HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1155 Pharmacies and Pharmacy Benefit Managers
SPONSOR(S): Finance & Facilities Subcommittee, Toledo
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Finance & Facilities Subcommittee	17 Y, 0 N, As CS	Grabowski	Lloyd

SUMMARY ANALYSIS

Pharmacy benefit managers (PBMs) represent health insurers and health plan sponsors, which include self-insured employers, union health plans, and government purchasers, in the selection, purchase, and distribution of pharmaceuticals. They also organize and service pharmacy networks.

Until recently, PBMs operated largely in the absence of federal or state regulation. In the past five years, a plurality of state legislatures have passed laws to prohibit specific practices by PBMs. In 2018, the Legislature created a registration program for PBMs. Since January 1, 2019, PBMs operating in the state are required to register with the Office of Insurance Regulation (OIR) by submitting a completed application form and fee for registration. Effective July 1, 2018, the Legislature also prohibited the use of "gag clauses" that prevent pharmacies from providing drugs to patients at the lowest applicable prices.

The Florida Pharmacy Act establishes a set of protections for licensed pharmacies regarding audits by PBMs and other payers. The Act addresses many of the complaints expressed by pharmacies in relation to perceived inequity, unfairness, or burdensome practices involved in such audits. However, the Pharmacy Act does not provide a mechanism for the enforcement of the protections provided to pharmacies. The Board of Pharmacy is tasked with adopting rules to implement the provisions of the Act and setting standards of practice within the state, but the Board has no authority to regulate the actions of PBMs and insurers.

The bill transfers the audit provisions of the Florida Pharmacy Act to the Florida Insurance Code. This change gives OIR the authority to enforce these provisions and respond to potential violations. In addition, the bill expressly authorizes pharmacies to appeal audit findings made by health plans and PBMs using the existing dispute resolution program available through AHCA.

The bill establishes a financial penalty for PBMs that fail to register with OIR in accordance with current law. To date, OIR has lacked the authority to actively enforce the registration requirement adopted by the Legislature in 2018. Accordingly, the bill establishes a $10,000 fine for any PBM failing to register with OIR.

The bill also expressly makes a health insurer or HMO responsible for violations of the pharmacy audit provisions, even if a PBM is contracted to manage pharmacy benefits on behalf of the insurer or HMO.

The bill has an indeterminate, negative fiscal impact to the OIR and no fiscal impact to local government.

The bill provides an effective date of July 1, 2021.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

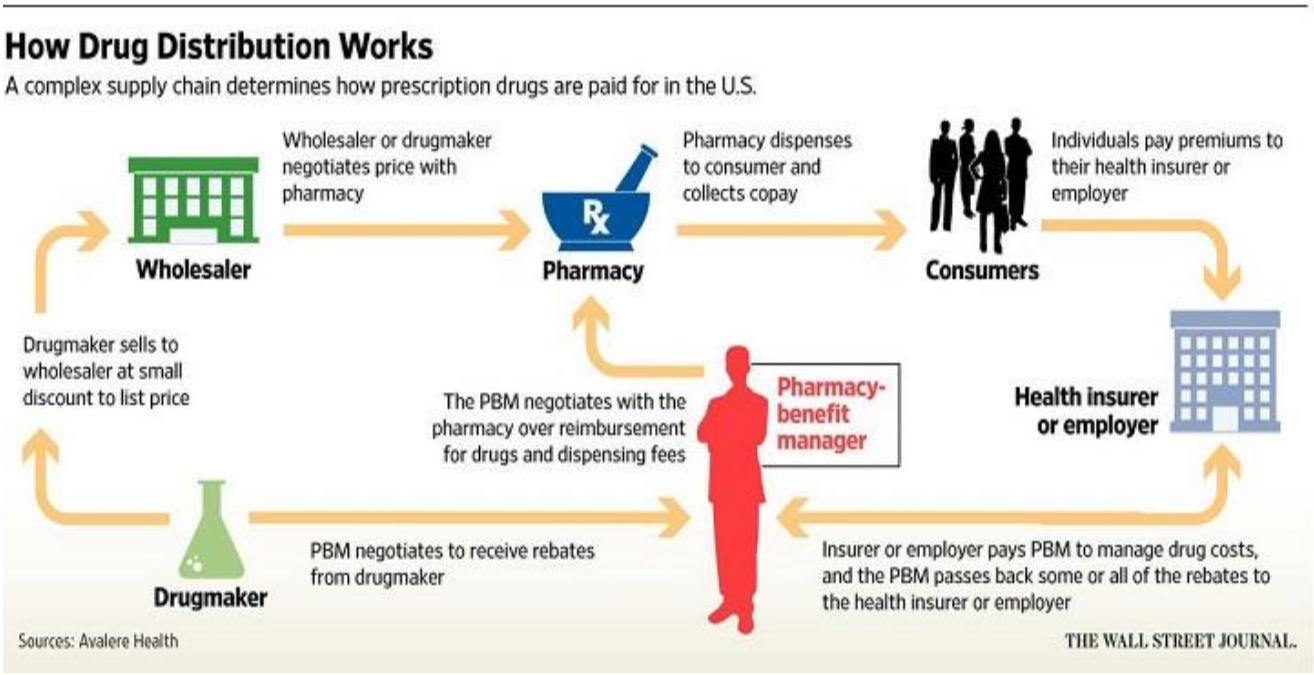
Background

Pharmacy Benefit Managers

Pharmacy benefit managers (PBMs) represent health insurers and health plan sponsors, which include self-insured employers, union health plans, and government purchasers, in the selection, purchase, and distribution of pharmaceuticals.[1]

PBMs negotiate with drug manufacturers, on behalf of health plan sponsors, in an effort to purchase drugs at reduced prices or with the promise of additional rebates. This often involves the development of drug formularies, which are tiered drug lists that incentivize the use of some drugs over others.[2] PBMs simultaneously negotiate with pharmacies to organize pharmacy networks and establish reimbursements for dispensing prescription drugs to patients.

The U.S. pharmaceutical supply system is complex, and involves multiple organizations that play differing, but sometimes overlapping, roles in drug distribution and contracting. PBMs generally do not take physical possession of prescription drugs when performing their core pharmaceutical management functions, but they play an integral role in determining how much a health plan sponsor and a patient will pay for a given drug.[3] The following graphic offers a simplified glimpse of the prescription drug supply chain.



PBMs have become major participants in the pharmaceutical supply chain. These entities first emerged as claims processors in the late-1960s and early 1970s, but began to assume much more complex

[1] "Health Policy Brief: Pharmacy Benefit Managers," *Health Affairs*, September 14, 2017. https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/healthpolicybrief_178.pdf (last accessed March 25, 2021).
[2] Academy of Managed Care Pharmacy (AMCP), *Formulary Management*, https://www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-care-pharmacy/formulary-management (last accessed March 25, 2021). See also, Pharmaceutical Care Management Association (PCMA), *Pharmacy Contracting & Reimbursement*, Available at https://www.pcmanet.org/policy-issues/pharmacy-contracting-reimbursement/ (last accessed March 25, 2021).
[3] Henry J. Kaiser Family Foundation, *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, March 2005, available at https://www.kff.org/other/report/follow-the-pill-understanding-the-u-s/ (last accessed March 25, 2021).

responsibilities in the 1990s in concert with advancements in information technology.[4] Currently, PBMs are responsible for managing the pharmacy benefits of about 270 million Americans.[5] Around 60 PBMs are currently operational in the United States, and the three largest – Express Scripts, CVS Caremark, and OptumRx – have a combined market share of more than 75%.[6]

PBM Revenue Streams

PBMs generate revenue from:

- Administrative fees from their clients (insurers, self-insured employers, union health plans, and government) for the administration of claims and drug dispensing;
- Rebates negotiated from drug companies – in some cases, the rebates are shared between the PBM and the health insurer or plan sponsor; and,
- Fees charged to pharmacies, which may including per prescription fees from network pharmacies and/or fees associated with participating in a PBM's network.[7]

Each PBM generates revenues from all or some combination of these sources. In theory, the negotiating power of PBMs should translate into savings for patients, employers and insurers in the form of reduced drug costs. In addition, health plan sponsors benefit from sharing in the increased manufacturer rebates that PBMs are often able to realize,[8] which may also reduce costs for consumers and employers.

It is clear that some plan sponsors negotiate favorable terms when contracting with a PBM. A recent survey of PBMs indicated that roughly 91% of rebates received from pharmaceutical manufacturers were passed on to health plan sponsors in 2016.[9] However, it is also apparent that some small employers and less engaged plan sponsors may not receive such a large share of rebates negotiated by their contracted PBM.[10]

Some PBMs also generate revenue using spread pricing arrangements. A pricing spread occurs when a PBM is reimbursed by a plan sponsor at one price for a given drug, but pays a dispensing pharmacy a lower price for that drug. In other words, the PBM retains some portion of the plan sponsor reimbursement as earned income.[11] PBM critics contend that this practices increases costs for health plan sponsors, or alternatively, results in lower reimbursements to pharmacies.[12]

PBMs assert that their services result in significant savings for both insurers and patients.[13] Alternatively, PBMs have been characterized merely as "middlemen," who are hired by health plans to design formularies, negotiate rebates, set up pharmacy networks, and process claims.[14] Some critics contend that a large share of rebates are retained by PBMs rather than being passed through to payers and policy holders in the form of lower drug prices. Pharmacies and pharmacists have alleged that PBMs use contract clauses to block the flow of pricing information to patients. In a statement prepared

[4] "The ABCs of PBMs: Issue Brief." National Health Policy Forum. October 27, 1999, https://www.nhpf.org/library/issue-briefs/IB749_ABCsofPBMs_10-27-99.pdf (last accessed March 25, 2021).
[5] Pharmaceutical Care Management Association (PCMA), *The Value of PBMs*, https://www.pcmanet.org/the-value-of-pbms (last accessed March 25, 2021).
[6] Advisory Board Company, *Pharmacy benefit managers, explained*, November 13, 2019, https://www.advisory.com/daily-briefing/2019/11/13/pbms (last accessed March 25, 2021).
[7] Supra note 7.
[8] Id.
[9] Pew Charitable Trusts, *The Prescription Drug Landscape, Explored,* March 2019, https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored (last accessed March 25, 2021).
[10] Supra note 7.
[11] Prime Therapeutics, *Can You Follow the Money?*, March 17, 2017, https://www.primetherapeutics.com/en/services-solutions/connect/contributors/follow_the_money.html (last accessed March 25, 2021).
[12] "Policy Options To Help Self-Insured Employers Improve PBM Contracting Efficiency," *Health Affairs* Blog, May 29, 2019, https://www.healthaffairs.org/do/10.1377/hblog20190529.43197/full/ (last accessed March 25, 2021).
[13] Visante, *The Return on Investment (ROI) on PBM Services*, November 2016, https://www.pcmanet.org/wp-content/uploads/2016/11/ROI-on-PBM-Services-FINAL.pdf (last accessed March 25, 2021).
[14] "Rebates, Coupons, PBMs, And The Cost Of The Prescription Drug Benefit," *Health Affairs Blog*, April 26, 2018, https://www.healthaffairs.org/do/10.1377/hblog20180424.17957/full/ (last accessed March 25, 2021).

for the U.S. House Committee on Oversight and Government Reform, the National Community Pharmacists Association asserted that pharmacies have been subject to "take it or leave it" contracts with PBMs that include "clauses that restrict their (pharmacists) ability to communicate with patients".[15] In addition, PBM contracts with health plan sponsors have been criticized for being confidential and complex in nature.[16]

PBM Regulation

Until recently, PBMs operated largely in the absence of federal or state regulation. In the past five years, a plurality of state legislatures have passed laws to prohibit specific practices by PBMs.[17] Both the Legislature[18] and Congress[19] have prohibited the use of so-called "gag clauses" by PBMs. A gag clause refers to a contractual requirement that prevents a pharmacy or pharmacist from telling a patient when it would cost less to pay cash for a prescription than to pay the copayment under that patient's health insurance.

In 2018, the Legislature created a registration program for PBMs.[20] Since January 1, 2019, PBMs operating in the state are required to register with the Office of Insurance Regulation (OIR) by submitting a completed application form and fee. The registration requires that a PBM provide basic identifying information to the state, but does not authorize state oversight of PBM practices.[21] According to OIR, 63 PBMs are currently registered to operate in Florida.[22]

Current law also requires contracts between PBMs and insurers or HMOs to include specific limits on the cost sharing that will be incurred by patients. Each contract must specify that a patient's cost share shall equal the lower of the following prices:

- The applicable cost sharing obligation under a patient's insurance; or,
- The retail (or "cash") price of the drug prescribed.[23]

This prohibits PBMs from preventing patients from paying the lowest applicable price for a particular drug.

Pharmacy Audits

PBMs and health plan sponsors use audits to review payments to pharmacies. The audits are designed to ensure that procedures and reimbursement mechanisms are consistent with contractual and regulatory requirements. Several different types of audits have been developed to address changes in benefit and billing processes:

- Field/On-site audit – performed onsite at the pharmacy and involve physical observations, prescription reviews, inventory, and checks for compliance. Generally, the auditor will review claims from the previous 12 to 18 months of their specific claims and provide a range of prescriptions to have readily available for review beforehand.
- Purchase Verification audit – review the amounts and coding of medications that are submitted by pharmacies from wholesale receipts. These can be classified as investigational type audits and are in accordance with third party payor agreements.

[15] National Community Pharmacists Association. *Statement for the Record: National Community Pharmacists Association*. U.S. House Committee on Oversight and Government Reform. February 4, 2016, http://www.ncpa.co/pdf/ncpa-ogr-statement.pdf (last accessed March 25, 2021).
[16] Supra note 12.
[17] See National Conference of State Legislatures, *State Policy Options and Pharmacy Benefit Managers (PBMs)*, March 17, 2021 https://www.ncsl.org/research/health/state-policy-options-and-pharmacy-benefit-managers.aspx (last accessed March 25, 2021).
[18] Ch. 2018-91, L.O.F. Ss. 627.64741, 627.6572, and 641.314, F.S.
[19] P.L. 115-263.
[20] Ch. 2018-91, L.O.F.
[21] S. 624.490, F.S.
[22] Florida Office of Insurance Regulation, *Active Company Search for Pharmacy Benefit Managers,* https://www.floir.com/CompanySearch/index.aspx (last accessed March 25, 2021).
[23] Ss. 627.64741, 627.6572, and 641.314, F.S.

- Investigational audit – providers are contacted normally by telephone or mail and asked to provide photocopies of specific documents and records related to claims paid to the provider during a specified period of time. Documentation may include copies of original prescriptions, signature logs, computer records, and invoices showing purchase or receipt of dispensed medications.
- Desk/mail audit – uses automated means to review pharmacy claims and encounter data received by the plan or PBM. This type of audit requires the pharmacy to locate prescription records and send them to the plan or PBM. It is set up to evaluate prescribing patterns, physician referral patterns, utilization overrides, ingredient cost integrity, geographic prescribing reports, payment reports, and billed issues to identify possible abusive or fraudulent activity.
- Prescriber/member audits – have specific claim information submitted by the pharmacy and is then thoroughly verified by a prescriber/physician to ensure that each parties records coincide. It is essentially handled the same as a Desk/Mail Audit. Member Audits are similar to the Prescriber Audit with the exception that the corresponding claims are verified with the patient/customers verification.
- Telephone audit – pharmacy is contacted by the PBM usually to correct billing on a single or small number of claims. It is not used for large volumes of claims. Failure to comply with a telephone audit will normally result in the PBM reversing the claim and could lead to a desk or on-site audit.[24]

While the parameters of pharmacy audits are generally set in contracts between pharmacies and PBMs or payors, the Florida Pharmacy Act establishes a set of protections[25] for licensed pharmacies that are subject to audits by these entities. The Act attempts to address many of the complaints expressed by pharmacies in relation to perceived inequity, unfairness, or burdensome practices involved in audits. In particular, the Act provides the following rights to a pharmacy regarding an audit:

- To be given 7 days of notice prior to the initial onsite audit of each audit cycle.
- To have an onsite audit scheduled after the first 3 calendar days of the month, unless the pharmacist consents to an earlier audit date.
- To limit the audit period to 24 months from the date a claim was submitted to or adjudicated by the entity conducting the audit.
- To have an audit which requires clinical or professional judgment conducted by or in consultation with a pharmacist.
- To use the written and verifiable records of a hospital or authorized practitioner to validate a pharmacy record in accordance with state and federal law.
- To be reimbursed for a claim that was retroactively denied for a clerical, scrivener's, typographical, or computer error if the patient received the correct medication, dose, and instructions for administration, unless a pattern of errors exists or fraud is alleged, or the error results in actual financial loss to the entity.
- To receive a preliminary audit report within 120 days after conclusion of the audit.
- To produce documentation to challenge a discrepancy or finding within 10 days after the preliminary audit report is delivered to the pharmacy.
- To receive the final audit report within 6 months of receiving the preliminary audit report.
- To have penalties and recoupments based on actual overpayments and not according to accounting principles of extrapolation.

However, the Pharmacy Act does not provide a mechanism for the enforcement of these rights. The Board of Pharmacy is tasked with adopting rules to implement the provisions of the Act and setting standards of practice within the state, but the Board has no authority to regulate the actions of PBMs and insurers.[26]

[24] American Pharmacy Cooperative, Inc., *Audit Information – Types of Audits*, https://www.apcinet.com/Services/CAPS/AuditInformation/tabid/667/Default.aspx (last accessed March 25, 2021).
[25] S. 465.1885, F.S.
[26] Ss. 465.005, 465.0155, and 465.022, F.S. The authority of the Board of Pharmacy is limited to regulation of pharmacies and pharmacists.

Statewide Provider and Health Plan Claim Dispute Resolution Program

The Statewide Provider and Health Plan Claim Dispute Resolution Program (Program) was established in 2000 to provide assistance to contracted and non-contracted providers and health plans for resolution of claim disputes.[27] Under the Program, the Agency for Health Care Administration (AHCA) contracts with a resolution organization[28] to timely review and consider claim disputes submitted by providers and health plans and to recommend to the AHCA an appropriate resolution of those disputes.[29] The AHCA does not have authority to evaluate the recommendation of the resolution organization and must enter a final order adopting it within 30 days of receiving it.[30]

Although the vast majority of disputes under the program are initiated by hospital facilities, a pharmacy may also seek resolution of claims disputes under the program.

Effect of Proposed Changes

Pharmacy Benefit Managers

The bill establishes a financial penalty for PBMs that fail to register with OIR in accordance with current law. To date, OIR has lacked the authority to actively enforce the registration requirement adopted by the Legislature in 2018. Accordingly, the bill establishes a $10,000 fine for any PBM failing to register with OIR.

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The bill provides an effective date of July 1, 2021.

B. SECTION DIRECTORY:

Section 1: Transfers and amends s. 465.1885, F.S., relating to pharmacy audits; rights.
Section 2: Amends s. 624.490, F.S., relating to registration of pharmacy benefit managers.
Section 3: Provides an effective date of July 1, 2021.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

[27] S. 408.7057, F.S.; Agency for Health Care Administration, *Statewide Provider and Health Plan Claim Dispute Resolution Program - 2020 Annual Report*, February 2021, https://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Commercial_Managed_Care/cdrp.shtml (last accessed March 26, 2021).
[28] "Resolution organization" is a qualified independent third-party claim-dispute-resolution entity selected by and contracted with the AHCA. s. 408.7057(1)(c), F.S. The AHCA selected MAXIMUS, Inc. as the resolution organization.
[29] S. 408.7057(2)(a), F.S.
[30] S. 408.7057(4), F.S.

The OIR may require specialized staff to provide oversight of pharmacy audits by health plans and PBMs.[31] The Office may incur indeterminate costs to conduct these oversight activities.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The OIR has sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[31] Florida Office of Insurance Regulation, *Agency Analysis of HB 1155 of 2021*, March 2, 2021 (on file with Finance & Facilities Subcommittee staff).