

Draft date: 10/23/24

2024 Fall National Meeting Denver, Colorado

PHARMACEUTICAL BENEFIT MANAGEMENT REGULATORY ISSUES (B) WORKING GROUP

Monday, November 18, 2024 1:00 – 2:00 p.m. Gaylord Rockies Hotel—Aurora Ballroom B—Level 2

ROLL CALL

Joylynn Fix, Chair Ashley Scott, Vice Chair	West Virginia Oklahoma	Chlora Lindley-Myers/ Amy Hoyt/Cynthia Amann	Missouri
		David Dachs	Montana
Steven Dozier	Alabama	Cheryl Wolff	Nebraska
Lori K. Wing-Heier/ Kayla Erickson/Sarah Bailey	Alaska	Ralph Boeckman/ Erin Porter	New Jersey
Amy Seale	Arkansas	Renee Blechner/ Sahar Hassanin	New Mexico
		Alice McKenney	New York
Paul Lombardo/	Connecticut	Robert Croom/Ted Hamby	North Carolina
Michael Shanahan		TK Keen	Oregon
Howard Liebers	District of Columbia	Jodi Frantz	Pennsylvania
Sheryl Parker/Samantha Heyn	Florida	Carlos Vallés	Puerto Rico
Matthew Pickett	Illinois	Scott McAnally	Tennessee
Andria Seip	lowa	Tanji J. Northrup	Utah
Vicki Schmidt	Kansas	Jennifer Kreitler/	Washington
Daniel McIlwain	Kentucky	Ned Gaines	
Frank Opelka	Louisiana		
Chad Arnold/Joe Stoddard	Michigan	Nathan Houdek	Wisconsin
Norman Barrett Wiik/ T.J. Patton	Minnesota	Jill Reinking	Wyoming

NAIC Staff Support: Jolie H. Matthews

AGENDA

- 1. Hear a Discussion on Pharmacy Benefit Managers (PBMs) and How They Function—*Joylynn Fix (WV)*
 - John Jones (Pharmaceutical Care Management Association [PCMA])
 - Scott Woods (Pharmaceutical Research and Manufacturers of America [PhRMA])
 - Joel Kurzman (National Community Pharmacists Association [NCPA])



- Hear a Discussion on Providing Potential Assistance to the Producer Licensing Uniformity (D) Working Group to Create a New Section on PBM Licensure Best Practices and Uniform Standards in the State Licensing Handbook—Ashley Scott (OK)
- 3. Discuss Any Other Matters Brought Before the Working Group — Joylynn Fix (WV)
- 4. Adjournment

Agenda Item #1

Hear a Discussion on Pharmacy Benefit Managers (PBMs) and How They Function:

- John Jones (Pharmaceutical Care Management Association [PCMA])
- Scott Woods (Pharmaceutical Research and Manufacturers of America [PhRMA])
- Joel Kurzman (National Community Pharmacists Association [NCPA])



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Pharmacy Benefit Companies: The Intersection of Care and Cost Savings

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What to know about pharmacy benefit companies (PBMs)

What is a pharmacy benefit?

A pharmacy benefit is the part of your health insurance that covers prescription drugs.

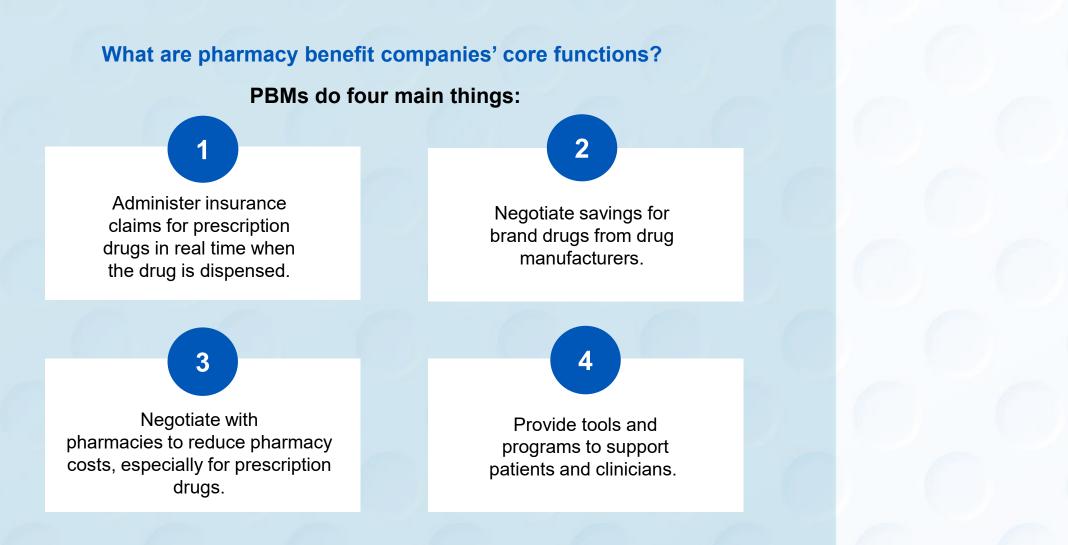
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	Preventative Care	No Copay	

What are PBMs?

PBMs are companies with expertise in prescription drug benefits and delivery. Public and private employers, unions, retirees, and government programs, hire PBMs to help them provide prescription drug coverage to **more than 275 million people** in the US.

Click here to learn more

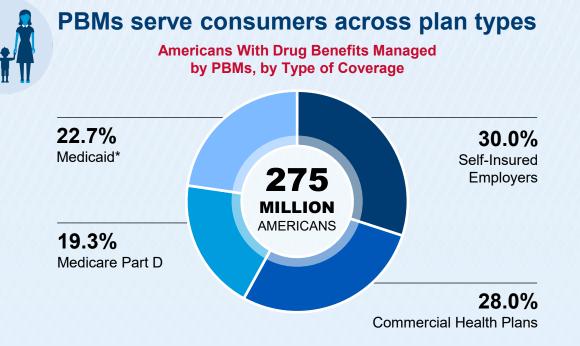




PBMs help the entire health care system by driving down drug costs, **saving payers and patients an average of \$1,040 per person per year,** and providing \$145 billion in overall value to the health care system.

About PCMA

The Pharmaceutical Care Management Association (PCMA) is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 275 million Americans who have health coverage from a variety of sponsors. PCMA continues to lead the effort in promoting PBMs and the proven tools they utilize, which are recognized by consumers, employers, policymakers, and others as key drivers in lowering prescription drug costs, increasing access, and improving outcomes.



*Excludes "Medicare/Medicaid Dual Eligibles" where drugs are covered by Medicare Part D, includes Managed Medicaid and fee-for-service Medicaid when a PBM is used.



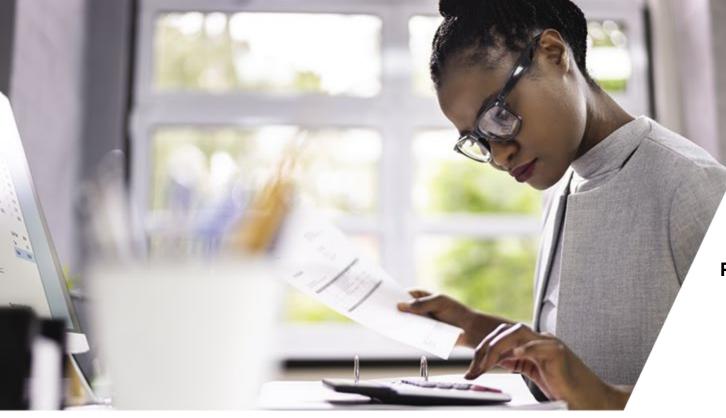
What does PBM expertise do for the US health care system?

Pharmacy benefit companies help secure lower health care costs for their customers and patients.

PBMs help save payers and patients 40-50% annually on drug and related medical costs.

Pharmacy benefit companies drive down costs for prescription drugs by pushing drug companies to compete to offer better prices (through rebates) for patients and families.

- History has shown that drug companies repeatedly and arbitrarily increase prices on existing medications, and there is no correlation between the price of a drug and how effective it is in treating a medical condition.
- Without PBMs, there would be no limit on the prices drug companies could charge.
- Evidence shows that there is no correlation between drug prices and rebates. Drug companies take enormous price increases for Part D drugs without rebates and for Part B drugs, for which PBMs do not negotiate rebates.



How do PBMs support patients?

PBMs add clinical value and advance better health outcomes by:

- **Supporting patient safety** by preventing potentially harmful drug interactions and reducing medication errors.
- Helping patients understand how and when to take their medication.
- **Improving care coordination** through offerings such as home delivery, saving patients time and money while increasing access and care coordination.

PBMs help patients afford their medications.

Pharmacy benefit companies administer over 3.6 billion scripts annually. Without the savings they negotiate, patients and payers could pay much more for prescription drugs.

• Pharmacy benefit companies offer programs to help patients facing high cost-sharing.

PBMs partner with pharmacists to benefit patients.

- PBMs establish broad networks of affordable, high-quality pharmacies that patients can rely on to get their drugs.
- PBMs help plan sponsors select the right mix of brickand-mortar, mail order, and specialty pharmacies for their networks.
- PBMs drive competition and quality among retail pharmacies.

PBMs help make drugs accessible to patients.

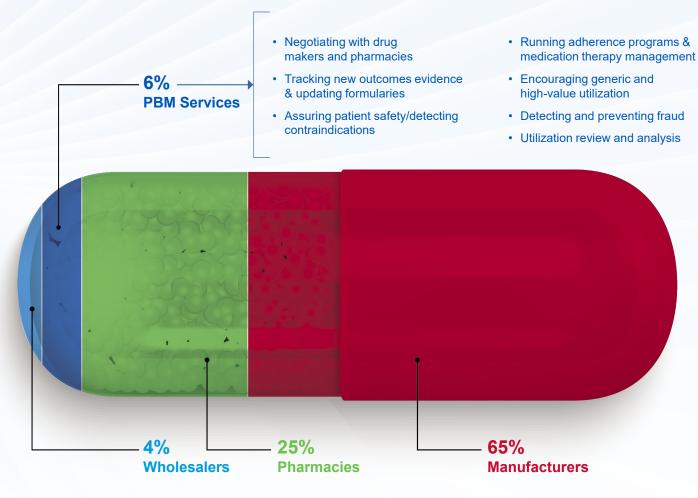
- Pharmacy benefit companies and health plan sponsors recognize the challenges posed by social determinants of health and proactive explore solutions.
- PBM programs like home delivery help to improve access for patients with transportation challenges and those living in areas where pharmacies are less accessible.

Share of drug dollar retained by drug supply chain participants

90% of the Rx dollar is retained by drug manufacturers and pharmacies

Employers and other health plan sponsors decide how they pay for pharmacy benefit company services.

- Most rebates are passed through the PBM to the employer or health plan sponsor (99.6% in Medicare and 91% in commercial health plans).
- Sometimes, employers and health plan sponsors choose to pay PBMs by asking them to retain a portion of drug company rebates, aligning incentives toward cost savings. This is a less common payment model among large employers.



Source: Visante estimates, based on data published by IQVIA, Pembroke, Altarum, USC Schaefer, and Health Affairs. Figure displays estimated total net expenditures (after rebates), both brands and generics. Includes only traditional PBM services, and excludes prescriptions filled by PBM-owned mail/specialty pharmacies, which cost less than retail but provide added margins to PBMs who own mail/specialty pharmacies.

How do PBMs support plan sponsors?

Plan sponsors are entities—employers, government programs like Medicare and Medicaid, labor unions, health insurers, state employee, and retiree plans, etc.—**that provide health care coverage.**

• Health plan sponsors choose the design of their drug benefits and participant cost sharing. PBMs offer a wide range of services and choices.

PBMs help employers and other plan sponsors by:

- Negotiating with drug companies and pharmacies to lower drug costs. PBMs also encourage the use of generic drugs, push pharmacies for high-quality performance, and negotiate value-based purchasing programs.
- **Providing business and operations expertise.** PBMs provide plan sponsors with a variety of coverage choices and flexibility in benefit design and payment structure.
- **Providing coverage recommendations.** PBMs help plan sponsors navigate coverage options, beginning with recommendations based on analyses performed by independent pharmacy and therapeutics (P&T) committees made up of clinical experts who review and evaluate clinical evidence.



How do plan sponsors choose a PBM?

Plan sponsors solicit PBM bids. PBMs must compete for business and tailor their offerings to meet plan sponsors' needs.

Adhering to contractual requirements. PBM contracts are comprehensive and include everything the PBM is required to do to fulfill its obligations to the plan sponsor. Pharmacy benefit companies provide value and achieve savings in part by:

Designing formularies. These lists of drugs covered by a health plan play a large role in driving rebates.

Sharing savings with patients. Differential patient cost sharing encourages patients to use lower-cost alternatives.

Promoting generic drugs. PBM formularies incentivize use of generics, and PBM contracts with pharmacies encourage generic substitution.

Promoting biosimilars. PBMs recognize the value of Biosimilars and strongly support policies to enhance biosimilar competition in the market.

Pharmacy benefit companies improve drug adherence by:

 Improving patient affordability, reviewing claims for indicators of non-adherence, providing clinical and other patient support programs, and providing targeted services focused on adherence for the elderly, disabled, home bound, non-English speaking, and other groups in need of additional support.

Pharmacy benefit companies provide additional value by:

- Preventing fraud, waste, and abuse through pharmacy audits.
- Increasing efficiency with shorter claims processing times and reducing the need for paper claims.
- Providing real-time reimbursement and coverage information for patients and their prescribers (RTBT).
- Streamlining the prior authorization process using technology (ePA).



PBM clinical expertise at work: How pharmacy benefit companies enable better health outcomes

CDC data shows that adherence to prescribed medication is associated with improved clinical outcomes for chronic disease management and reduced mortality from chronic conditions, and nonadherence is associated with higher rates of hospital admissions, poor health outcomes, increased morbidity and mortality, and increased health care costs. To help address this, PBMs use their expertise to provide medication adherence programs. These involve both clinical and operational components.

Clinical components.

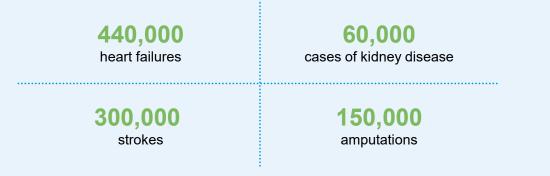
- Reviewing drugs to identify over or under-utilization or nonadherence.
- Flagging safety issues, including harmful drugs and drug combinations.
- Partnering with a wide range of expert clinicians, including specialty and community pharmacists, on identifying barriers to adherence and implementing the best strategies to meet a patient's needs.

Operational components.

- Providing counseling and coaching services that help patients stay on course with their treatment and anticipate side effects.
- Providing 24/7 patient access to customer service representatives and pharmacists as well as other clinicians.
- Sending reminders through text messages or phone alerts.
- Making dosages understandable and manageable by packaging drugs with dates and times.
- Making prescription access easy through home delivery, 90-day fills, and automatic refills.
- Providing targeted services focused on adherence for the elderly, disabled, home bound, non-English speaking, and other groups in need of additional support.

Impact of PBM role in medication adherence

PBMs help patients stick to their drug regimens, preventing more than ...





Beyond adherence: Other clinical and quality initiatives where pharmacy benefit companies use their expertise to empower patients

Pharmacy benefit companies are an integral part of a patient's coordinated care management.

- PBM relationships with other stakeholders (including plan sponsors, pharmacists, and prescribers) give them the ability to engage with the patient (directly or indirectly) and influence better patient outcomes.
- PBMs directly engage with patients through programs like medication therapy management and assessment.
- PBMs coordinate drug regimens with other health care services the patient is receiving, including from specialists.
- **Case study.** PBMs' efforts with pre-diabetic patients and the related efforts to manage co-morbidities for both diabetics and pre-diabetics (e.g., hypertension and obesity) demonstrate how this coordination works.

Click here to listen to the PBMs and Diabetes Care podcast



Click here to learn more about PBM involvement in care coordination





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NAIC PBM Regulatory Issues (B) Workgroup Community Pharmacy Perspective

November 18, 2024

Joel Kurzman Director, State Government Affairs



Who are we?

Founded in 1898, the National Community Pharmacists Association is the voice for the community pharmacist, representing over 18,900 pharmacies that employ more than 205,000 individuals nationwide. Community pharmacies are rooted in the communities where they are located and are among America's most accessible health care providers.



Profile of community pharmacies

- 18,900 pharmacies nationwide
- Local employers
 - Contribute to the tax base
 - Provide civic leadership
- 65% located in areas with populations <50,000
 - Essential health care providers in underserved areas
 - Local health care problem solvers



What community pharmacies provide











78%

have COLLABORATIVE PRACTICE AGREEMENTS with physicians





Community pharmacies' role





are lifelong friends with a councilman

are members of the chamber of commerce

OWNERS AND/

OR EMPLOYEES





of owners provide monetary support to 10 or more community organizations

AN ADDITIONAL



of owners provide monetary support to between five and nine community organizations

61% OWNERS AND/ OR EMPLOYEES

provide more than \$3,000 in monetary support to community organizations



OWNERS AND/OR EMPLOYEES are lifelong friends with a mayor



are members of a local business or civic organization



OWNERS AND/OR EMPLOYEES hold an elected local or state office



Reality for community pharmacies

- Take-it-or-leave-it contracts
- A lack of transparency in reimbursement pricing
- Underwater reimbursements often without recourse
- Retaliatory audits
- Network exclusion
- Prior authorization headaches
- No process for appeals or remedy for unfair practices
- Retroactive fees are unpredictable and often untraceable



Reality (cont.)

- PBMs control the pharmacy benefits of more than 270 million Americans¹
- 3 PBMs control nearly 80% of the market, 6 PBMs control 94%²
- Small business "negotiating" with Fortune 10 companies.

1: <u>https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf</u>

2. Ibid.



Reality (cont.): vertical integration

Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2024 CENTENE BlueCross BlueShield **Elevance** cigna CVSHealth. Humana. UNITEDHEALTH GROUP Health (NYSE: UNH) (private) (NYSE: CNC) (NYSE: CI) (NYSE: CVS) (NYSE: ELV) (NYSE: HUM) Medicaid Anthem 🗣 🕅 BlueCross BlueShield wellcare Humana. cigna aetna United Healthcare Insurer Wellpoint ambetter. PRIME Humana Scarelon Centene Pharmacy EXPRESS SCRIPTS* PBM CVS caremark OPTUMRX HERAPEUTICS Pharmacy Solutions Services¹ Magellan Rx¹ (GPO) **EMISAR** Zinc synergie Ascent allianceRx³ Specialty AcariaHealth CenterWell. OPTUM' accredo. CVS specialty CVS specialty Specialty Pharmacy PHARMACY CAREPATHIX Pharmacy Specialty Pharmacy BioPlus¹² accredo. PARAGON Kroger+ CONVIVA ♥CVS USMM⁴. EVERNORTH.7 minute clinic Provider Oak St.10 ScenterWell Scarelon¹³ OPTUM Care Health Services Community 10 ScenterWell¹⁵ VillageMD.9 signifyhealth.

https://www.drugchannels.net/2024/05/mapping-vertical-integration-of.html



Reality (cont.)

- Nearly 90% of prescriptions are covered by insurance
 - Pharmacy sets the price only with cash pay
- Community pharmacies compete with PBM-owned or affiliated retail, mail-order, and/or specialty pharmacies
- PBMs reimburse their owned/affiliated pharmacies more than community pharmacies¹

1 Just a few examples include:

https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/5e384f26fc490b221da7ced1/1580748598035/FL+M aster+Final+Download.pdf and https://wahealthalliance.org/groundbreaking-pbm-study-wspa-and-wha-release-results/ and https://www.mbp.ms.gov/news/mississippi-board-pharmacy-completes-audit-optum-2022-claims



PBM impact on patient access

- Steering to PBM-owned retail, mail-order, or specialty pharmacies leaves patients with little control over healthcare decisions
- Network access hurdles particularly in preferred networks limit patient access to pharmacies
- Between 2013 and 2022, 10% of rural independent pharmacies closed.¹
- In 2023, independent pharmacies closed at rate of nearly one per day. On track for the same in 2024.²
- 1 in 4 neighborhoods is considered a pharmacy shortage area³

1 <u>https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf</u>

2 IQVIA and 2023 NCPA Digest

3 USC/NCPA Pharmacy Access Initiative



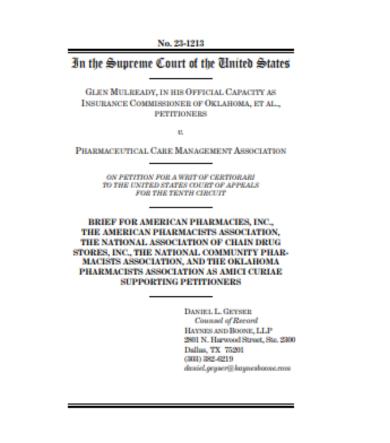
Growing consensus on need for reform

- Bipartisan issue
- 400 + bills in recent years, 225 + bills in 2024
- Coverage in major media
- Reports
- OIC enforcement actions
- Legal activity



States' rights to regulate PBMs

- Rutledge is law
- Mulready v. PCMA only a 10th Circuit issue
- Amicus brief filed June 2024
- 32 State AGs, Solicitor General urging SCOTUS to take case





Solutions: oversight

PBM licensure

- Licensure with the insurance commissioner
 - PBMs administer a health insurance benefit
 - Defining PBM, including their role as both a drug benefits manager and a pharmacy.
- 50 states currently register or license PBMs in some capacity
 - Not all as PBMs (e.g., third-party administrators)
 - Not all licensed by insurance commissioner (e.g., Board of Pharmacy, Attorney General)
- Broad OIC authority, including rulemaking and enforcement
- Access to data is critical



Solutions: enforcement

BEST PRACTICES for Enforcement of PBM Regulation

- NCPA 50-state <u>resource</u> to help members file complaints with their state insurance regulators
- NCPA developing tools to facilitate patient complaints in the pharmacy
- NCPA advocates Best Practices for Enforcement of PBM Regulations

This document shares the best practices we have seen in states for enforcing regulations of pharmacy benefit management companies (PBMs). This is needed perspective because even the most comprehensive laws and regulations addressing the egregious business practices of PBMs fail short if they are not enforced. The National Community Pharmacists Association advocates for strong oversight authority granted to departments of insurance with specific expertise, resources, and tools to implement an enforcement program. For more information, please visit our <u>PBM reform webpage</u>.

STRUCTURE

- Oversight and enforcement authority for the Office of Insurance Commissioner (OIC)
- Authority included in state's PBM licensing language, but authority is not limited to licensing process (Arkansas)
- OIC authority expressly stated throughout
- statutes (<u>Colorado</u>)
- OIC authority should include requirement for rulemaking (<u>North Dakota, West Virginia</u>)
- Example of what rulemaking can include (<u>Arkansas</u>) Applicable to all PBMs, including those serving ERISA plans (<u>Tennessee</u>)

LICENSING FEES

NCPA

- Funds should be placed in an account dedicated to
- PBM oversight (<u>Florida, Kansas</u>)
 Application fees and renewal application fees should
- be sufficient to fund the OIC's duties (<u>West Virginia</u>)
 Appropriations for implementation (<u>Florida</u>)
- Application fee minimum of \$5,000

COMPLAINTS AND REPORTING

- Designate a primary contact or contacts in the OIC for consumer and pharmacy PBM concerns (<u>Florida</u>, <u>Indiana</u>)
- Should include state tracking of Insurance
 Department capacity for PBM oversight (headcount,
 budget, funding sources, etc.) in the <u>NAIC insurance</u>
 Department Resources Report
- Standardized PBM complaint form on OIC websites should allow a consumer, pharmacy, or pharmacist to file administrative complaints (Alabama, South Carolina, Tennessee)
- Electronic system for submitting such complaints and tracking the Insurance Department's Investigation and resolution of any such complaint
- Director can delegate adjudicative function to subordinate employees of the Insurance Department and hold fact-finding hearings to adjudicate complaints
- Establish a process for timely resolution of such complaints
- Annual and quarterly reporting (<u>West Virginia</u>)
 Network adequacy not less strict than Medicare standards (<u>Arkansas</u>)

AUDITING OF PBMs

- OIC authority and prerogative (<u>Colorado, Georgia</u> Tennessee proposed, <u>West Virginia</u>)
 Require at least biennial audits (<u>Florida</u>)
- Require at least blennial addits (<u>Florida</u>)
 Access to all information needed to conduct audit
- (Georgia, Tennessee proposed)
 Costs associated charged to PBM (Florida, Georgia
- Tennessee proposed)

 Example of what PBM audits can examine: <u>indiana</u>

S) FINES

THE VOICE OF THE COMMUNITY PHARMACIST*

- Up to \$10,000 per violation, no maximum (West Virginia)
- Fines to above-mentioned account should be dedicated to PBM oversight

REPEAT VIOLATIONS

- Should be expressly stated in statute/rule with Increasing penalties (<u>Arkansas, Georgia, Minnesota</u>)
 Cease and desist
- Suspension from servicing state employee health plans
- Suspension of license
- Revocation of license
 Defining "knowing and willful" violations (Florida)
- OIC may refer to state attorney general for additional Investigation or enforcement action (<u>South Carolina</u>)

APPEALS PROCESS

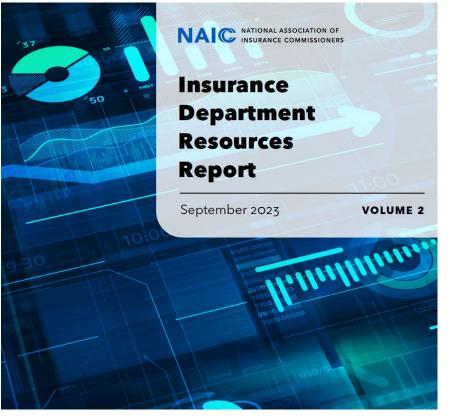
- Appeals process with timelines (<u>Tennessee</u>, <u>West Virginia</u>)
- External appeals process with OIC or delegated third-party reviewer (<u>Tennessee</u>, South Carolina proposed)
- Authority for restitution (Tennessee proposed West Virginia)
- Successful appeals applicable to similar claims by other providers (<u>Florida, Tennessee</u>)

100 Daingerfield Road Alexandria, VA 22314-2888 703.683.8200 PHONE 703.683.3619 FAX



Solutions: what NAIC can do

- Craft a uniform electronic state-level and PBM-specific complaint form for use across all states and maintain database of complaints
- Track insurance department resources dedicated to PBM oversight in its Insurance Department Resources Report (IDRR)





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Agenda Item #2

Hear a Discussion on Providing Potential Assistance to the Producer Licensing Uniformity (D) Working Group to Create a New Section on PBM Licensure Best Practices and Uniform Standards in the State Licensing Handbook—Ashley Scott (OK)

Agenda Item #3

Discuss Any Other Matters Brought Before the Working Group—Joylynn Fix (WV)