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PBM Regulation in the States
An Overview

Presented to
The National Conference of Insurance Legislators
Health Committee
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Who are we?

NCPA members are **community-based healthcare professionals** and entrepreneurs. NCPA members employ more than 250,000 individuals nationwide.

Independent pharmacists are **uniquely positioned** to **customize solutions** to healthcare challenges affecting **local communities and employers.**

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Profile of Community Pharmacists

- **22,000 pharmacies nationwide**
- **Local employers**
  - Contribute to the tax base
  - Provide civic leadership
- **80% are located in areas with populations <50,000**
  - Essential health care providers in underserved areas
  - Local health care problem solvers

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Reality for Community Pharmacies

- **91% of prescriptions are covered by insurance**
  - If medication is covered by insurance, the patient's price is set by the PBM, not by the pharmacy
  - If cash transaction, the pharmacy sets the price
- **What community pharmacies charge patients and are reimbursed is often determined *by a competitor***
  - PBMs own or are affiliated with competing retail and/or mail-order and/or specialty pharmacies
  - PBMs often require or incent patients to use the PBM-owned pharmacy

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Regulation in the Prescription Drug Supply Chain

- **Regulation:**
  - Manufacturer: highly regulated
  - Wholesaler: highly regulated
  - Prescriber: highly regulated
  - Pharmacist: highly regulated
  - Insurer: highly regulated
  - Pharmacy Benefit Manager: **largely unregulated**

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Regulation in the Prescription Drug Supply Chain

- **Usually, PBMs have no fiduciary duty to anyone but their shareholders**
  - Not to patients
  - Not to health plans / plan sponsors
  - Not to the state

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Effect of Lack of Oversight and Regulation

- **On Patients**
  - PBM steering to PBM-owned retail, mail order or specialty pharmacies (with whom the patient has no relationship or which may not be geographically convenient)
  - Network access hurdles – particularly in preferred networks – limit patient access to pharmacies

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Effect of Lack of Oversight and Regulation

- **On Community Pharmacies**
  - Take-it-or-leave-it contracts
  - A lack of transparency in reimbursement pricing
  - Underwater reimbursements without recourse
  - Retaliatory audits
  - Network exclusion
  - Prior authorization headaches
  - No process for appeals or remedy for unfair practices
  - Retroactive fees lead to unpredictability

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How PBMs Make Money

- **Administrative fees paid by plan sponsors**
- **Administrative fees paid by pharmacies**
- **Rebates**
  - Discounts the manufacturer gives to PBMs for formulary placement
- **Spread pricing**
  - Profit-taking that results from the difference between what the PBM reimburses the pharmacy for a medication and what it bills the health plan for that medication cost

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PBMs make money from almost every player in the prescription supply chain, including the patient…
yet they never touch a medication.

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Why Insurance Commissioner Oversight is Needed

- **PBMs have extraordinary market power**
  - 3 PBMs control as much as 89% of the market: 238 million lives[1] out of 266 million lives[2]
  - Fortune 25: #6 United HealthGroup, #7 CVS/Caremark, #22 ExpressScripts
  - Administer plans that touch almost every citizen in every state: *an extraordinary number of lives*

- 1: Mathematical calculation based on number of covered lives CMS/Caremark, UnitedHealth and ESI self-reported.
- 2: From testimony of PCMA CEO Mark Merritt before the U.S. House of Representatives Energy & Commerce Committee Subcommittee on Health, December 13, 2017

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Why Insurance Commissioner Oversight is Needed

- **PBMs administer a health *insurance* benefit**
  - Insurance commissioner is logical overseer
  - Insurance commissioner regulates insurance and often, unfair trade practices
  - Insurance commissioners know that ERISA was never meant to block state regulation

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State Trends in PBM Regulation

- **Insurance commissioner most common**
  - Also Board of Pharmacy, AG or other department
- **Require PBM licensure or registration:** 25 states
- **Fair Audit Law:** 40 states
- **Reimbursement Transparency:** 34 states
- **Fiduciary:** 0 states
- **Network access:** 9 AMMO, 30 AWP states (not all apply to PBMs)
- **Pharmacy Patient Protections:** (copay clawbacks, gags, bans on add'l certifications, etc)
- **Disclosure (pricing, spread, etc):** 3 states

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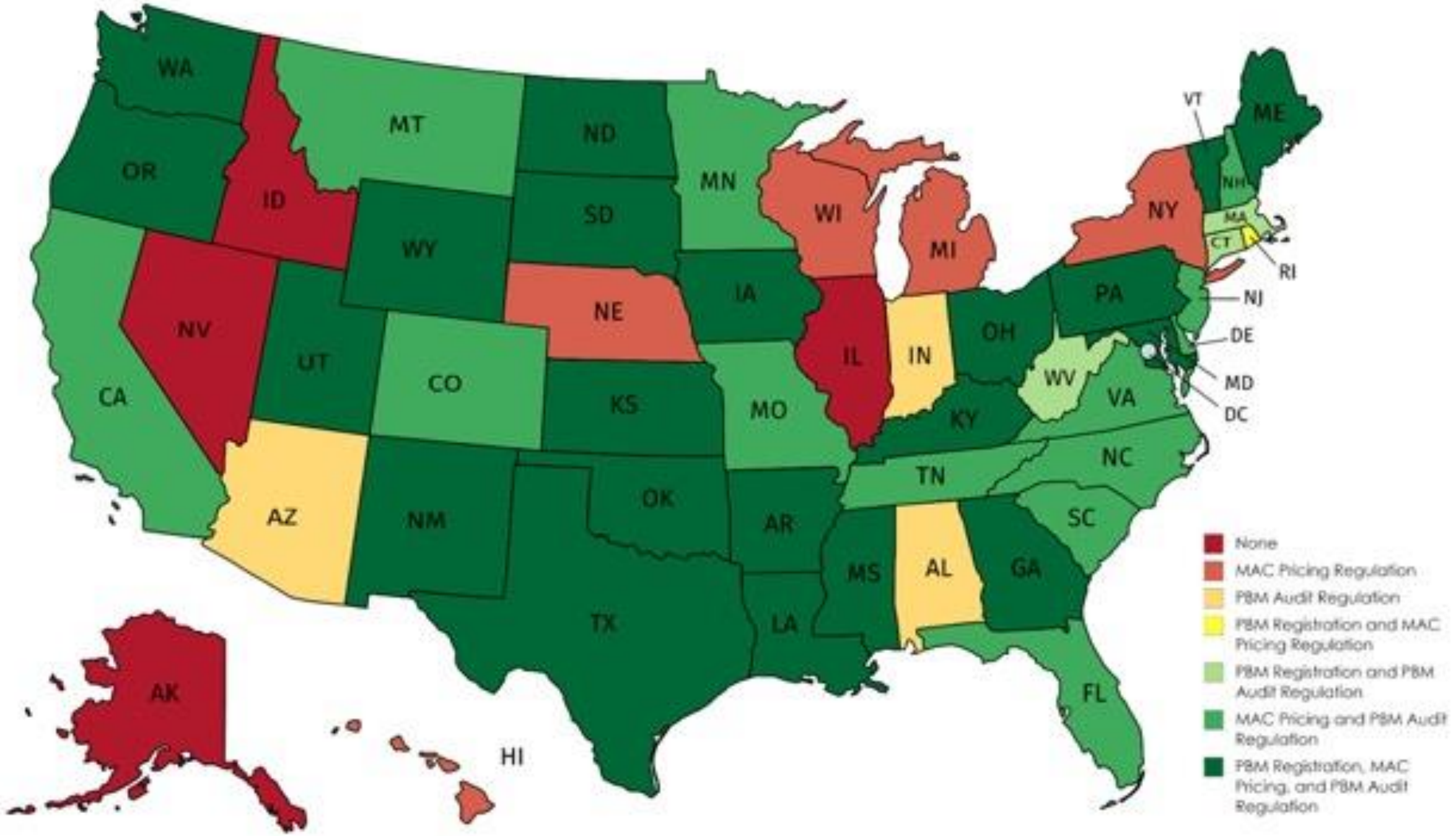
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MAC Pricing Regulation
PBM Audit Regulation
PBM Registration and MAC Pricing Regulation
PBM Registration and PBM Audit Regulation
MAC Pricing and PBM Audit Regulation
PBM Registration, MAC Pricing, and PBM Audit Regulation

A mishmash of often weak, poorly enforced regulation.

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Model legislation should require fair, consistent processes and consumer protections

- **Insurance Commissioner oversight, plus…**
  - PBM Licensure or registration
  - Authority to promulgate rules, levy penalties
  - Require PBM to be fiduciary of plan sponsor
- **Reimbursement transparency**
  - Pricing methodology and conditions for inclusion on MAC list
  - Appeals process
  - Ban on retroactive fees whose amount is not known at adjudication

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Model legislation should require fair, consistent processes and consumer protections

- **Fair audit processes**
  - Procedures, notice, time period, range of prescriptions, appeals process
  - Recoupment: no commission-based auditor compensation, no recoupments without audit, recoupment only for amount of overpayment excluding ingredient costs if legally dispensed
- **Patient protections**
  - Ban on mandatory mail order and limits on pharmacy choice
  - Prohibitions against bans on home delivery
- **Apply all PBM regulation to PBMs who administer Medicaid managed care plans**

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NCPA strongly supports the passage and enforcement of state-level regulation of PBMs.

The aim is simple fairness.

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