

Revised: 4/1/22

2022 Spring National Meeting Kansas City, Missouri

#### PHARMACY BENEFIT MANAGER REGULATORY ISSUES (B) SUBGROUP

Monday, April 4, 2022 9:00 – 10:00 a.m. Loews—City Beautiful D—Ballroom Level

#### **ROLL CALL**

TK Keen, Chair	Oregon	Ralph Boeckman/	New Jersey
Laura Arp, Vice Chair	Nebraska	Erin Porter	
Anthony L. Williams	Alabama	Renee Blechner/	New Mexico
Lori K. Wing-Heier/	Alaska	Paige Duhamel	
Kayla Erickson/Sarah Bailey		Robert Croom/Ted Hamby	North Carolina
Beth Barrington	Arkansas	Kelli Price	Oklahoma
Jessica Ryan	California	Ana Paulina Gomez	Pennsylvania
Paul Lombardo/Kathy Belfi	Connecticut	Carlos Vallés	Puerto Rico
Howard Liebers	District of Columbia	Katrina Rodon	South Carolina
Andria Seip	lowa	Scott McAnally/	Tennessee
Vicki Schmidt	Kansas	Brian Hoffmeister	
Daniel McIlwain	Kentucky	Tanji J. Northrup	Utah
Jeff Zewe	Louisiana	Don Beatty	Virginia
Chad Arnold/Joe Stoddard	Michigan	Jennifer Kreitler/	Washington
Andrew Kleinendorst	Minnesota	Ned Gaines	
Chlora Lindley-Myers/	Missouri	Ellen Potter/Michael Malone	West Virginia
Amy Hoyt/Cynthia Amann		Nathan Houdek/	Wisconsin
David Dachs	Montana	Jennifer Stegall	
		Bryce Hamilton	Wyoming

NAIC Staff Support: Jolie H. Matthews

#### **AGENDA**

- 1. Hear an Update from Oklahoma on the Implementation of its Pharmacy Benefit Manager (PBM) Law)—Kelli Price (OK)
- 2. Hear a Discussion from Oregon on PBM Regulation and Beyond—Ralph Magrish (Executive Director of Oregon's Prescription Drug Affordability Board) and Numi Griffith (OK)
- 3. Hear a Discussion From a Consumer Perspective on the Subgroup's 2022 Charge to Develop a White Paper Examining PBM Business Practices—Carl Schmid (HIV + Hepatitis Policy Institute) and Anna Schwamlein Howard (American Cancer Society Cancer Action Network, Inc.—ACS CAN)

- 4. Discuss Any Other Matters Brought Before the Subgroup—TK Keen (OR)
- 5. Adjournment

SharePoint/NAIC Support Staff Hub/Member Meetings/2022 National Meetings/Spring National Meeting/Agenda/PBMSubgrprev 4-1-22.docx

#### Agenda Item #1

Hear an Update from Oklahoma on the Implementation of its Pharmacy Benefit Manager (PBM) Law—Kelli Price (OK)



## PHARMACY BENEFITS MANAGERS, LEGAL COMPLIANCE & ENFORCEMENT

Kelli Price

Managing Counsel / Director of PBM Compliance and Enforcement Division

April 4, 2022



#### Patient's Right to Pharmacy Choice Act, Title 36 O.S. §§ 6958-6968. Effective Nov. 1, 2019

Oklahoma's Pharmacy Choice Act "establish[es] minimum and uniform access to a provider and standards," prohibits restrictions of a "patient's right to choose a pharmacy provider," and prohibits anti-competitive practices:

- Urban, suburban, and rural geographical requirements for pharmacy access;
- Prohibits PBMs and benefit plans from requiring patients to use pharmacies that are directly or indirectly owned by the PBM or benefit plans;
- Requires PBMs and plans to list all pharmacies and providers on promotional materials, if any are listed;
- Bars PBMs or plans from charging pharmacies certain fees (for submission of a claim, etc.);
- Bars PBMs from reimbursing independent pharmacies at a lesser amount than PBMowned pharmacies;
- Bars PBMs from denying a pharmacy opportunity to participate in a pharmacy network
  if it is willing to follow the same rules as everyone else (ANY WILLING PROVIDER);
- Prohibits gag clauses;
- Prohibits incentives related to mail-order, cost-sharing, co-pays, or other discounts



## Rutledge Decision (141 S. Ct. 474) and Impact on Oklahoma PBM Regulation

In December, 2020, the U.S. Supreme Court decided the *Rutledge v. PCMA* case out of Arkansas and the 8<sup>th</sup> Circuit.

At issue: Arkansas statute ("Act 900") that required PBMs to tether their reimbursement rates to the acquisition costs pharmacies pay, by updating price schedules whenever wholesale drug prices increase.

• Employee Retirement Income Security Act (ERISA) preempts "any and all state laws" that "relate to any employee benefit plan."

Court ruling: "ERISA does not pre-empt state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage."

- No Preemption of:
  - √ Health care cost regulation
  - √ Health plan intermediaries
  - ✓ Issues not covered by ERISA regs



## Enjoined from enforcement...

- On October 25, 2019 (6 days before it was scheduled to take effect), Pharmaceutical Care Management Association (PCMA), a trade association of PBMs, sued to enjoin enforcement of the Patient's Right to Pharmacy Choice Act. *PCMA v. Glen Mulready and Oklahoma Insurance Department* (CIV-19-77-J) is still currently pending final resolution in the United States District Court for the Western District of Oklahoma.
- Initially, the litigation prevented OID from moving forward with enforcement of the Patient's Right to Pharmacy Choice Act. On July 9, 2020, federal district court for the Western District of Oklahoma ruled the Commissioner could proceed with enforcement of the majority of the provisions of the Act. PCMA appealed that ruling to the 10<sup>th</sup> Circuit Court of Appeals in Denver and filed an emergency motion to stay enforcement of the Act. The 10<sup>th</sup> Circuit denied PCMA's emergency motion.
- As of September 1, 2020, the Commissioner was able to proceed with enforcement of the Act (with the exception of regulating promotional materials & network access when related to Medicare plans).



#### PCMA v. Glen Mulready: Where are we now?

 In October 2021, arguments on Motion for Summary Judgment were submitted

 In January 2022, Notice of Supplemental Authority was filed regarding *PCMA v. Wehbi*, 8<sup>th</sup> Cir. (N.D. 2021)

 The U.S. District Court's ruling is expected any day now...



## Compliance & Enforcement: Settlements and Hearings

• So far in 2022, the OID has entered into 5 Settlement Agreements including:

\$2,626,149.59 Reimbursements to Pharmacies\*

\$2,726,529.36 Penalties against PBMs\*

(\*In one agreement, distribution is dependent on USWD Court ruling)

- 2 cases against PBMs are scheduled for hearings in April regarding alleged pharmacy network adequacy violations
- Many more are pending resolution through settlements or hearings





176,976

Alleged Violations of PBMs received and reviewed since 9/1/2020, including:

23,587

alleged violations from Jan. 2022 through Mar. 2022

36,085

alleged violations from Oct. 2021 through Dec. 2021

25,959

alleged violations from Sept. 2020 through June 2021

91,331

alleged violations from July 2021 through Sept. 2021



**Enforcement** actions taken against PBMs, include:

Cease & Desist

Orders

13 Other Orders

Settlement Agreements entered

87,172

**Alleged Violations Resolved** 



Refunds & Increased reimbursements to Pharmacies





To be reimbursed to Pharmacies



by PBMs

**New Applications for PBM Licenses** 



Refunds & Increased reimbursements to Pharmacies



To be reimbursed to Pharmacies



issued



## Issues we are seeing:

- When is a regulation a "cost regulation" versus "central to plan administration?"
  - PMBs offer "cost saving programs" to employers as a "central" part of an ERISA plan. For example, if plan members can fill prescriptions at only X Brand pharmacy, then costs to the plan & members are less.
  - Regulation says a patient's co-pay for a specific drug cannot exceed \$30 for 30 days supply
- May settlements outside the formal Administrative process be confidential or are they always subject to FOIA / Open Records requests?
- Medicare contracts require PBMs to comply with state pharmacy network adequacy requirements. Are more collaborative enforcement agreements on the horizon?



## Issues we are seeing (cont'd):

- Not all ERISA plans are created equal with respect to preemption:
  - Self-Funded plans vs. Fully-Insured plans, etc.
- For purposes of licensing, should a PBM and its financial status be reviewed for stability and solvency?
- To what extent should "proprietary information" of a PBM be protected or disclosed?
- Legislative maneuvering:
  - Changes in definitions:
    - What is a PBM? What is Pharmacy Benefits Management?
    - What's in a name? "Health plan"... "Insurer"... "Carrier"
  - Employers don't want to be defined as a PBM.
  - Pharmacies want to be reimbursed fairly and ensure anti-competitive practices are limited, no matter the health plan type.



## PBMs & Enforcement: Setting Your Team Up for Success!

OID created a division focused solely on PBM compliance & enforcement, hiring staff with applicable knowledge and expertise including:

- An industry expert/pharmacist consultant
  - From the beginning, OID hired an industry expert who had retired recently as a pharmacist. Previously, he had owned his own pharmacy, worked for other pharmacies, he was an auditor for a PBM, and was Director of Pharmacy at 2 health insurance companies. His industry expertise has been invaluable to OID, particularly his ability to explain the interests and processes of the various industry stakeholders and how they interact and conflict with each other.
- 3 PBM Compliance & Enforcement Officers (who have prior insurance related, investigation, or pharmacy experience)
- 2 Attorneys with insurance, medical, litigation and/or legislative experience



## PBMs & Enforcement: Setting Your Team Up for Success! (Cont'd)

- Through its website, OID created a process for customers to submit their complaints against PBMs on-line.
  - As a customer fills in their answers, the software is prompted to ask more specific questions based on the type of complaint and the specific violations alleged.
  - The questions are tailored in order to allow OID to gather, from the beginning, as much information and evidence as possible. This allows OID to save time, minimize unnecessary correspondence and response time, and more quickly determine what, if any, violation exists and if enough evidence exists to prove the elements of a particular violation.
  - Complaints and accompanying evidence are then routed to the PBM Compliance and Enforcement Division's email address where the OID Agent reviews it and begins their investigation.



## PBMs & Enforcement: Setting Your Team Up for Success! (Cont'd)

- Develop Standard Correspondence and Forms:
  - ✓ The PBM Compliance & Enforcement Division developed templates for typical correspondences sent to PBMs and complainants.
  - ✓ The Division also developed a "Blue Sheet" specific to PBM violations of Oklahoma regulations which OID agents use to succinctly summarize their investigations and more quickly refer their cases to legal for enforcement actions.
- OID's PBM legal team developed a standard "Invitation to Settle" letter which has helped facilitate conversation, leading to quick and amicable resolutions, rather than necessitating litigation.



## PBMs & Enforcement: Challenges, Lessons Learned & Success

- The language of legislation can open or close loopholes.
  - ✓ Check with a regulating attorney Can the intent of the language actually be *enforced* legally?
  - ✓ Grammar and the structure of paragraphs matter!
  - ✓ Using specific terms can create loopholes unintentionally. For example: "specialty pharmacy" or "specialty drugs." When possible, keep it general.
- Lack of Communication between a PBM and a pharmacy (or PSAO) is often the culprit that leads to contention.
  - ✓ Check to see if the parties have actually tried to communicate with each other.
  - ✓ Check to see if a technology issue has led to a break-down in communication (ex. Software isn't speaking the same language).



## PBMs & Enforcement: Challenges, Lessons Learned & Success

- Ask for the specific information you *really* need, so you don't end up with reams of documents that you will have to sort and filter through...
  - ✓ What elements are needed to prove a violation of statute?
  - ✓ Ask the complainant and/or the PBM for information and documentation related to each element necessary to prove a violation.
  - ✓ If you ask for a large document, ask the complainant or PBM to reference the specific information within the document you are really looking for.
- Communication with all stakeholders is key!
  - ✓ Contention in the industry has led to mistrust all-around. Having in-depth conversations and explaining *WHY* we need specific information, documents, or language in legislation has been a huge help in building trust and cooperation with all sides.
  - ✓ Building relationships has led to quicker and more amicable resolutions and helped to bring clarity and close loopholes in legislation.







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#### Agenda Item #2

Hear a Discussion from Oregon on PBM Regulation and Beyond—Ralph Magrish (Executive Director of Oregon's Prescription Drug Affordability Board) and Numi Griffith (OK)

## PBM Regulation in Oregon

Presenters:

Numi Lee Griffith, Senior Policy Advisor Ralph Margrish, PDAB Executive Director

Division of Financial Regulation



#### Statutes and rules

#### Pharmacy benefit manager legislation in Oregon

- 2013 Oregon Laws Chapter 570 HB 2123
- 2017 Oregon Laws Chapter 73 HB 2388
- 2019 Oregon Laws Chapter 526 HB 2185

#### **Statutes**

Oregon Revised Statutes § 735.530 - 535.552

#### Regulations

Oregon Administrative Rules § 836-200-400 - 836-200-440

### Market conduct requirements for PBMs

- PBMs must register with DCBS to do business in the state of Oregon (2013).
- PBMs must have appeals process for maximum allowable cost (MAC) transactions (2013).
- Restrictions on drugs that may be placed on a MAC list (2013).
- Pharmacy audits must be based on identifiable transactions, not probability sampling, extrapolation, or similar means (2013).
- PBM may not require patients to use mail order pharmacy (2017).
- PBMs may not 'claw back' claims except in limited circumstances such as fraudulent submission or duplicate claims (2017)

### **Implementation**

#### **PBM** registration

- Currently, 55 PBM companies are registered with the state.
- Annual registration fee set by rule, currently \$1,100.

#### **Limitations**

- Enforcement is driven by pharmacy complaints.
- Regulations do not apply to carriers who directly administer their pharmacy benefits.

### **PBM transparency**

#### Joint Task Force for Fair Pricing of Prescription Drugs (2018-19)

- Recommendations for transparency across the supply chain
  - Total rebates, by NDC, paid to PBMs
  - > Total rebates paid to insurers
- 2019 SB 872 would have implemented the task force recommendations for PBMs and other stakeholders

#### **Oregon Secretary of State Audits Division**

 The Oregon Secretary of State has begun an audit of all PBM contracts used by Medicaid Managed Care Entities in Oregon.

### **PBM transparency & PDAB opportunities**

- Oregon's PDAB legislation passed in 2021 which directs the board to conduct affordability reviews for the healthcare system or high out-of-pocket costs for residents.
- The PDAB will convene this summer for first time and develop annual workplan, which includes identifying PBM transparency issues and making recommendations to the legislative assembly.
- The PDAB is tasked with studying the entire prescription drug distribution and payment system in this state and polices adopted by other states and countries that are designed to lower the list price of prescription drugs.

## PDAB mandate — drug affordability reviews

In conducting drug affordability reviews, the PDAB is directed to look at multiple factors in the purchasing and supply chain, including:

- The estimated total amount of the price concession, discount, or rebate the manufacturer provides to each pharmacy benefit manager registered in this state for the prescription drug under review, expressed as a percentage of the prices.
- The estimated average price concession, discount, or rebate <u>the</u>
   manufacturer provides or is expected to provide to health
   insurance plans and pharmacy benefit managers in this state for therapeutic alternatives.

## **Getting to net cost – removing the fog**



## Where Are The Costs Hiding?

#### **Transparency will:**

- Identify where the profits are distributed and living between industry and PBMs.
- Attempt to quantify them.
- Identify its impact on the system and consumers.
- Inform what drugs get presented to PDAB for affordability reviews.



## Analytic opportunities to inform policy

#### Seeing the whole transaction end to end, seeing the blind spots.

- Identify the most expensive drugs by utilization.
- Which have shown significant price increases and contributed to raised carrier operating costs and consumer premiums and copays.
- Extrapolate information to identify how rebates and incentives drive cost and impact consumers.

## Questions?

#### Agenda Item #3

Hear a Discussion from a Consumer Perspective on the Subgroup's 2022 Charge to Develop a White Paper Examining PBM Business Practices—Carl Schmid (HIV + Hepatitis Policy Institute) and Anna Schwamlein Howard (American Cancer Society Cancer Action Network, Inc.—ACS CAN)

# Role of PBMs in Patient Access & Affordability of Prescription Drugs & Potential Solutions

NAIC PBM Regulator Issues (B) Subgroup April 4, 2022

Carl Schmid



**Anna Schwamlein Howard** 



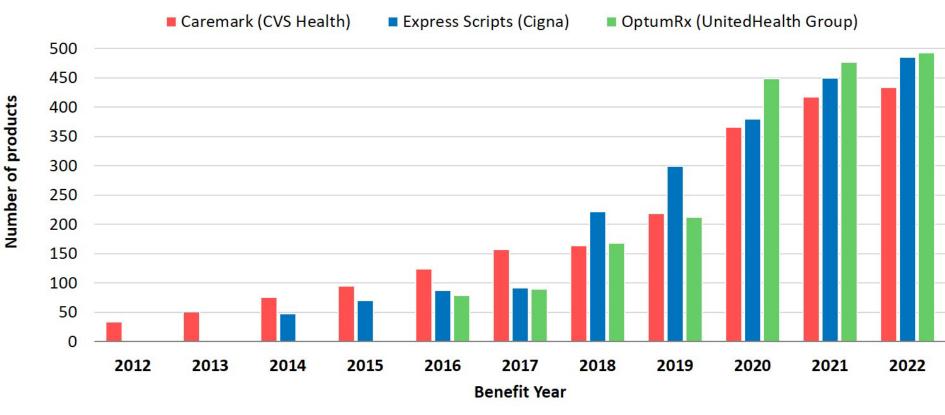
### Role of PBMs on Rx Access & Affordability

#### Formulary Decisions

- Which Drugs Covered
- Adding Newly Approved Drugs
- Removal of Drugs
- Non-medical Switching
- Increased Use of Drug Exclusions



### **PBM Drug Exclusions**

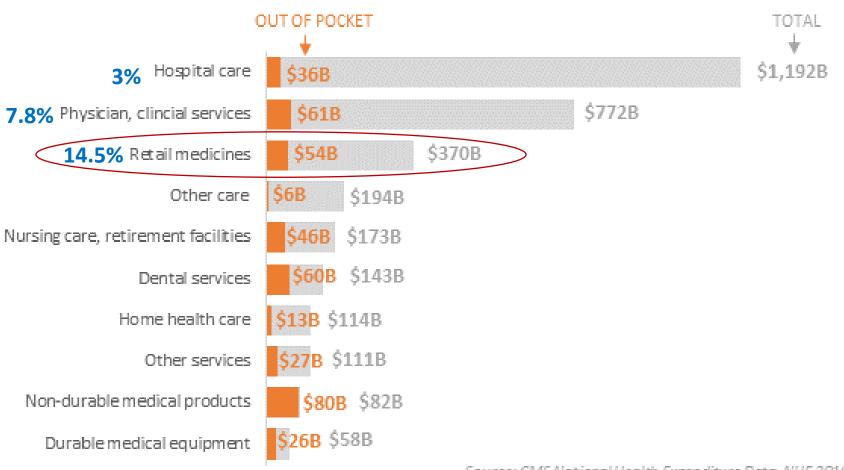


Source: Drug Channels Institute analysis of company reports; Xcenda. Note that some data have been restated due to midyear additions to exclusion lists. Express Scripts did not publish exclusion lists before 2014. OptumRx did not publish exclusion lists before 2016. Note that PBMs may exclude many of the same medications, so certain products may appear on multiple lists.

Published on Drug Channels (www.DrugChannels.net) on January 19, 2022.



## **Personal Healthcare Spending – 2019**

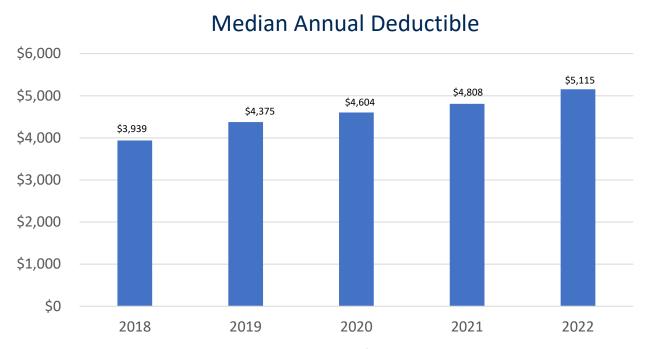






## **Increasing Deductibles**

Median QHP Deductibles - Silver Level



The PY22 silver plan median deductible is \$5,155, which is an increase of 6% from PY21 and 23% from PY18.

Source: <a href="https://www.cms.gov/CCIIO/Resources/Data-">https://www.cms.gov/CCIIO/Resources/Data-</a> Resources/Downloads/2022QHPPremiumsChoiceReport.pdf



## **Patient Affordability Study**

- ► About a third (32%) of single-person households with private insurance in 2019 could not pay a \$2,000 bill, and half (51%) could not pay a \$6,000 bill.
- Over 40% of multi-person households can't cover a mid-range employer family plan deductible of \$4,000, and 61% don't have enough to cover a high-range deductible.
- ▶ With an average out-of-pocket maximum for single coverage of \$4,272 in 2021 the study concludes: "Most households do not have enough liquid assets to meet the typical out-of-pocket maximum."

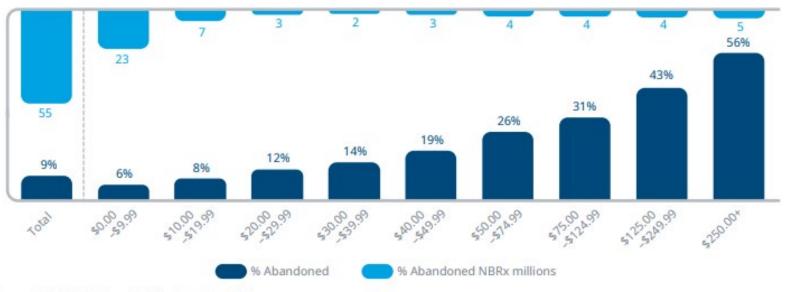
Gregory Young, Matthew Rae, Gary Claxton, Emma Wager, and Krutika Amin, Peterson-KFF Health System Tracker (Mar. 10, 2022), <a href="https://www.healthsystemtracker.org/brief/many-households-do-r-have-enough-money-to-pay-cost-sharing-in-typical-private-health-plans/">https://www.healthsystemtracker.org/brief/many-households-do-r-have-enough-money-to-pay-cost-sharing-in-typical-private-health-plans/</a>



## **Cost-Sharing and Rx Abandonment**

Patients starting new therapy abandoned 55 million prescriptions at pharmacies in 2020 with increasing frequency as costs rise

Exhibit 45: 14-day Abandonment Share of New-to-Product Prescriptions by Final Out-of-Pocket Cost in 2020, All Payers, All Products



Source: IQVIA LAAD Sample Claims Data, Dec 2020



## Role of PBMs on Rx Access & Affordability

#### Patient Costs

- Drug Tiering
  - Can be based on Rebates
  - "Specialty Drugs"
  - Discriminatory Plan Design
    - Adverse Tiering
- Beneficiary often pays Deductible & Co-insurance on List Price of the Drug
  - Does not account for any rebate PBM receives
  - Patients who generate the rebates don't benefit at pharmacy counter
- Copay Accumulator Adjustment Programs



# Silver Plans: Copay vs Coinsurance (FFE & CA 2022)

#### Preferred:

- 67% of plans use copayments (Average \$99)
- 33% of plans use coinsurance (Average 37%)

### Non-preferred:

- 24% of plans use copayments (Average \$159)
- 76% of plans use coinsurance (Average 45%)

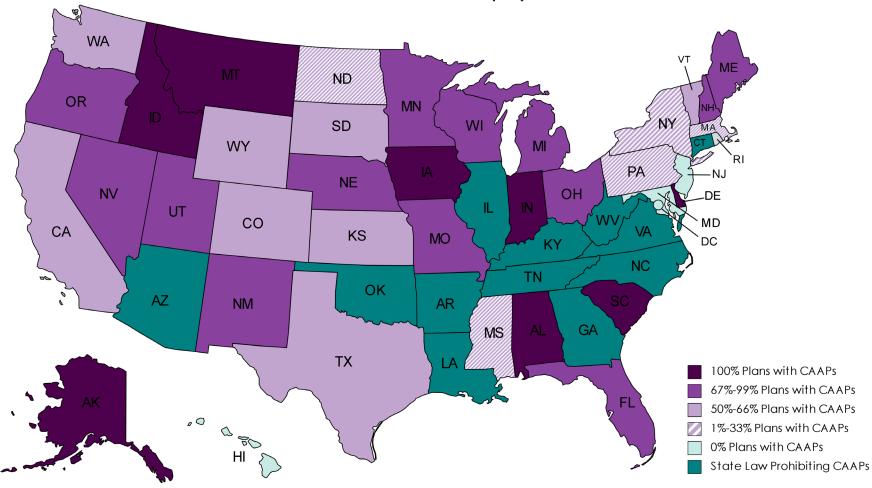
### Specialty:

- 7% of plans use copayments (Average \$493)
- 93% of plans use coinsurance (Average 44%)



### **National Overview**

Percent of Plans in States with Copay Accumulator Policies





Plan deductible: \$4,600

Annual out-of-pocket maximum: \$8,550

Monthly medication cost: \$1,680

Copay assistance total: \$7,200

· Cost-sharing for specialty tier prescription: 50% after deductible is met

#### Scenario 1: Plan Without a Copay Accumulator Program

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total	Insurer collects
Copay Assistance	\$1,680	\$1,680	\$1,240	\$840	\$840	\$840	\$80	\$0	\$0	\$0	\$0	\$0	\$7,200	
Remaining Deductible	\$2,920	\$1,240	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0		\$8,550
Consumer Pays	\$0	\$0	\$0	\$0	\$0	\$0	\$760	\$590	\$0	\$0	\$0	\$0	\$1,350	

Deductible is met

Copay assistance limit is met

Out-of-Pocket maximum is met

#### Scenario 2: Plan With a Copay Accumulator Program

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total	Insurer collects
Copay Assistance	\$1,680	\$1,680	\$1,680	\$1,680	\$480	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$7,200	
Remaining Deductible	\$4,600	\$4,600	\$4,600	\$4,600	\$3,400	\$1,720	\$40	\$0	\$0	\$0	\$0	\$0		\$15,160
Consumer Pays	\$0	\$0	\$0	\$0	\$1,200	\$1,680	\$1,680	\$40	\$840	\$840	\$840	\$840	\$7,960	

# Patient Scenarios



## Role of PBMs on Rx Access & Affordability

#### Pharmacy Access

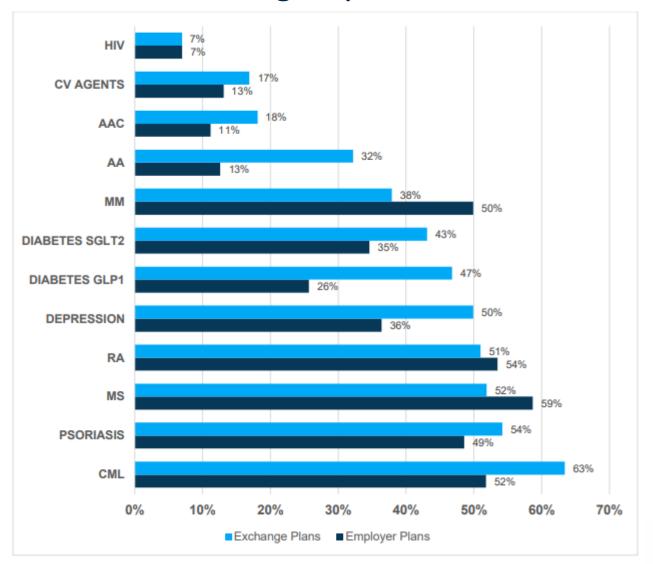
- Mail order, specialty, or retail
- Which pharmacy you can use

#### Access Restrictions

- Utilization Management (step-therapy, PA)

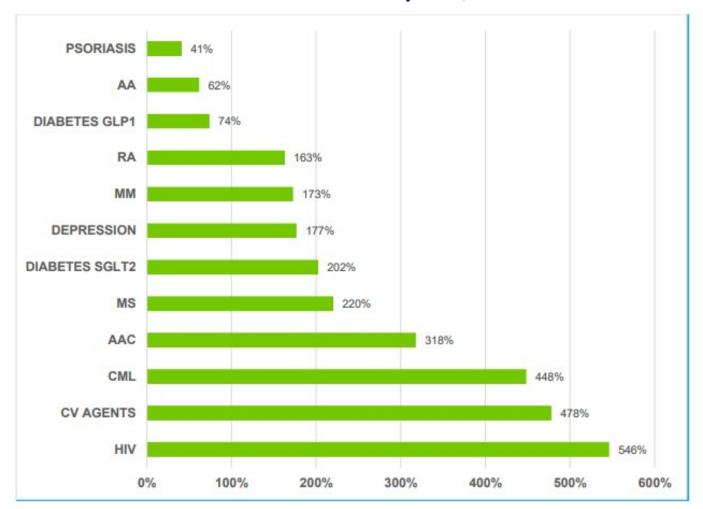


# Employer and Exchange Plans' Use of UM for Single-Source Brand Drugs, by TA, 2020





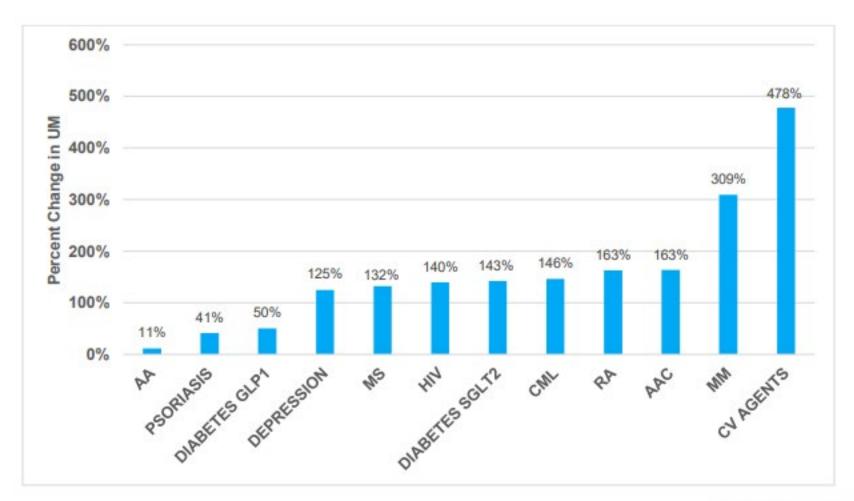
## Change in ST for Single-Source Brand Drugs in the Commercial Market by TA, 2014-2020



AA: Atypical Antipsychotics, GLP1: Glucagon-like peptide-1, RA: Rheumatoid Arthritis, MM: Multiple Myeloma, SGLT2: Sodium-glucose Cotransporter-2, MS: Multiple Sclerosis, AAC: Asthma/Allergy Corticosteroids, CML: Chronic Myeloid Leukemia, CV: Cardiovascular



# Change in Use of UM for Single-Source Brand Drugs in the Commercial Market by TA, 2014-2020



AA: Atypical Antipsychotics, GLP1: Glucagon-like peptide-1, MS: Multiple Sclerosis, SGLT2: Sodium-glucose Cotransporter-2, CML: Chronic Myeloid Leukemia, RA: Rheumatoid Arthritis, AAC: Asthma/Allergy Corticosteroids, MM: Multiple Myeloma, CV: Cardiovascular



## NAIC Draft Model Act

### Model Act is an important first step:

- Regulation
- Licensing
- Prohibition on gag clauses
- Enforcement mechanism

## NAIC White Paper

- Strongly support the development of a white paper
  - Include stakeholder comments
  - Highlight direct consumer impact of proposed policies
- Opportunity to build upon policies included in NAIC Model section 8 drafting note

## Section 8 Drafting Note

- PBM network adequacy
  - AR, DE and OK have network adequacy standards to ensure patients have convenient access pharmacies
- Prohibit spread pricing
  - AR, DE, LA, VA have laws that prohibit spread pricing

## Additional Items to Include

- Prior Authorization requirements
  - DE limits use of prior auth
- Mid-year formulary changes
  - WI requires mid-year changes to be reported to the enrollee within 30 days
- PBM complaints
  - NH and OK allow for consumer complaint process

## Additional Items to Include

- Clearly defining carrier obligations
  - NM and ME laws impose obligations on issuers
- Share rebates with patients
  - WV requires patients to benefit from PBM rebates
- Impact of <u>Rutledge</u> decision

## Thank you!

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#### Agenda Item #4

Discuss Any Other Matters Brought Before the Subgroup—TK Keen (OR)