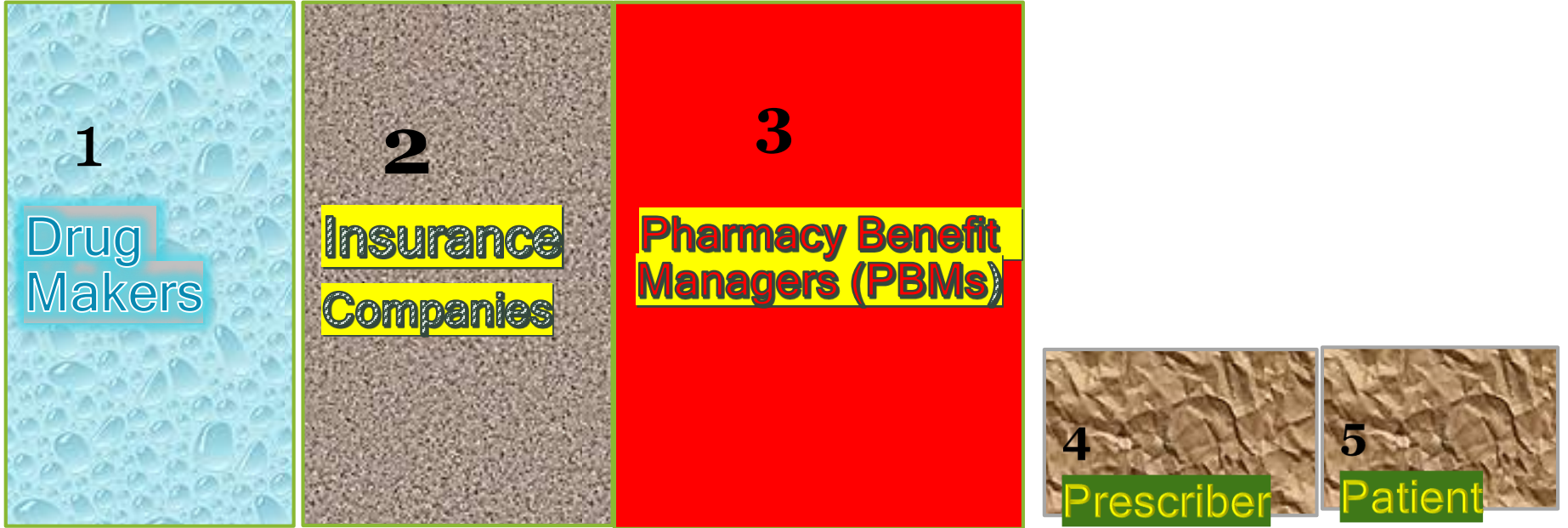
*Today the same self-injectables have a list prices
greater than \$6,000/mo*

**Other Forces
At Play Here**



ACTH Gel

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



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.”

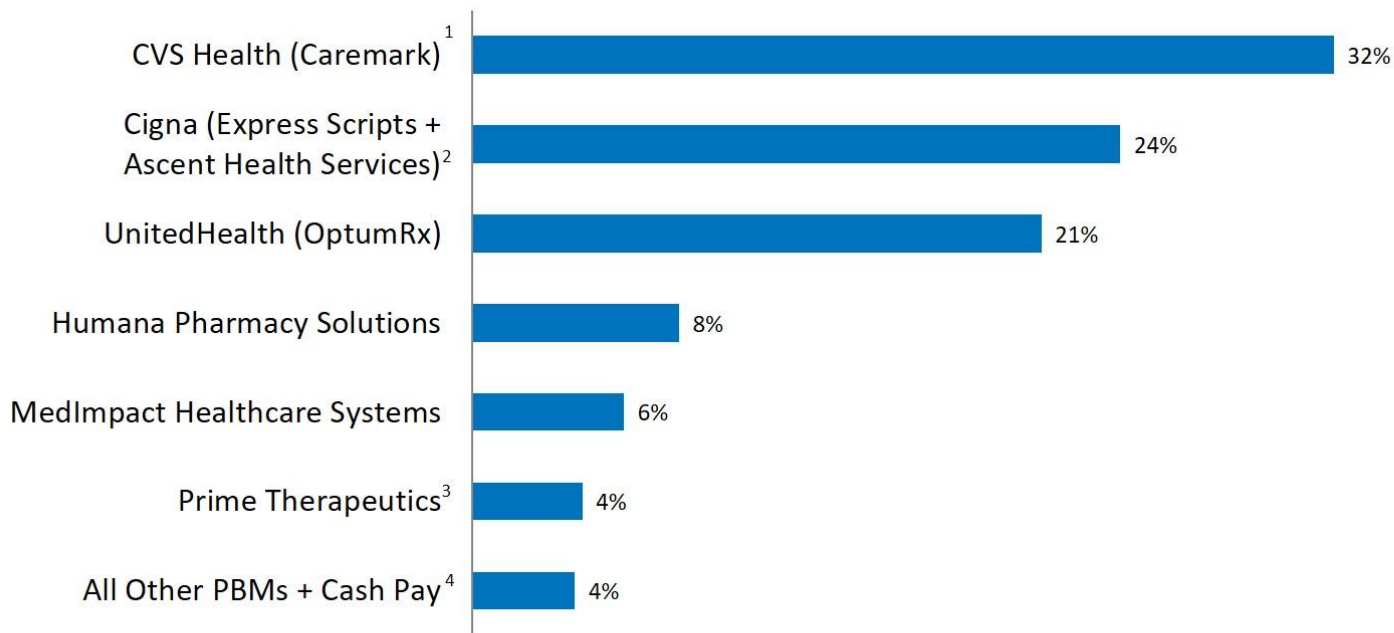
- Adjudicate pharmacy claims
- Patient cost share
- Pharmacy network
- **Construct/maintain formulary**
- **SITE of CARE**

Who are the Big 3 PBMs?

- **Express Scripts (ESI) (#22 Fortune 500 -2018)**
- **CVS Caremark (CVS Health) (#5 Fortune 500-2018)**
- **Optum Rx (United Health) (#7 Fortune 500 – 2018)**

SOURCES: Insurance companies start to bring PBM in-house: CVS Health's PBM business could be under threat. *Forbes*. July 28, 2015. <http://www.forbes.com/sites/greatspeculations/2015/07/28/insurance-companies-start-to-bring-pbm-in-house-cvs-healths-pbm-business-could-be-under-threat/#69b4f3d23df2>. Accessed January 10, 2017; Britschgi C. Pharmacy benefit managers could be in legislative crosshairs. *Watchdog.org*. <http://watchdog.org/285187/pharmacy-benefit-managers-legislative-crosshairs/>. January 3, 2017. Express Scripts covers 83 million. (Express Scripts Corporate Overview, downloadable at <http://lab.express-scripts.com/about>.) CVS Caremark covers approximately 90 million. (CVS Health At A Glance, <https://www.cvshealth.com/about/facts-and-company-information>.)

PBM Market Share, by Total Equivalent Prescription Claims Managed, 2020



1. Excludes Drug Channels Institute estimates of double-counted network claims for mail choice claims filled at CVS retail pharmacies.

2. Includes Cigna claims, which fully transitioned to Express Scripts by the end of 2020. Includes Ascent Health Services, which includes Kroger Prescription Plans and a partial year of Prime Therapeutics.

3. Excludes Drug Channels Institute estimates of 2020 claims for which Ascent Health Services handled rebate negotiations and pharmacy network contracting.

4. Figure includes some cash pay prescriptions that use a discount card processed by one of the 6 PBMs shown on the chart.

Source: [The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers](#), Drug Channels Institute, Exhibit 92. Total equivalent prescription claims includes claims at a PBM's network pharmacies plus prescriptions filled by a PBM's mail and specialty pharmacies. Includes discount card claims. Note that figures may not be comparable with those of previous reports due to changes in publicly reported figures of equivalent prescription claims. Total may not sum due to rounding.

Pharmacy Benefit Managers

Vertical Business Relationships Among Insurers, PBMs, and Specialty Pharmacies, 2019



Source: Drug Channels Institute research. AllianceRx Walgreens Prime is jointly owned by Prime Therapeutics and Walgreens Boots Alliance.

This chart appears as Exhibit 77 in *The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute. Available at <http://drugch.nl/pharmacy>

Vertical Integration-PBMs/Insurance Companies AND CLINICS

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



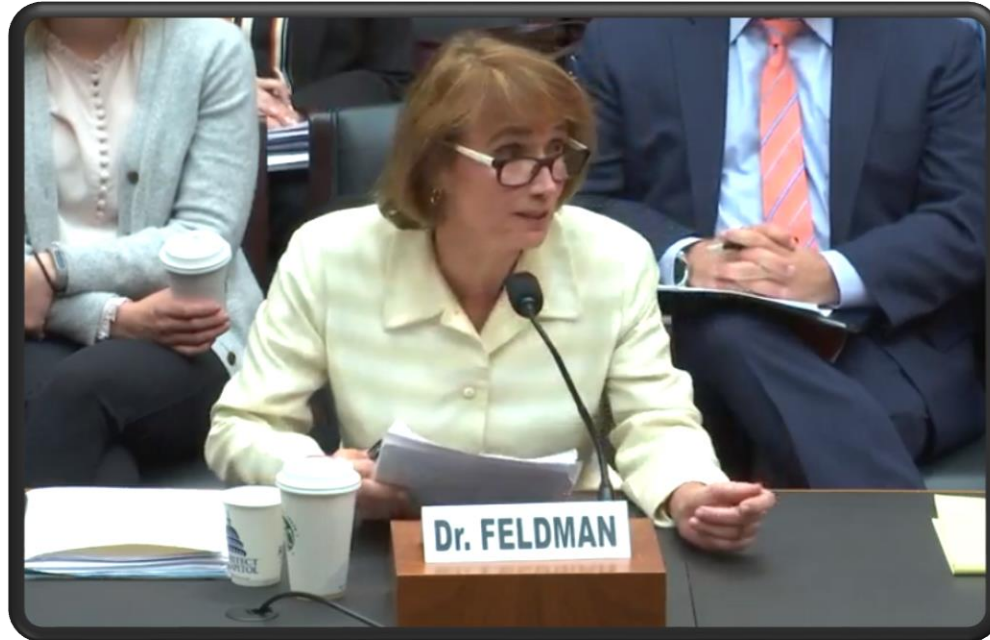
1. Cigna partners with providers via its [Cigna Collaborative Care](#) program. However, Cigna does not directly own healthcare providers.

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.

- **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**
 - More affordable pharmacy channels
 - Encouraging use of generics & affordable brands
 - **Higher priced and brands preferred**

Health Subcommittee - Energy and Commerce 2019



PBMs Ultimately Determine

What - Constructing the Formulary

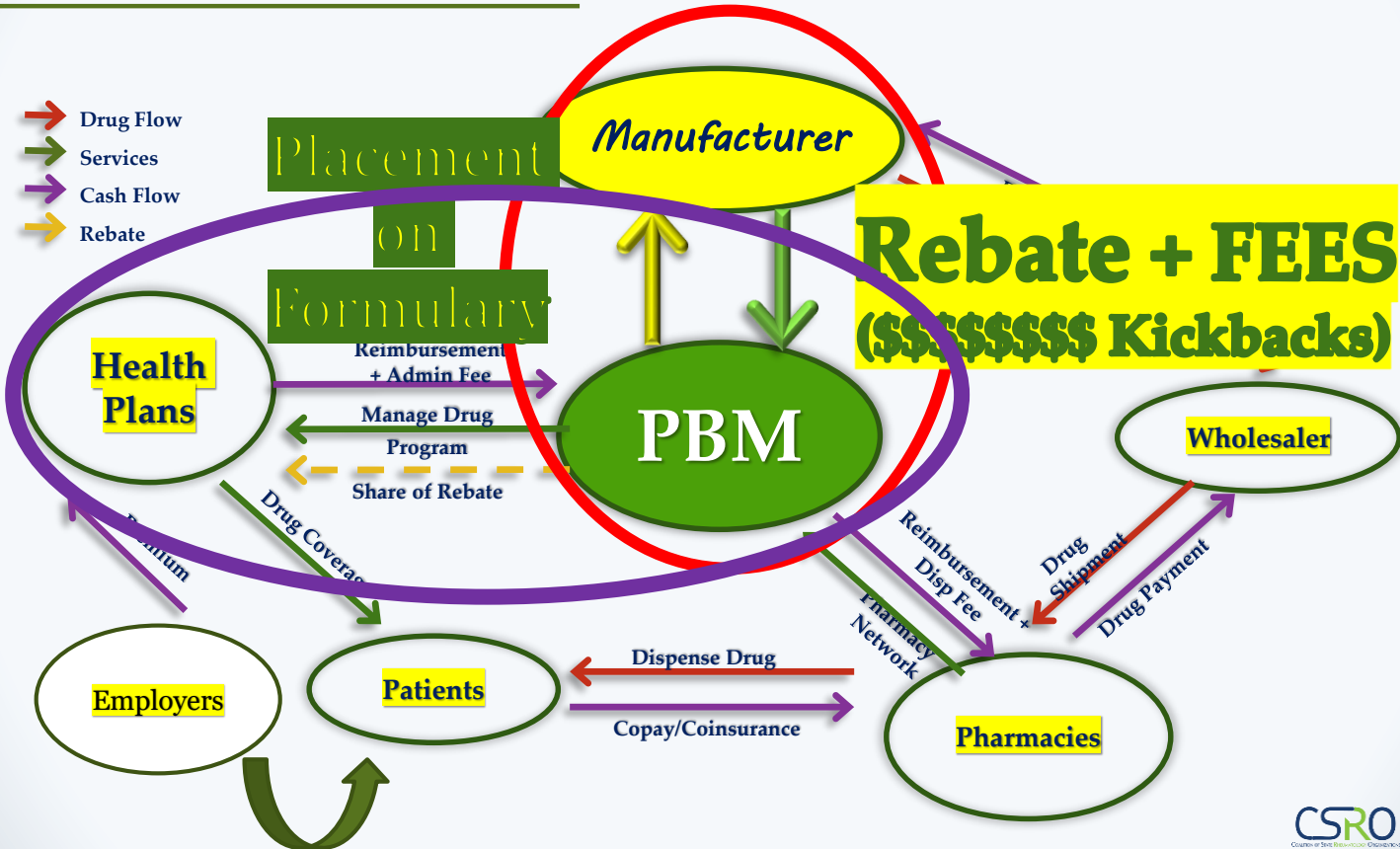
When - Step therapy, Non-Med Switch

Where - Pharmacy network, Site of Care

How Much - Copay, Co-insurance

Breaking Down the Drug/Money/Services Flow

SIMPLIFIED VERSION



If An Expensive Drug
Is Not on the Formulary...

No Matter How Great It Is...

No One Takes It

Why Do Manufacturers Fight For Preferred Placement?

- **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.....

The Rebate Story...

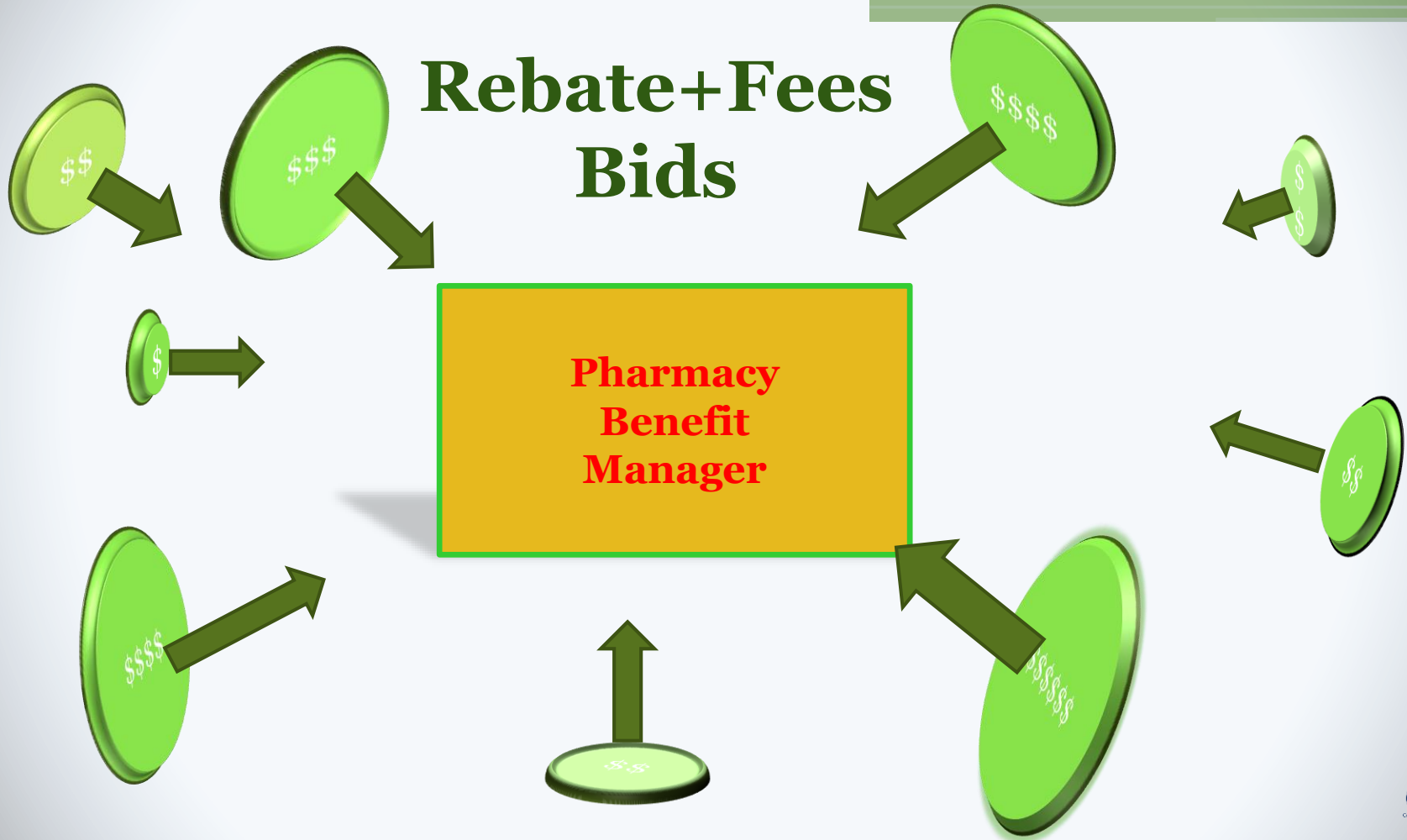
*Can't Forget About
The Fees!*

**What About the
Aggregators?**

How it works...

- **“Bidding war”** - Preferred Place on Formulary
 - Largest price concession (Rebate + Fees)
 - Best chance at the preferred spot.
- **Drug utilization** – determined by
 - Rebates/Fees
 - NOT Doctor – Patient Relationship
 - Not Lowest List Price Of Drugs

Rebate+Fees Bids



The Equation

Total Formulary Rebate =

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**

Which Drug Has The Best Bid?

| | Drug A | Drug B | Drug C |
|------------------|------------|------------|------------|
| List Price | \$2,000/mo | \$4,000/mo | \$5,000/mo |
| Rebate % | 60% | 40% | 40% |
| Formulary Rebate | \$1,200 | \$1,600 | \$2,000 |

PBMs Claim They “SAVE” Billions Of Dollars Through Their Preferred Formularies (& Use of UM tools)

Calculating “Savings” the PBM way

- 2 Identical Dresses -
 - One is list priced at \$1000 and the other at \$100
 - Both are offered at 50% off list price

Which Dress Would PBMs Pick for Their Dress Formulary??

PBMs would pick the \$1000 dress

PBM Industry Report - Greater Use Of UM Tools

Can Generate \$1T In Savings Over Next

Where do the “Savings” Go?

- Lower premiums?
- Lower co-pays / coinsurance amounts?
- Lower list prices of medications?

Hmmmm.....

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SOURCES: Insurance companies start to bring PBM in-house: CVS Health's PBM business could be under threat. *Forbes*. July 28, 2015. <http://www.forbes.com/sites/greatspeculations/2015/07/28/insurance-companies-start-to-bring-pbm-in-house-cvs-healths-pbm-business-could-be-under-threat/#69b4f3d23df2>. Accessed January 10, 2017; Britschgi C. Pharmacy benefit managers could be in legislative crosshairs. *Watchdog.org*. <http://watchdog.org/285187/pharmacy-benefit-managers-legislative-crosshairs/>. January 3, 2017. Express Scripts covers 83 million. (Express Scripts Corporate Overview, downloadable at <http://lab.express-scripts.com/about>.) CVS Caremark covers approximately 90 million. (CVS Health At A Glance, <https://www.cvshealth.com/about/facts-and-company-information>.)

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

- PBMs receive rebates/fees based on a % of the list price of the medicine.
- These price concessions can be 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.**

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

- **Administration fees** - Manufacturers pay admin fees that are often based on list price
- **Price protection rebate**- List price increase above a ceiling
 - Triggers additional rebate payments.
- **Specialty pharmacy fees** – some fees are % of list price
- **Vendor 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 subsidiaries for services rendered as "**bona fide service fees**" (collectively, "**Other Pharma Revenue**")

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.

| <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 increases 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 |

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- **Administration fees** - Manufacturers pay admin fees that are often based on list price
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**MOST IMPORTANT -Patient Cost
Patient Co-insurance %
Is Based On List Price**

Co-insurance Based on List Price

- 20% -Prices \$10K/mo or more
- Copay cards from the manufacturer – Pay patient cost share
- Helps patients chronic diseases *also* by reducing deductible

PBMs Thought

“WAIT JUST A MINUTE!”

“How can we make money on this?”

Accumulator Adjustment Program

A *utilization management tool* that **disallows** money paid by a drug manufacturer in the form of a **copay card** to **count toward the deductible/OOP costs** of the patient.

“Deductible Double Dipping”

(collects deductible amount from both manufacturer and patient)

CVS Caremark

- **Plan Design Optimization: leverages** the **value** of copay cards to **enhance** program **savings** by increasing the copay to **optimize** the **value** of the manufacturer program.

Deductible Double Speak

- High/Low
- Individual
- Family
- In/Out of-network
- HSA
- Max Out of Pocket



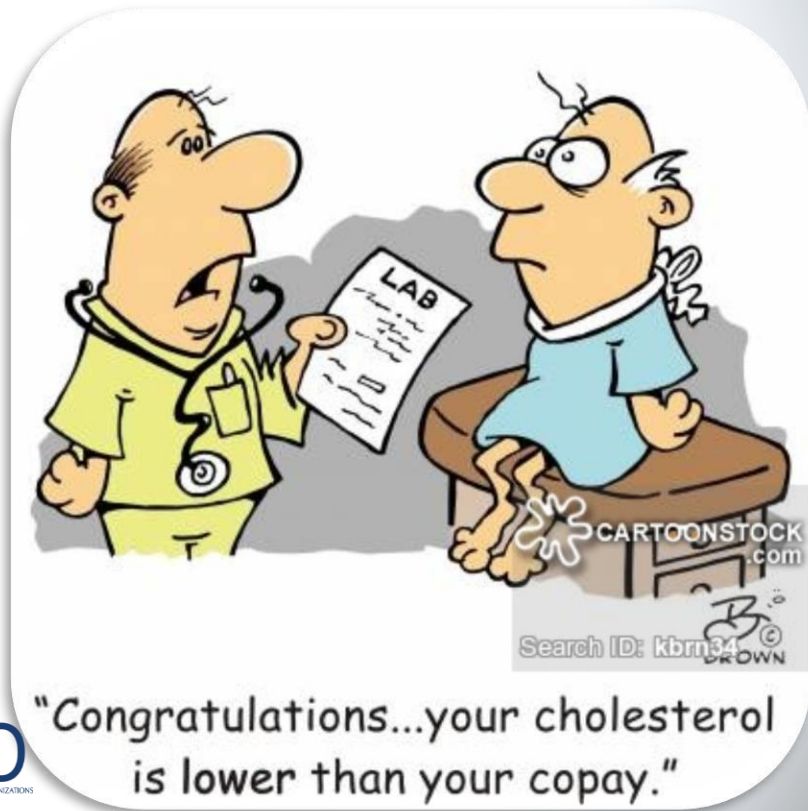
Copay Cards Are Bad!

Medical Side Doesn't Offer
Co-pay Assistance

Copay Cards

Entice Patients, Hook Patients

On Expensive Medications



How Often are Copay Cards used When There is a Lower Priced Generic?

- An IQVIA analysis of claims data from 2013-2017
- The use of copay cards on those brand drugs is

0.4%

of total commercial market volume

This is due at least in part to:

- *Formulary exclusions and generic substitution*

Which have curtailed copay cards for brands that have lost exclusivity

Source: IQVIA NSP, NPA and FIA data sets; IQVIA Analysis

Who are Most Affected by Accumulators

- **Chronic Disease Patients**
 - Economically forced off their prescription without consequence
- **Patients taking \$\$ specialty drugs**
 - Single source drugs – no lower cost alternative
 - Co-insurance % of list price
- **Patients with High Deductible Plans**

PBM Market Fails On

Accountability

Conflict of Interests

Fiduciary Responsibility

Transparency

How Do They Get Away With This?

“Safe Harbor” From the Anti-Kickback Statute



Who Regulates PBMs?

- **Federal**

- HHS/CMS - Part D - **Rebate Rule Redo - PCMA (lawsuit)**
- Federal Trade Commission - *maybe - never met a PBM they didn't like*
- DOJ - Allowed mergers
- **Congress** - Senate and House Bills - **“Safe Step ACT”**

- **States** (ERISA issues)*

- Legislation - CSRO.info/map - *Rutledge v PCMA (SCOTUS)*
- Board of Pharmacy,
- Insurance commissioners
- Attorney General

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.

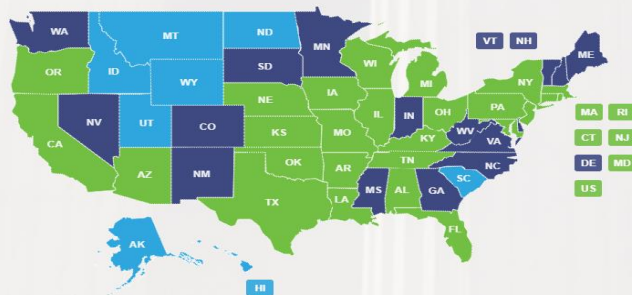
3. NO LEGISLATION?

[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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Disclaimer

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.

The information presented in this tool is presented for informational purposes, and should not be considered legal advice. CSRO and its representatives are not rendering legal services through the information published within the tool, and the information presented should not be used as a substitute for professional services.

**CSRO MAP
 TOOL**

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 STATE**

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TENNESSEE

ACCUMULATOR ADJUSTMENT PROGRAMS

ACTIVE LEGISLATION HB 619 & SB 1397

READ THE BILL

TAKE ACTION

STEP THERAPY

ACTIVE LEGISLATION HB 677 & SB 1310

READ THE BILL

TAKE ACTION

GET UPDATES FOR TN

Enacted Active

MA

RI

CT

NJ

DE

MD

US





HB 0619

by *Rudder

Show Co-Prime Sponsors

(SB 1397)

by *Swann

Show Co-Prime Sponsors

Show Caption Text

Insurance Companies, Agents, Brokers, Policies - As introduced, requires an insurer to include cost sharing amounts paid by the enrollee, or on behalf of the enrollee by another person, when calculating an enrollee's contribution to an applicable cost sharing requirement. - Amends TCA Title 56, Chapter 7.

[Bill History](#)
[Amendments](#)
[Video](#)
[Summary](#)
[Fiscal Note](#)
[Votes](#)

HB0619 ACTIONS

| | DATE |
|--|------------|
| Passed Senate as amended, Ayes 30, Nays 0 | 04/27/2021 |
| Senate adopted Amendment (Amendment 1 - SA0414) | 04/27/2021 |
| Senate substituted House Bill for companion Senate Bill. | 04/27/2021 |
| Received from House, Passed on First Consideration | 04/22/2021 |
| Engrossed; ready for transmission to Sen. | 04/21/2021 |
| Passed H., Ayes 91, Nays 0, PNV 0 | 04/21/2021 |
| H. Placed on Regular Calendar for 4/21/2021 | 04/15/2021 |
| Placed on cal. Calendar & Rules Committee for 4/15/2021 | 04/14/2021 |
| Rec. for pass; ref to Calendar & Rules Committee | 04/06/2021 |
| Placed on cal. Insurance Committee for 4/6/2021 | 03/31/2021 |
| Rec. for pass by s/c ref. to Insurance Committee | 03/30/2021 |
| Placed on s/c cal Insurance Subcommittee for 3/30/2021 | 03/24/2021 |
| Assigned to s/c Insurance Subcommittee | 02/20/2021 |
| P2C, ref. to Insurance Committee | 02/11/2021 |
| Intro., P1C. | 02/10/2021 |
| Filed for introduction | 02/08/2021 |

SB1397 ACTIONS

| | DATE |
|---|------------|
| Companion House Bill substituted | 04/27/2021 |
| Placed on Senate Regular Calendar for 4/27/2021 | 04/23/2021 |
| Recommended for passage with amendment/s, refer to Senate Calendar Committee Ayes 9, Nays 0 PNV 0 | 04/21/2021 |
| Placed on Senate Commerce and Labor Committee calendar for 4/21/2021 | 04/14/2021 |
| Reset on Final calendar of Senate Commerce and Labor Committee | 04/09/2021 |
| Placed on Senate Commerce and Labor Committee calendar for 4/7/2021 | 04/07/2021 |
| Action deferred in Senate Commerce & Labor Committee to 4/7/2021 | 04/06/2021 |
| Placed on Senate Commerce and Labor Committee calendar for 4/6/2021 | 03/30/2021 |
| Action deferred in Senate Commerce and Labor Committee to 4/6/2021 | 03/30/2021 |
| Placed on Senate Commerce and Labor Committee calendar for 3/30/2021 | 03/24/2021 |
| Passed on Second Consideration, refer to Senate Commerce and Labor Committee | 02/22/2021 |
| Introduced, Passed on First Consideration | 02/11/2021 |
| Filed for introduction | 02/11/2021 |

Senate

Meet the Lt. Governor

House of Representatives

Meet the Speaker

Joint Committee

Committees

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.



TENNESSEE - ACCUMULATOR PROGRAMS

Contact your legislators and urge them to support HB 619

Accumulator Adjustment Programs, also known as "out-of-pocket protection" or "coupon adjustment" programs, are a utilization management tool being used by insurers and pharmacy benefit managers. These alternative cost-sharing structures prevent the value of co-pay assistance from being applied towards a patient's deductible as an out-of-pocket expense. In the past, once the value of a patient's co-pay assistance was depleted, a patient's deductible had been met, ensuring they could afford otherwise financially inaccessible drugs. Now, PBMs are double dipping, preventing patients from being able to afford medically necessary drugs.

What does the bill do?

HB 619 requires any payments made by, or on behalf of a patient, to be counted towards their deductible or other cost-sharing obligations.

What can you do?

CSRO encourages you to make your voice heard by contacting your Tennessee state legislators in support of HB 619. You may do so using the tool located to the right of this message. **We highly encourage personalization of the message provided** - personalized messages have a higher degree of visibility.

Compose Your Message

- State Senator
- State Representative

Subject

Message Body

Please add your own story about this issue to personalize your message

I am writing to request your support for HB 619.

As a rheumatologist providing care to Tennesseans with musculoskeletal

Enter Your Info

Your Information

Prefix * First Name * Last Name *

Email *

Send me text alerts

Mobile Number *

Home Information

Street Address *

ZIP Code * Enter Zip for **City** and **State**

Business Information

Your Title Company

Street Address

ZIP Code Enter Zip for **City** and **State**

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



LOUISIANA - ACCUMULATORS

Please consider personalizing your message – lawmakers are inundated with email in the virtual environment and personalized messages have a much greater chance of being seen directly by lawmakers. Contact your legislators and urge them to support SB 94 Accumulator...



WISCONSIN - ACCUMULATOR PROGRAMS

Please consider personalizing your message – personalized messages have a much greater chance of being seen directly by legislators. Contact your legislators and urge them to support SB 215 Accumulator Adjustment Programs, also known as "out-of-pocket protection" or...



FEDERAL - STEP THERAPY

Contact your legislators and urge them to support S464 What does the bill do? Step therapy has become an impediment to appropriate care for patients across specialties. S464 reforms the step therapy process to ensure patients get the right treatment at the right...



ILLINOIS - ACCUMULATOR BAN REPEAL

CSRO opposes HB 2948 What's the issue? Accumulator Adjustment Programs, also known as "out-of-pocket protection" or "coupon adjustment" programs, are a new utilization management tool being used by insurers and pharmacy benefit managers. These alternative cost-sharing...



FLORIDA - NON-MEDICAL SWITCHING

Contact your legislators and urge them to support SB 1612 Florida patients can have coverage of their medications restricted at any time. No laws in Florida prohibit insurers from changing coverage during the course of the plan year – when patients are locked into...



MICHIGAN - ACCUMULATOR PROGRAMS

Contact your legislators and urge them to support HB 4353 Accumulator Adjustment Programs, also known as "out-of-pocket protection" or "coupon adjustment" programs, are a new utilization management tool being used by insurers and pharmacy benefit managers. These alternative...

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View and search for legislation.

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Elected Officials Candidates

ZIP Code



TENNESSEE - ACCUMULATOR PROGRAMS

Contact your legislators and urge them to support HB 619 Accumulator Adjustment Programs, also known as "out-of-pocket protection" or "coupon adjustment" programs, are a utilization management tool being used by insurers and pharmacy benefit managers. These alternative...



RHODE ISLAND - ACCUMULATOR PROGRAMS

Contact your legislators and urge them to support HB548 Accumulator Adjustment Programs, also known as "out-of-pocket protection" or "coupon adjustment" programs, are a utilization management tool being used by insurers and pharmacy benefit managers. These alternative...



NEW MEXICO - ACCUMULATORS & PBM TRANSPARENCY

Contact your legislators and urge them to support SB 2019 Accumulator Adjustment Programs, a adjustment" programs, a insurers and pharmacy t



SOUTH DAKOTA

Contact your legislators and urge them to support SB 2019 Accumulator Adjustment Programs, a adjustment" programs, a by insurers and pharmac



FLORIDA - ACCUMULATOR PROGRAMS

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TEXAS - ACCUMULATOR PROGRAMS

Contact your legislators and urge them to support SB 1612 Florida patients can have coverage of their medications restricted at any time. No laws in Florida prohibit insurers from changing coverage during the course of the plan year – when patients are locked into...



KANSAS - STEP THERAPY

Contact your legislators and urge them to support SB 1612 Florida patients can have coverage of their medications restricted at any time. No laws in Florida prohibit insurers from changing coverage during the course of the plan year – when patients are locked into...



OKLAHOMA - NON-MEDICAL SWITCHING

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MISSOURI - STEP THERAPY

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CALIFORNIA - STEP THERAPY

Please consider personalizing your message – personalized messages have a much greater chance of being seen directly by legislators. Contact your legislators and urge them to support SB 1612 Florida patients can have coverage of their medications restricted at any time. No laws in Florida prohibit insurers from changing coverage during the course of the plan year – when patients are locked into...



TENNESSEE - STEP THERAPY

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OREGON - STEP THERAPY AUTHORIZATION

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NEW JERSEY - STEP THERAPY

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NEW YORK - ACCUMULATOR PROGRAMS

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IOWA - NON-MEDICAL SWITCHING

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PENNSYLVANIA - ACCUMULATOR PROGRAMS

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UKIAH COUNTY - NON-MEDICAL SWITCHING

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OREGON - ACCUMULATOR PROGRAMS

Contact your state legislators and urge them to support SB 560 Accumulator Adjustment Programs, also known as "out-of-pocket protection" or "coupon adjustment" programs, are a utilization management tool being used by insurers and pharmacy benefit managers. These alternative...



ARKANSAS

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NEBRASKA

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CONNECTICUT

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MARYLAND

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KENTUCKY

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MASSACHUSETTS - ACCUMULATOR PROGRAMS

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ARKANSAS - ACCUMULATOR PROGRAMS

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NEW YORK - NON-MEDICAL SWITCHING

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TEXAS - NON-MEDICAL SWITCHING

Contact your legislators and urge them to support SB 1612 Florida patients can have coverage of their medications restricted at any time. No laws in Florida prohibit insurers from changing coverage during the course of the plan year – when patients are locked into...



ALABAMA - ACCUMULATOR PROGRAMS

Contact your legislators and urge them to support SB 1612 Florida patients can have coverage of their medications restricted at any time. No laws in Florida prohibit insurers from changing coverage during the course of the plan year – when patients are locked into...



OHIO - ACCUMULATOR PROGRAMS

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MASSACHUSETTS - ACCUMULATOR PROGRAMS

Contact your legislators and urge them to support SB 1612 Florida patients can have coverage of their medications restricted at any time. No laws in Florida prohibit insurers from changing coverage during the course of the plan year – when patients are locked into...



ARIZONA - PRIOR AUTHORIZATION

Contact your legislators and urge them to support SB 1612 Florida patients can have coverage of their medications restricted at any time. No laws in Florida prohibit insurers from changing coverage during the course of the plan year – when patients are locked into...



OREGON - STEP THERAPY & PRIOR AUTHORIZATION

Contact your legislators and urge them to support SB 44 & HB 2517 What do the bills do? Step therapy & prior authorization have become an impediment to appropriate care for patients across specialties. These bills reform prior authorization...



NEW JERSEY - STEP THERAPY

Contact your legislators and urge them to support A4815 & S3051 What do the bills do? Step therapy has become an impediment to appropriate care for patients across specialties. These bills reform the step therapy process to ensure patients get the right...



NEW YORK - ACCUMULATOR PROGRAMS

Contact your legislators and urge them to support A1741 & S5299 Accumulator Adjustment Programs, also known as "out-of-pocket protection" or "coupon adjustment" programs, are a utilization management tool being used by insurers and pharmacy benefit managers. These alternative...



IOWA - NON-MEDICAL SWITCHING

Contact your legislators and urge them to support SF 178 & HF 656 Iowa patients can have coverage of their medications restricted at any time. No laws in Iowa prohibit insurers from changing coverage during the course of the plan year – when patients are locked into...



PENNSYLVANIA - ACCUMULATOR PROGRAMS

Contact your legislators and urge them to support SB 196 Accumulator Adjustment Programs, also known as "out-of-pocket protection" or "coupon adjustment" programs, are a utilization management tool being used by insurers and pharmacy benefit managers. These alternative...



OKLAHOMA - ACCUMULATOR PROGRAMS

Contact your legislators and urge them to support SB 92 & HB 2678 Accumulator Adjustment Programs, also known as "out-of-pocket protection" or "coupon adjustment" programs, are a utilization management tool being used by insurers and pharmacy benefit managers. These alternative...



ARIZONA - STEP THERAPY

Contact your legislators and urge them to support SB 1270 What does the bill do? Step therapy has become an impediment to appropriate care for patients across specialties. SB 1270 reforms the step therapy process to ensure patients get the right treatment at the right...

YAY! West Virginia PBM House Bill 2263,

- “Requires pharmacy benefit managers to be licensed by the State,
- Report on network adequacy,
- Protects pharmacists from telling patients about lower costs alternatives, prevents clawbacks and spread pricing,
- Patients **cost sharing** for their medication will be calculated at the point-of-sale and **based on a price equal to 100% of the rebate** that PBMs collect*
- Allows for patients to choose their own pharmacy

***Rebate aggregators**

Recent Legislation

- **Accumulators**

- 3 bills signed into law: KY, OK, AR
 - TN -has yet to be transmitted to the Governor.
- 24 state bills introduced this year
 - 15 bills still pending (CT, FL, IA, LA, MA, MI, NV, NY, OH, OR, PA, RI, TN, TX, WI)
 - 6 bills have died (AL, MD, MN, NE, NM, SD).
 - AL PBM legislation is still alive but was stripped of accumulator provision and otherwise watered down.
- We are working with the Primary Immune Foundation to involve the Pennsylvania Rheumatology Association directly in advocating for the state's accumulator legislation.

- **Step Therapy**
- 2 states have passed laws this year: AR, NE, soon AZ
 - Active bills remain in: CA, MA, MO, NJ, OR, PA, TN, & RI.
 - Of these bills we believe that CA, NJ, and OR are likely to pass this session.
- **Non-medical Switching** - no signed bills yet
- Active legislation : FL, IA, MA, MN, NY, OH, OK, PA, TX.
 - Of these bills, FL, IA, MN, and OK are effectively dead.
 - MA, NY, OH, and TX remain in play. NY and TX – best odds
- **Cigna \$500 Switching Incentive**
- Dr. M. Feldman is co-authoring an op-ed with NORM on this issue.
- CSRO co-signed the attached letter authored by AARDA opposing the practice.

State Drug Affordability Legislation

- Limits on Pricing vs Reimbursement
 - Oregon
- Maryland - Affordability Board

Obstacles to “Buy and Bill”

Federal/State Obstacles

Commercial Obstacles

Federal/State Obstacles

Self- Administered Drug List (SAD List)

Loss of Access to Part B – *(not paid for)*

Part B – Drug Pricing Reforms

State Drug Affordability legislation/boards

SAD List – Only Part D Formulation Will Be Paid For- Once on the SAD List....

Medications with Dual Formulations

Part B – Provider administered

Part D – Self administered

What Determines Which Drugs Move To The SAD List??

❑ Fifty Percent Rule

Greater than 50% of usage is Part D

Drug is Self-Administered ***by the patient** a majority of the time

Definition of “By the patient” according to CMS guidelines

****Medicare Beneficiaries And Not Other Individuals***

(that is, spouses, friends, or other care givers are not considered the patient)

❑ Interval of Dosing

≥ 4 weeks more likely to be Provider Administered

What We Did...

•CSRO Met With:

- First Coast Services Options (FCSO - FL & Puerto Rico), Palmetto (both Carolina's and Virginia's), Noridian (California & Nevada)
- Worked with GHLF to survey patients -
 - Did they self-inject as defined by MC?
- Recalculate Part D usage presented to MACs - Working Group
- Met with CMS representative - discussed Stelara and the broad issues with the SAD list

Part B Drug Pricing Reform

- ❑ **Part B Demonstration Project – Created An Uproar**
- ❑ **International Pricing Index - IPI**
- ❑ **Most Favored Nation - MFN**
- ❑ **HR.3 - ? fate**

H.R. 3 - The Lower Drug Costs Now Act

- Title I - 3 “buckets” of drugs for the new negotiation 125 drugs - highest net spending in the US.
- Those selected for negotiation would get a “maximum fair price,” capped at 120% of average international price.
- Providers reimbursed at maximum fair price + 6% instead of ASP plus 6%. Pt. coinsurance would be assessed against the maximum fair price as well.

H.R. 3 – The Lower Drug Costs Now Act

- Title III - Part D OOP cost-sharing
- \$2,000 annual cap on OOP spending
- Circumstances allow beneficiaries to spread out that \$2,000 over the course of the year

Latest Part B Issue

- Consolidated Appropriations Act - Congress is ordering CMS to change pricing (for reimbursement) Cimzia and Orencia
- [2017 OIG report](#) - \$.5 billion was loss in 2018 and 2019
- *OIG: “CMS did not concur with our recommendation. ... CMS stated this could negatively affect beneficiary access to medically necessary drugs as well as increase the cost of these drugs....further analysis on the cost, policy, and operational implications would need to be conducted to determine whether such a change in law would be appropriate.”*

CMS Response to CSRO

- *“We also appreciate your question regarding the changes required as a result of the Consolidated Appropriations Act, 2021.*
- *Section 405 of the CAA, 2021 was explicit with the date (7/1/2021) CMS is to implement those provisions.*
- *CMS is planning to issue program instruction in accordance with the authority provided under statute.”*

PhRMA's Part B Proposal

- A “market-based adjustment” (rebate) would be paid to MC if a drug’s commercial net price was lower than its average sales price.
- The 10% of Part B beneficiaries without any supplemental insurance would have a flat \$20 copay instead of the current 20% coinsurance.
- No change to the buy-and-bill system (should not lower physician reimbursement)
 - The rebates would be paid retroactively by the company directly to the government.

***Note that commercial net prices are not usually lower than ASPs, but where this is the case, the difference is significant.

Commercial Obstacles to “Buy and Bill” for Provider Administered Medications

- ❑ White Bagging, Brown Bagging and Clear Bagging
- ❑ Formulary Exclusions, Step Therapy and Non-medical Switching
- ❑ Mandated Site of Care Change – *Health plans/ Vivio*

Pharmacy Benefit Managers^S



Health Insurance Companies

Pharmacy Benefit Managers



Specialty Pharmacy

Physician Administered
Medications

Formulary Construction

Utilization Management Tools

Why Integrate The Medical And Pharmacy Side – According To HR Executives?

“According to a J.P. Morgan survey, half of top human resources executives don't believe that integrating medical and drug benefits will drive overall healthcare savings. Here are two notable quotes:”

"There's too much money to be made.

They're not offering integrated services to give up revenue."

"More ways to hide money."

Consequences

Buy and Bill Channel Management

White Bagging – From Specialty Pharmacy Owned By The PBM

Buy and Bill Utilization Management

Formularies with Exclusions, Step Therapy and Non-Medical Switching

Mandated Change in Site of Care to Plan Owned Infusion Centers

Vivio

Carves out Specialty Drugs for Self Funded Businesses

“Our Formula To Reduce Your Spend &
Take Better Care Of Your Employees And Their Families”

“Achieve Better Outcomes For Your Employees
While Lowering Your Current Spend **25-35%**”

Vivio Sounds Too Good To Be True to Employers

- Non-medical Switching
- White Bagging
- Mandated Biologic Tapering
- Mandated Change In Site Of Care

What's a Rheumatologist To Do?

With Sufficient Thrust Pigs Fly Just Fine!!



Formulary Construction in America

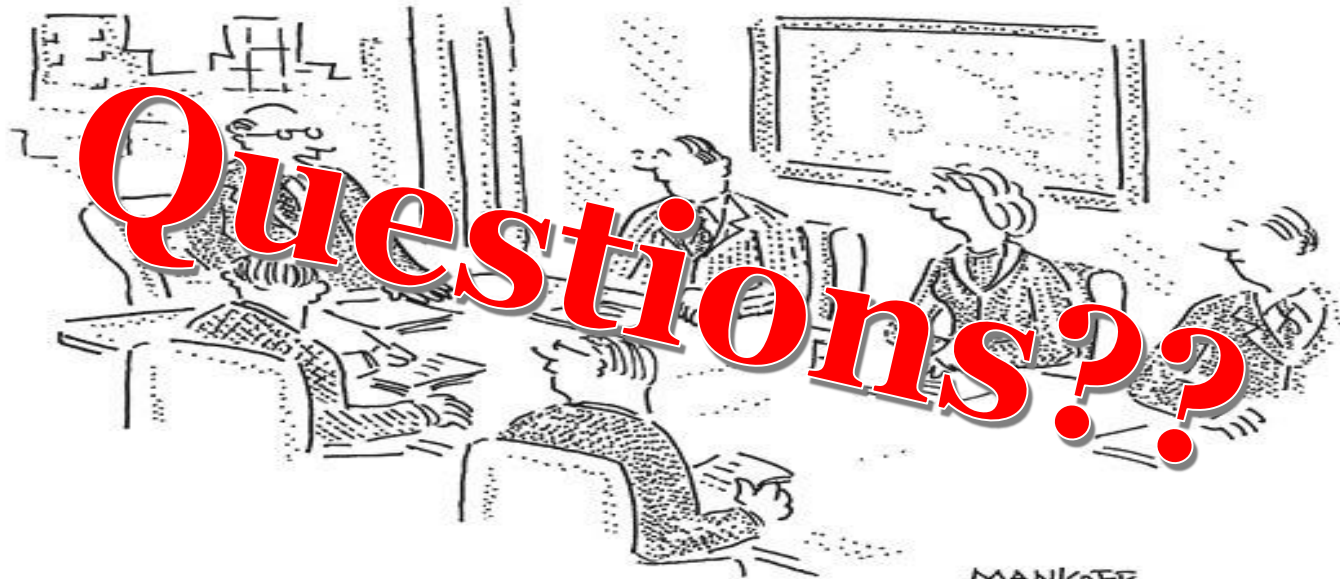
“Perfectly Legal”

and

“Perfectly Wrong”

NolaRheum@gmail.com

The Transparency Problem



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