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The *voice* of the
community
pharmacist.

Community Pharmacy Perspective

NAIC Pharmacy Benefit Managers Regulatory
Issues Subgroup

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Profile of Community Pharmacists

- **19,400 pharmacies nationwide**
- **Local employers**
 - Contribute to the tax base
 - Provide civic leadership
- **80% located in areas with populations <50,000**
 - Essential health care providers in underserved areas
 - Local health care problem solvers



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 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, mail-order, and/or specialty pharmacies
 - PBMs often require or incent patients to use the PBM-owned pharmacy



Reality for Community Pharmacies: Contracts with PBMs

- 3 PBMs control as much as 80% of the market.¹
- Role of PSAO in contracting process
 - Anti-trust laws prevent a PSAO from declining a contract on behalf of a pharmacy
 - GAO conducted a study on the role and ownership of PSAOs and stated that "over half of the PSAOs we spoke with reported having little success in modifying certain contract terms as a result of negotiations. This may be due to PBMs' use of standard contract terms and the dominant market share of the largest PBMs. Many PBM contracts contain standard terms and conditions that are largely non-negotiable."²

1: <https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html>

2: [GAO-13-176](#).



Why oversight is necessary

- Conflicts of interest incentivize anticompetitive behavior
 - 79% of respondents to NCPA [survey](#) said their patients' prescriptions were transferred to another pharmacy in the previous six months without their patients' knowledge or consent. Community pharmacies lost a median of 12 patients during that time period.
 - Wisconsin [report](#): "When PBMs own pharmacies, they might favor their own pharmacies, even if other pharmacies have lower costs." Similar findings from [California](#), [Minnesota](#), and [New York](#).
- Rising Drug Costs
 - [USC Schaeffer Center](#): "U.S. consumers and employers and the government often overpay for generics as pharmacy benefit managers (PBMs) and their affiliated insurer companies game opaque and arcane pricing practices to pad profits."
- Lack of accountability
 - Lawsuit against PBM for failure to contain costs: "[Express Scripts] was not 'contractually obligated' to contain costs."
 - *60 Minutes*, <https://www.cbsnews.com/news/the-problem-with-prescription-drug-prices/>



State efforts to regulate PBMs

- Licensure/registration: 42 states
- Any willing pharmacy: 28 states
- Anti-mandatory mail-order: 31 states
- Laws addressing reimbursements to PBM-affiliated pharmacies: 12 states



Obstacles to Reform: Overly broad exclusions and exemptions

- Some state PBM laws exclude PBMs that serve ERISA plans or Medicare Part D plans.
 - Full exclusion: all ERISA plans or Part D plans are exempt.
 - Example, NC Gen. Stat. 58-56A-4: “This section shall not apply with respect to claims under an employee benefit plan under the Employee Retirement Income Security Act of 1974 or Medicare Part D.”
 - Qualified exclusion: “preempted” ERISA plans are exempt.
 - Example, SD Laws 58-29E-1: “The term does not include a self-funded plan that is exempt from state regulation pursuant to ERISA...”
- What is the impact of a qualified exclusion?
- NCOIL Model PBM Act: “Nothing in this Act is intended or shall be construed to be in conflict with existing relevant federal law.”



Obstacles to Reform: Overly broad exclusions and exemptions

- Guidance from federal courts on ERISA preemption
 - SCOTUS in *Rutledge v. PCMA*: “[N]ot every state law that affects an ERISA plan or causes some disuniformity in plan administration has an impermissible connection with an ERISA plan.” ERISA is “primarily concerned with pre-empting laws that require providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits or by binding plan administrators to specific rules for determining beneficiary status.”
 - Federal courts in the 8th Circuit (*PCMA v. Wehbi*) and the Western District of Oklahoma (*PCMA v. Mulready*) have expanded upon the *Rutledge* ruling.
- Part D preemption
 - If state law purports to either (1) regulate the same subject matters as a Part D “standard,” or (2) frustrate the purpose of a Part D standard, it is preempted. Part D “standards” are defined in *Wehbi* as either (1) Medicare Part D statutory provision OR (2) a regulation promulgated under Part D and published in the CFR.



Obstacles to Reform: Overly broad exclusions and exemptions

- State responses
 - Legislation (e.g., Maryland HB 601 (2021) (“...to repeal the exclusion of certain persons that provide prescription drug coverage or benefits through plans subject to ERISA; and to apply the provisions to certain persons that offer certain plans or programs in the State...”).
 - Studies
 - Report of the Maryland Insurance Administration on *Rutledge v. Pharmaceutical Care Management Association* and its impact on Title 15, Subtitle 16 of the Maryland Insurance Article: “Relying on *Rutledge*, we conclude that none of the Maryland PBM laws if applied to a PBM contracted to an ERISA plan would have an impermissible connection with or an impermissible reference to ERISA plans.”
 - Texas House Committee on Insurance: Study the impacts of the U.S. Supreme Court’s 2020 decision in *Rutledge v. Pharmaceutical Care Management Association* and the federal No Surprises Act(2021 Consolidated Appropriations Act, Public Law No. 116-620) on the Texas insurance market.
 - New York: “The Department is inviting public comments about the applicability of the Pharmacy Benefit Manager (“PBM”) laws set forth in New York Insurance Law Article 29 and New York Public Health Law Section 280-a, as well as the application of any rules promulgated thereunder, on PBM conduct while providing pharmacy benefit management services to Medicare Part D plans in New York.”
- NAIC ERISA Working Group recently approved an analysis of *Rutledge* decision to be included in ERISA Handbook.



Obstacles to Reform: Pharmacists can't speak out

- Pharmacists are in a unique position to know:
 - How PBM practices impact patient costs and access;
 - Whether those practices conflict with state laws.
- Pharmacists may be prevented from alerting the Insurance Commissioner, or other regulatory authority
 - Fear of retaliation
 - “[I]ndependent pharmacists do not file complaints [with the Insurance Administration] because they are then retaliated against by the PBMs through audits and increased scrutiny.” Maryland Insurance Administration. “Maryland Insurance Administration Pharmaceutical Services Workgroup Report” 13 (Jan. 21, 2018).
 - New Mexico NMSA 59A-61-5: “A pharmacy benefits manager shall not. . . prohibit, restrict or limit disclosure of information by a pharmacist or pharmacy to the superintendent; [] or prohibit, restrict or limit pharmacies or pharmacists from providing to state or federal government officials general information for public policy purposes.”
 - Inappropriate source of complaint
 - Pharmacists have issued complaints only to be told that the department can accept complaints only from consumers.



Obstacles to Reform: Loopholes

- To whom does the law apply?
 - Insurer vs. PBM
 - Does the state law apply to plans that originate out of state?
- Contractual loopholes
 - Ex. SC Laws 38-71-2230
 - (A) A pharmacy benefits manager or representative of a pharmacy benefits manager shall not. . . (5) require the use of mail order for filling prescriptions unless required to do so by the health benefit plan or the health benefit plan design.
 - (B) A claim for pharmacist services may not be retroactively denied or reduced after adjudication of the claim unless the. . . (4) adjustment was agreed upon by the pharmacy prior to the denial or reduction.



Obstacles to Reform: Loopholes

- Definitions
 - Spread pricing
 - Ex. OCGA 33-64-10: “A pharmacy benefits manager shall report in the aggregate to a health plan the difference between the amount the pharmacy benefits manager reimbursed a pharmacy and the amount the pharmacy benefits manager charged a health plan.”
 - Does this account for retroactive adjustments after claim adjudication? Does it cover claim adjudication fees or other price concessions?
 - Rebates
 - Rebates can be handled by group purchasing organizations (GPOs). The largest PBM/insurers have ownership interest in GPOs. If GPO handles the rebate negotiations with manufacturers, how does that impact transparency requirements?

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