Vote NO on FL HB 961

The "Prescription Drug Cost Reduction Act" inappropriately interferes with private contracts and restricts the tools that pharmacy benefit managers (PBMs) use to reduce prescription drug costs and maintain high-quality patient care, which will result in higher costs for Florida patients and employers. The bill does nothing to reduce prescription drug costs and is protectionist legislation meant to pad the profits of Florida independent pharmacies, which have grown by 32.4% over the last 10 years.

Regulating the Entities that Lower Prescription Drug Costs

- HB 961 defines PBM services as including "control[ling] the cost of covered prescription drugs." PBMs administer prescription drug coverage and do not set the price of prescription drugs. Brand and generic drug manufacturers set the prices of their products.

- PBMs are the only entities in the drug supply chain whose chief responsibility is to lower the cost of prescription drugs. PBMs do not set the price of prescription drugs but negotiate aggressively with drug manufacturers to bring down the cost so that the resulting savings are passed to consumers through their employer or health plan.

- HB 961 would permit pharmacies and pharmacists to disclose confidential contract terms and payment rates to the Legislature, which would ultimately raise costs and potentially lead to tacit collusion among competing pharmacies.

- The bill would require PBMs to disclose all "financial and utilization records, data, and information" to the Department of Financial Services with no exclusion of ERISA plans, Medicare and other federal programs that are not regulated by the state. The provision is overly broad and vague – and the public disclosure of proprietary information, such as rebates, could lead to increased costs by divulging sensitive information that could lead to higher drug costs by giving drug manufacturers the "answer key" to rebates their competitors have negotiated.

Imposing an Inappropriate PBM Fiduciary Mandate Would Raise Health Care Costs

- PBM clients are health plans, employers, the State of Florida, and other payers, which hire PBMs to administer pharmacy benefits. HB 941 would require a PBM to be a fiduciary to *both* their clients and patients, which would present two conflicts: being a fiduciary itself to clients and being a fiduciary to two entities.

- According to the U.S. Department of Labor (DOL) and federal courts, PBMs are not fiduciaries. Imposing fiduciary duties on PBMs would raise drug benefit costs by increasing their legal liability and undermining their ability to effectively implement cost management tools for their clients.

    - According to the DOL, third party administrators, such as PBMs "who have no power to make any decisions as to plan policy, interpretations, practices or procedures, but who perform [certain] administrative functions for an employee benefit plan…are not fiduciaries of the plan."[1]
    - Federal courts have struck down state PBM fiduciary mandates as being preempted by the Employee Retirement Income Security Act (ERISA).[2]

- Imposition of a fiduciary mandate would create a conflict between PBMs' contractual obligations to their clients and a fiduciary duty to act "solely in the interest of plan participants." For example, a PBM's contract may call for the use of PBM tools such as prior authorization and step therapy that are designed to reduce costs for *all* participants, but which may result in higher costs or less access to a given drug for a particular group of participants. In this case, implementing the contract would conflict with a fiduciary duty.

- A fiduciary mandate would impact employers and health plans that now cover some 5.7 million beneficiaries in Florida. If Florida implements a PBM fiduciary mandate, projected drug costs for fully insured employers and commercial health plans would increase by $4.4 billion in the state over the next 10 years.[3]

Redefining Maximum Allowable Cost (MAC) Lists

- HB 961 inappropriately expands the definition of a MAC list. A MAC list specifies the most a PBM will reimburse a pharmacy for a particular *generic* drug. MAC lists are not used for brand drugs.

- Identical generic drugs can be made by multiple manufacturers, which sell them at different prices to pharmacies. MAC lists encourage pharmacies to purchase generics at the lowest possible cost—driving competition among wholesalers and generic drug manufacturers—which ultimately provides value to health plan sponsors and consumers.

- PBMs set and regularly update MAC lists to reflect a market-based average acquisition cost of a well-run independent or chain pharmacy. MAC lists help PBMs fairly compensate both independent and chain pharmacies while providing cost-effective drug benefits to payers.

- Independent pharmacies and chains buy drugs at different prices and terms from various wholesalers. PBMs are *not* involved in these transactions and have *no* insight into the prices that pharmacies pay.

    - To determine a fair reimbursement for the generic drugs that pharmacies dispense, PBMs survey market data to calculate the average cost for those drugs, including information from nationally recognized pricing reference services (e.g., Medi-Span), wholesalers, and drug manufacturers.

Mandating Contracting Terms Between Private Entities

- HB 961 incorrectly defines spread pricing as "the practice by a [PBM] of charging or claiming from a payor an amount that is more than the amount the [PBM] paid to the pharmacy or pharmacist who filled the prescription or who provided the pharmacy services."

    - Spread pricing (or risk mitigation pricing) provides employers a price certain for prescription drug benefit payments to pharmacies, where the PBM takes on the risks of daily fluctuations in drug prices and differing pharmacy charges for the same drug and is incentivized to push pharmacies to reduce their acquisition costs.
    - HB 961 does not contemplate that PBMs are at risk for drug prices and can (and in fact do) sometimes pay pharmacies more than PBMs are paid by clients. Spread pricing *does not* necessarily guarantee a net-positive outcome for PBMs—instead it is a client-demanded contracting option that brings much needed predictability to many employer accounts.

- Research has found that about 37% employers chose traditional spread pricing contracts with their PBMs in 2018.[4] Smaller employers (43%) were more likely to report spread pricing than large employers (29%).[5] The very existence of spread pricing contracting is evidence of the demand for this type of contracting flexibility.

- This bill interferes in the ability of employers to choose contract terms that best suit their needs. Some employers choose spread contracts or flat dollar amounts (versus rebates) to ensure predictability in knowing what their prescription drug costs will be. That choice should be theirs to make.

- Beyond disclosures to their clients, this bill would require that PBMs pass through all income, rebates, etc. to their clients and hold all funds for providing PBM services in trust. This would be an unprecedented state-issued mandate on the business model and operations of PBMs, raising serious ERISA concerns.

- If HB 961 is passed, service fees will be the predominant method of PBM compensation going forward. Unlike risk mitigation and performance-based payment methods, service fees are not directly tied to incentives to reduce pharmaceutical costs or negotiate for lower net costs for specific drugs. Many employers prefer risk-based contracting strategies that incentivize performance and value. Moving to a flat, service fee model is going backward in time, to fee-for-service for pharmaceutical benefits.

Undermining Competition, Raising Costs, and Risking Patient Safety with Network Mandates

- HB 961 would create an "any willing provider" (AWP) requirement for pharmacy networks, with no terms and conditions on network inclusion. After submitting an application with a PBM, a pharmacy would be included in a network within 30 days, "without a probation period, an exclusion period, or minimum inventory requirements." The U.S. Departments of Justice and Health and Human Services have identified major Florida metropolitan areas as Medicare fraud "heat zones,"[6] but if HB 961 passed, PBMs would have to include all pharmacies in the network, even if they were under investigation – or even excluded from participating in federal programs.

- According to the Federal Trade Commission, networks and selective contracting generate significant savings that are passed on to consumers in the form of lower premiums, lower out-of-pocket costs, and better services, while AWP laws lead to higher drug prices because when a retail pharmacy "faces no threat of sales losses if it fails to bid aggressively for inclusion in the payers' networks," it has no incentive to offer its most competitive terms. Opening networks to any willing provider reduces the volume of sales for all network participants, ultimately resulting in smaller discounts.[7]

- Researchers at George Mason University and the University of Pennsylvania found that AWP policies such as HB 961 are associated with 5.8% higher per-capita drug expenditures.[8]

- Proponents of AWP laws claim that these policies are needed to ensure patient access to retail pharmacies. The data tell a different story: Today, consumers have unprecedented levels of access to retail pharmacies. Since 2010, the number of independent pharmacies in Florida has increased by 377 stores (32.4%), and the number of chain pharmacies has increased by 66 stores (2.2%).[9] Independent pharmacies make up 33.4% of the total pharmacy market in Florida.[10] According to Medicare, 90% of Medicare Part D beneficiaries live within 5 miles of a retail pharmacy and in urban areas that number drops to only 1.1 miles.[11]

- HB 961 would gut the ability of health plans and PBMs to create preferred networks. PBMs contract with independent, chain, mail-order, and specialty pharmacies to provide patients with access to a range of high-quality pharmacies, while balancing savings for patients and payers. PBMs require pharmacies to compete on service, price, convenience, and quality to be included in preferred networks. Pharmacies that agree to participate in such arrangements are designated as "preferred," and become members of a preferred pharmacy network.

- HB 961 prohibits specialty pharmacy accreditation, putting patient safety at risk and increasing costs for Floridians. New research shows that only 2% percent of specialists who work with specialty pharmacies believe that all drug stores "have the expertise and capability to provide the different types of specialty medications to patients."[12]

- Given the patient population served by specialty pharmacies, it is not only commonplace—but a best practice—for health plans and PBMs to require accreditation for specialty pharmacies to participate in their networks, where there is a greater need for robust infrastructure, such as nursing staff capacity and 24/7 access. These patient-centered services and coordinated benefit management strategies enhance adherence to prescribed drug therapies, improve the quality of care and reduce expenditures on unnecessary hospitalizations.

- HB 961 would prohibit PBMs from the "practice of pharmacy," but many PBM-affiliated mail-order and specialty pharmacies are already licensed and regulated as nonresident pharmacies by the Board of Pharmacy.

Creating a Solution in Search of a Problem with Affiliated Lines of Business

- HB 961 proposes unprecedented, wide-ranging changes to the Florida pharmacy market by prohibiting health plans and PBMs from offering or implementing plan designs that require patients to utilize affiliated pharmacies and proscribing health plans and PBMs from patient or prospective patient specific advertising, marketing, or promoting an affiliated pharmacy.

- In September 2018, when the U.S. Department of Justice approved the merger of health care corporations that operate in the PBM and insurance markets, the Antitrust Division said that one merger "is unlikely to result in harm to competition or consumers."[13] In October 2018, the Antitrust Division said that another merger would "allow for the creation of an integrated pharmacy and health benefits company that has the potential to generate benefits by improving the quality and lowering the costs of the healthcare services that American consumers can obtain."[14]

- In the run-up to the implementation of Medicare Part D, Congress asked the Federal Trade Commission (FTC) to study if PBM-owned mail order pharmacies would pose a conflict of interest.[15] The FTC produced a voluminous study concluding that no such conflict existed. The 2005 study still reflects the current views of the FTC.

- HB 961 goes so far as to prohibit a specific pharmacy name on an insurance card – which raises First Amendment questions, especially since many PBMs and insurers have affiliated mail-order, specialty, or retail pharmacies that have the same name as the insurer or PBM. Just because a pharmacy name may be on the insurance card does not mean that an insurer or PBM is "steering" a patient to that pharmacy – the plan manual will include the names of all the pharmacies where a patient can fill her prescription.

Bottom Line: Guaranteeing Profit for Pharmacists at the Expense of Consumers and Employers

- HB 961 would eliminate the cost of participating in PBM networks and accountability once in a network, mandate inflated dispensing fees, and guarantee profit on every transaction at the expense of consumers and plan sponsors. No other businesses are granted such a privileged position in any supply chain.

- Florida employers—and the State itself—that use PBMs to manage their pharmacy benefits, will bear the resulting inflated drug costs.

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[1] 29 CFR 2509.75-8 - Questions and answers relating to fiduciary responsibility under the Employee Retirement Income Security Act of 1974.
[2] Pharm. Care Mgt Ass'n v. District of Columbia, 613 F.3d 179 (D.C. Cir. 2010).
[3] Increased Costs Associated With Proposed State Legislation Impacting PBM Tools," Visante, January 2019.
[4] Pharmacy Benefit Management Institute. 2018 Trends in Drug Benefit Design, Plano, TX PBMI. Available from www.pbmi.com/benefitdesignrpts
[5] Id.
[6] *See* U.S. Department of Health and Human Services, "Medicare Fraud Strike Force," available at: https://oig.hhs.gov/fraud/strike-force/.
[7] Federal Trade Commission. (March 7, 2014). Letter to the Centers for Medicare and Medicaid Services, Department of Health and Human Services.
[8] Jonathan Klick and Joshua D. Wright. *Faculty Scholarship*. "The Effect of Any Willing Provider and Freedom of Choice Laws on Prescription Drug Expenditures."
[9] Quest Analytics analysis of NCPDP data, April 2019.
[10] *Id.*
[11] Adam Fein. (2018). The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers.
[12] North Star Opinion Research, https://www.pcmanet.org/wp-content/uploads/2016/08/pr-dated-06-15-15-final-ny-specialty-pharmacy-summarymemo.pdf.
[13] U.S. Department of Justice. "Statement of the Department of Justice Antitrust Division on the Closing of Its Investigation of the Cigna–Express Scripts Merger." September 17, 2018. Available at: https://www.justice.gov/atr/closing-statement.
[14] U.S. Department of Justice. "Justice Department Requires CVS and Aetna to Divest Aetna's Medicare Individual Part D Prescription Drug Plan Business to Proceed with Merger." October 10, 2018. Retrieved from https://www.justice.gov/opa/pr/justice-department-requires-cvs-and-aetna-divest-aetna-s-medicare-individual-part-d.
[15] Federal Trade Commission. (August 2005). Pharmacy Benefit Managers: Ownership of Mail order Pharmacies.