HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 7045 PCB HMR 20-02 Prescription Drug Price Transparency
SPONSOR(S): Health & Human Services Committee, Health Market Reform Subcommittee, Andrade
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health Market Reform Subcommittee	14 Y, 1 N	Grabowski	Calamas
1) Appropriations Committee	27 Y, 0 N	Helpling	Pridgeon
2) Health & Human Services Committee	16 Y, 0 N, As CS	Grabowski	Calamas

SUMMARY ANALYSIS

Pharmacy benefit managers (PBMs) represent health insurers, self-insured employers, union health plans, and government purchasers in the selection, purchase, and distribution of pharmaceuticals. Until recently, PBMs operated largely in the absence of federal or state regulation. PBMs earn profits through a combination of revenues, which may include administrative fees charged to health plans, retention of drug rebates paid by pharmaceutical manufacturers, fees charged to network pharmacies, among others.

HB 7045 imposes additional reporting requirements that must be included in contracts between PBMs and health insurers and HMOs. A PBM must disclose information on aggregate pharmaceutical rebates, administrative fees, spread pricing revenues, and other collected fees to each health plan for which it provides services, as well as the Office of Insurance Regulation (OIR).

PBMs routinely audit pharmacies on behalf of health insurers and HMOs. 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 rights for licensed pharmacies that are subject to these audits. However, the Board of Pharmacy has no authority to enforce these rights. The bill reproduces several audit-related provisions of the Florida Pharmacy Act in the context of the Florida Insurance Code, including those that set timelines for onsite audits and require the timely submission of audit reports to pharmacies. The bill authorizes OIR to enforce the pharmacy audit provisions.

Pharmaceutical manufacturers are regulated by federal and state law. In Florida, the Department of Business and Professional Regulation's (DBPR) Division of Drugs, Devices, and Cosmetics issues permits to manufacturers who produce or sell prescription drugs in the state. The bill requires prescription drug manufacturers to provide notice of upcoming product price increases as a condition of receiving a permit from DBPR. A manufacturer will be required to notify all health plans at least 60 days in advance of a drug price increase, along with the amount of the forthcoming price increase. Manufacturers would also be required to submit an annual report to DBPR and OIR on each drug price increase, along with a justification for the price increase. Health plans, if making a formulary change based on a drug price increase notification, are required to provide 30 days' notice of the change to affected patients.

The bill also requires:

- The Department of Management Services (DMS) to conduct an annual audit of a pharmacy benefit vendor contracted under the State Group Insurance Program.
- The Agency for Health Care Administration (AHCA) to contract for an analysis of pharmacy benefit practices under the Statewide Medicaid Managed Care (SMMC) program.
- The AHCA to complete an analysis of pharmacy networks under the SMMC program to determine if participating health plans or PBMs are favoring some pharmacies over others.

The bill has a negative, but likely insignificant, fiscal impact on AHCA, DBPR, DMS, and OIR, which can be absorbed using existing resources. The bill has no fiscal impacts on local governments.

The bill takes effect upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

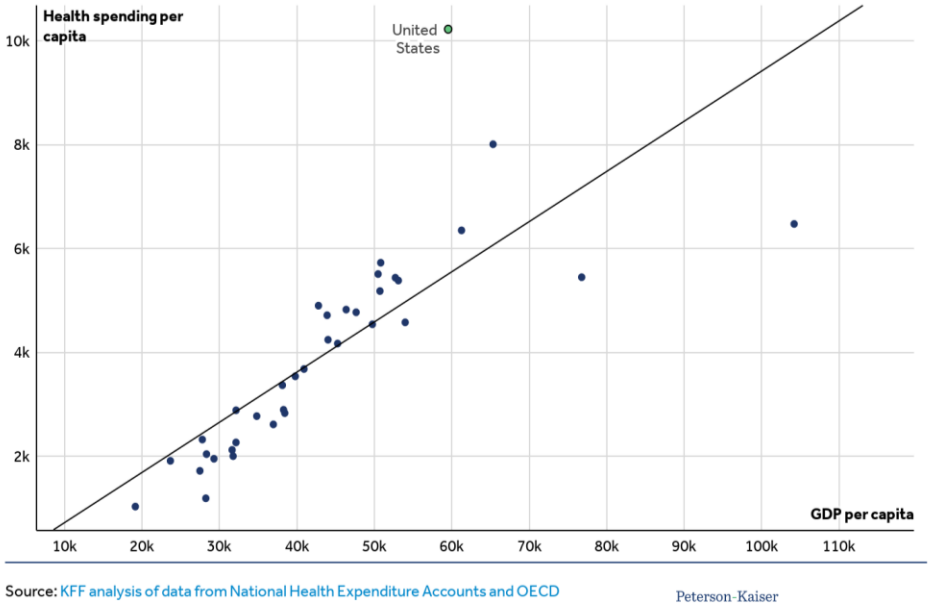
A. EFFECT OF PROPOSED CHANGES:

Background

Prescription Drugs

The United States spends $3.5 trillion on health care, or $10,739 per person, each year. One-tenth of that, approximately $333.4 billion, is spent on retail prescription drugs,[1] with 14 percent ($46.7 billion) paid out-of-pocket by consumers.[2] The United States spends significantly more on healthcare than any country in the world and is an outlier even when compared to other developed and wealthy nations, even after adjusting for drug industry rebates.[3] The United States overall spends 30 to 190 percent more on prescription drugs than other developed countries and pays up to 174 percent more for the same prescription drug.[4]

GDP per Capita and Health Spending per Capita, 2017 (U.S. Dollars, PPP Adjusted)[5]



Although many patients are shielded from the high list prices of prescription medications by their insurance coverage, the number of patients with high-deductible health plans is increasing. The rising prices of drugs mean more costs are being passed on to consumers in the form of deductibles,

[1] U.S. Centers for Medicare & Medicaid Services, *National Health Expenditures 2017 Highlights,* Dec. 6, 2018, *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf (last accessed January 3, 2020).
[2] U.S. Centers for Medicare & Medicaid Services, *National Health Expenditures by Type of Service and Source of Funds, CY 1960-2017*, available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html (last accessed January 3, 2020).
[3] Peterson-Kaiser Health System Tracker, *How Does Health Spending in the U.S. Compare to Other Countries?*, https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/#item-start (last accessed January 3, 2020); Robert Langreth, *The U.S. Pays a Lot More for Top Drugs Than Other Countries,* BLOOMBERG, (Dec. 18, 2015), https://www.bloomberg.com/graphics/2015-drug-prices/ (last accessed January 3, 2020).
[4] Peterson-Kaiser Health System Tracker, *What Are the Recent and Forecasted Trends in Prescription Drug Spending?, https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-start* (last accessed January 3, 2020); *See also,* David O. Sarnak, et. al, *Paying for Prescription Drugs Around the World: Why is the U.S. an Outlier?*, The Commonwealth Fund, Issue Brief: Oct. 2017, available at: https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2017_oct_sarnak_paying_for_rx_ib_v2.pdf (last accessed January 3, 2020).
[5] Id. Adjusted for purchasing power parity.

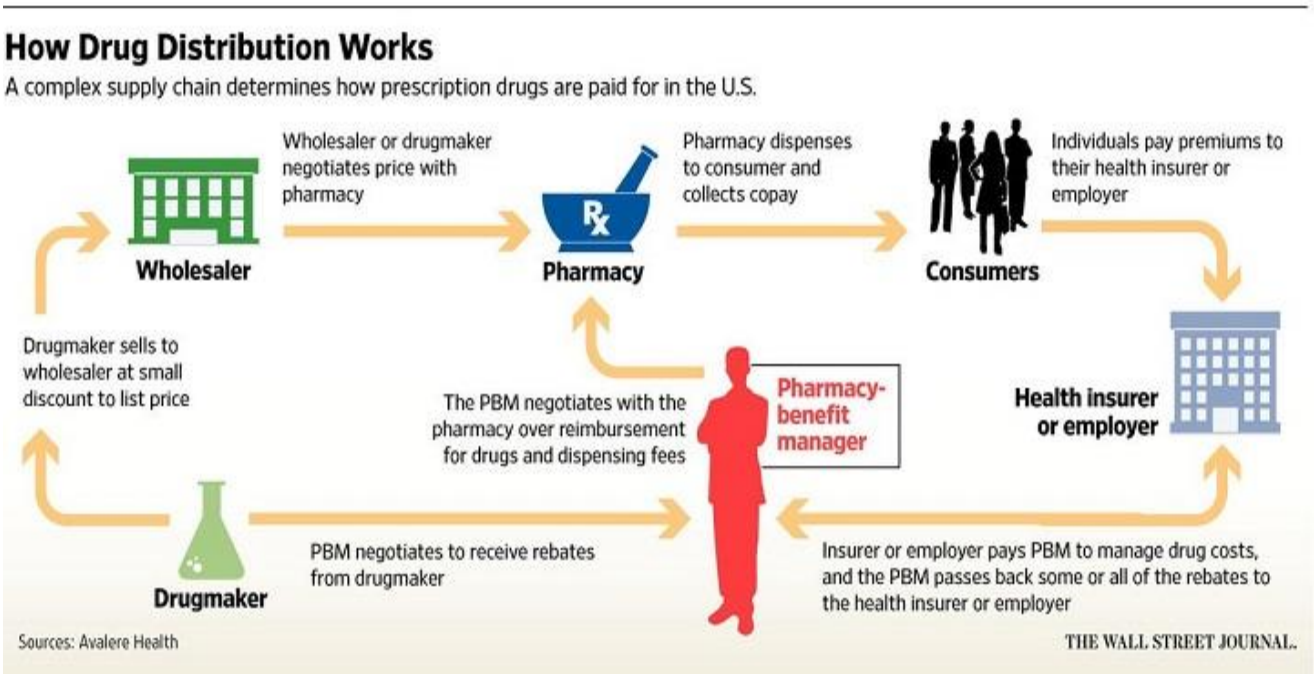
premiums, or coinsurance.[6] Insurers and other health plan sponsors increasingly rely on pharmacy benefit managers to restrain spending on prescription drugs.

Pharmacy Benefit Managers

Pharmacy benefit managers (PBMs) represent health insurers and plan sponsors, which include self-insured employers, union health plans, and government purchasers, in the selection, purchase, and distribution of pharmaceuticals.[7]

PBMs negotiate with drug manufacturers, on behalf of 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.[8] PBMs simultaneously negotiate with pharmacies to 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 plan sponsor and a patient will pay for a given drug.[9] 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 responsibilities in the 1990s in concert with advancements in information technology.[10] Currently, PBMs

[6] Daniel H, Bornstein SS, for the Health and Public Policy Committee of the American College of Physicians, *Policy Recommendations for Pharmacy Benefit Managers to Stem the Escalating Costs of Prescription Drugs: A Position Paper From the American College of Physicians*, Ann Intern Med. 2019;171:823–824. Available at https://annals.org/aim/fullarticle/2755578/policy-recommendations-pharmacy-benefit-managers-stem-escalating-costs-prescription-drugs (last accessed January 9, 2020).
[7] "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 January 3, 2020).
[8] Academy of Managed Care Pharmacy (AMCP). *Formulary Management*, available at https://www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-care-pharmacy/formulary-management (last accessed January 2, 2020). See also, Pharmaceutical Care Management Association (PCMA). *Pharmacy Contracting & Reimbursement*, Available at https://www.pcmanet.org/policy-issues/pharmacy-contracting-reimbursement/ (last accessed January 2, 2020).
[9] 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 January 9, 2020).
[10] "The ABCs of PBMs: Issue Brief." National Health Policy Forum. October 27, 1999, available at https://www.nhpf.org/library/issue-briefs/IB749_ABCsofPBMs_10-27-99.pdf (last accessed January 3, 2020).

are responsible for managing the pharmacy benefits of about 270 million Americans.[11] 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%.[12]

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.[13]

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,[14] 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.[15] 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.[16]

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.[17] PBM critics contend that this practices increases costs for health plan sponsors, or alternatively, results in lower reimbursements to pharmacies.[18]

PBMs assert that their services result in significant savings for both insurers and patients.[19] 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.[20] 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 for the U.S. House Committee on Oversight and Government Reform, the National Community

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[11] Pharmaceutical Care Management Association (PCMA). *The Value of PBMs*, available at https://www.pcmanet.org/the-value-of-pbms (last accessed January 3, 2020).
[12] Advisory Board Company, *Pharmacy benefit managers, explained*, November 13, 2019, available at https://www.advisory.com/daily-briefing/2019/11/13/pbms (last accessed January 6, 2020).
[13] Supra note 7.
[14] Id.
[15] Pew Charitable Trusts, *The Prescription Drug Landscape, Explained,* March 2019, available at https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored (last accessed January 7, 2020).
[16] Supra note 7.
[17] Prime Therapeutics, *Can You Follow the Money?*, March 17, 2017, available at https://www.primetherapeutics.com/en/services-solutions/connect/contributors/follow_the_money.html (last accessed January 10, 2020).
[18] "Policy Options To Help Self-Insured Employers Improve PBM Contracting Efficiency," *Health Affairs* Blog, May 29, 2019, available at https://www.healthaffairs.org/do/10.1377/hblog20190529.43197/full/ (last accessed January 11, 2020).
[19] Visante. *The Return on Investment (ROI) on PBM Services*, November 2016, available at https://www.pcmanet.org/wp-content/uploads/2016/11/ROI-on-PBM-Services-FINAL.pdf (last accessed January 3, 2020).
[20] "Rebates, Coupons, PBMs, And The Cost Of The Prescription Drug Benefit," *Health Affairs Blog*, April 26, 2018, available at https://www.healthaffairs.org/do/10.1377/hblog20180424.17957/full/ (last accessed January 7, 2020).

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".[21] In addition, PBM contracts with health plan sponsors have been criticized for being confidential and complex in nature.[22]

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.[23] Both the Legislature[24] and Congress[25] 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.[26] 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. The registration requires that a PBM provide basic identifying information to the state, but does not authorize state oversight of PBM practices.[27] According to OIR, 42 PBMs were registered to operate in Florida during calendar year 2019.[28]

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.[29]

This requirement prohibits PBMs from applying any mechanisms that would prevent a patient from paying the lowest applicable price for a particular drug.

State Group Insurance Program

The State Group Insurance Program (SGI Program) is outlined under s. 110.123, F.S., and is administered by the Division of State Group Insurance (DSGI) within the Department of Management Services (DMS). The SGI Program is an optional benefit for all state employees including all state agencies, state universities, the court system, and the Legislature, and includes health, life, dental, vision, disability, and other supplemental insurance benefits. The SGI program typically makes benefits changes on a plan year basis, January 1 through December 31.

As part of the SGI program, DMS is required to maintain the State Employee Prescription Drug Program (Prescription Drug Plan).[30] DMS contracts with CVS/Caremark, a PBM, to administer the

[21] National Community Pharmacists Association. *Statement for the Record: National Community Pharmacists Association*. U.S. House Committee on Oversight and Government Reform. February 4, 2016. Available at http://www.ncpa.co/pdf/ncpa-ogr-statement.pdf (last accessed December 21, 2017).
[22] Supra note 18.
[23] See National Conference of State Legislatures, *PBM State Legislation*, May 16, 2019, available at https://www.ncsl.org/research/health/pbm-state-legislation.aspx (last accessed January 10, 2020).
[24] Ch. 2018-91, L.O.F. Ss. 627.64741, 627.6572, and 641.314, F.S.
[25] Public Law No.115-263.
[26] Ch. 2018-91, L.O.F.
[27] S. 624.490, F.S.
[28] E-mail correspondence from Grant Phillips, Florida Office of Insurance Regulation, September 9, 2019 (on file with staff of the Health Market Reform Subcommittee).
[29] Ss. 627.64741, 627.6572, and 641.314, F.S.
[30] S. 110.12315, F.S.

Prescription Drug Plan.[31] DMS has negotiated contract language that prevents CVS/Caremark from using spread pricing at retail pharmacies. In addition, the contract stipulates that the PBM will pass through 100% of the rebates received from pharmaceutical manufacturers to DMS.[32] Private health plan sponsors may also use these types of contract clauses to define which types of revenue may be earned by contracted PBMs.

Florida Medicaid

Medicaid is the health care safety net for low-income Floridians. Medicaid is a partnership of the federal and state governments established to provide coverage for health services for eligible persons. The program is administered by the Agency for Health Care Administration (AHCA) and financed by federal and state funds. AHCA delegates certain functions to other state agencies, including the Department of Children and Families (DCF), which makes eligibility determinations.

The state uses a comprehensive managed care delivery model for primary and acute care services provided to most Medicaid enrollees, the Statewide Medicaid Managed Care (SMMC) program.[33] The SMMC program provides acute health care services through managed care plans contracted with AHCA in the 11 regions across the state. Specialty plans are also available to serve distinct populations, such as the Children's Medical Services Network for children with special health care needs, or those in the child welfare system. Medicaid recipients with HIV/AIDS, serious mental illness, dual enrollment with Medicare, chronic obstructive pulmonary disease, congestive heart failure, or cardiovascular disease may also select from specialized plans.

The managed care plans participating in the SMMC program may contract with PBMs for the administration of pharmacy benefits, or they may manage the benefit internally. AHCA recently contracted with a consulting firm to undertake an analysis of PBM practices in the Florida Medicaid program.[34] It is currently unclear how PBMs may be generating revenues by virtue of serving the Medicaid population.

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:

- Concurrent daily review audit – intended to make immediate changes to a claim before payment is made and is triggered when a PBM or health plan sponsor's computer systems identify an unusual prescription, which can be identified according to the volume dispensed or number of days supplied.
- Retrospective audit – may be conducted as a desktop audit or an in-pharmacy audit. PBM or health plan sponsor staff conduct a desk audit remotely by contacting pharmacies to obtain supporting documentation, such as the written prescription, for a claim the staff are reviewing.
- In-pharmacy audit – most extensive type of audit and can last for days or weeks. During an in-pharmacy audit, audit staff require pharmacies to provide documentation for prescriptions dispensed during a specified time period. When the auditors identify errors or lack of documentation to support the claim, they notify the pharmacy and request repayment of all or a portion of the prescription cost.

[31] Department of Management Services, *myFlorida, Prescription Drug Plan*, available at http://mybenefits.myflorida.com/health/health_insurance_plans/prescription_drug_plan (last accessed March 6, 2019).
[32] See *Pharmacy Benefit Management Services*, Contract between CaremarkPCS Health, L.L.C. and Florida Department of Management Services, available at https://www.dms.myflorida.com/content/download/107930/607791/2015_PBM_Contract_REDACTED_FINAL.pdf (last accessed January 22, 2020).
[33] S. 409.964, F.S.
[34] E-mail correspondence from James Kotas, Deputy Chief of Staff for the Agency for Health Care Services, January 22, 2020 (on file with staff of the Health Market Reform Subcommittee). AHCA has awarded the project to Milliman, Inc. The Agency has an existing contract with Milliman for actuarial services that will facilitate the project.

- Investigative audit – occurs where there is a suspicion of fraud or abuse.[35]

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 rights[36] 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 PBM 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.[37]

Prescription Drug Manufacturers

Federal Regulation of Drug Manufacturers

The United States Food and Drug Administration (FDA) is responsible for ensuring that foods, drugs, biological products, and medical devices are effective and safe for public consumption.[38] The FDA regulates these areas under the authority of the Federal Food, Drug, and Cosmetic Act (FDCA).[39] The FDCA prohibits any drug from being introduced or delivered for introduction into interstate commerce unless approved by the FDA. The FDCA further prohibits adulterated or misbranded drugs and devices from being introduced, delivered for introduction, or received in interstate commerce.

As a condition of providing drugs under the Medicaid program, pharmaceutical manufacturers must also participate in the 340B program. The program, named after its section number in the Public Health Service Act, requires drug manufacturers to provide drugs to eligible facilities and pharmacies at

[35] American Pharmacy Cooperative, Inc., *Audit Information – Types of Audits*, available at https://www.apcinet.com/Services/CAPS/AuditInformation/tabid/667/Default.aspx (last accessed January 11, 2020).
[36] S. 465.1885, F.S.
[37] 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.
[38] U.S. Food & Drug Administration, *What We Do*, available at https://www.fda.gov/AboutFDA/WhatWeDo/default.htm (last accessed January 7, 2020).
[39] 21 U.S.C. § 355(a).

substantially reduced prices.[40] Eligible facilities and pharmacies, referred to as "covered entities", are generally health care providers that serve low-income or otherwise disadvantaged populations. These include qualifying hospitals, federal grantees from the Health Resources & Services Administration (HRSA), the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services' Office of Population Affairs, and the Indian Health Service.[41]

State Regulation of Drug Manufacturers

The Department of Business and Professional Regulation's (DBPR) Division of Drugs, Devices, and Cosmetics and the Department of Health's (DOH) Board of Pharmacy regulate prescription drugs in the state from manufacture to distribution and dispensing. All entities engaged in any process along this continuum must be either licensed or permitted to engage in such activity, subject to relevant laws and rules and enforcement authority of DBPR or DOH. Due to the overlap in these two industries, the law requires entities permitted or licensed under either DBPR or the Board to comply with the laws and rules of both.[42]

The DBPR's Division of Drugs, Devices, and Cosmetics protects the health, safety, and welfare of Floridians from adulterated, contaminated, and misbranded drugs, drug ingredients, and cosmetics by enforcing Part I of ch. 499, F.S., the Florida Drug and Cosmetic Act.[43] The Florida Drug and Cosmetic Act conforms to FDA drug laws and regulations and authorizes DBPR to issue permits to Florida drug manufacturers and wholesale distributors and register drugs manufactured, packaged, repackaged, labeled, or relabeled in Florida.[44]

Florida has 18 distinct permits based on the type of entity and intended activity, and includes permits for entities within the state, out of state, or even outside of the United States.[45] DBPR has broad authority to inspect and discipline permittees for violations of state or federal laws and regulations, which can include seizure and condemnation of adulterated or misbranded drugs or suspension or revocation of a permit.[46]

Florida law contains a variety of provisions that make trade secret information exempt or confidential and exempt[47] from public record requirements. Some exemptions only protect trade secrets, while others protect "proprietary business information" and define that term to specifically include trade secrets. Current law makes trade secret information provided to the Department of Business and Professional Regulation in a prescription drug permit application confidential and exempt.[48]

Prescription Drug Manufacturer Permit

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[40] 42 U.S.C. § 256b. See also Health Resources & Services Administration, *340B Drug Pricing Program*, available at https://www.hrsa.gov/opa/index.html (last accessed February 18, 2020).
[41] Health Resources & Services Administration, *340B Eligibility*, available at https://www.hrsa.gov/opa/eligibility-and-registration/index.html (last accessed February 18, 2020).
[42] Ss. 499.067 and 465.023, F.S.
[43] Florida Department of Business and Professional Regulation, *Division of Drugs, Devices, and Cosmetics,* available at http://www.myfloridalicense.com/DBPR/drugs-devices-and-cosmetics/ (last visited January 7, 2020).
[44] S. 499.01, F.S.
[45] A permit is required for a prescription drug manufacturer; a prescription drug repackager; a nonresident prescription drug manufacturer; a prescription drug wholesale distributor; an out-of-state prescription drug wholesale distributor; a retail pharmacy drug wholesale distributor; a restricted prescription drug distributor; a complimentary drug distributor; a freight forwarder; a veterinary prescription drug retail establishment; a veterinary prescription drug wholesale distributor; a limited prescription drug veterinary wholesale distributor; an over-the-counter drug manufacturer; a device manufacturer; a cosmetic manufacturer; a third party logistics provider; or a health care clinic establishment. S. 499.01(1), F.S.
[46] Ss. 499.051, 499.062, 499.065. 499.066, 499.0661, and 499.067, F.S.
[47] There is a difference between records the Legislature designates as exempt from public record requirements and those the Legislature deems confidential and exempt. A record classified as exempt from public disclosure may be disclosed under certain circumstances. *See WFTV, Inc. v. The School Board of Seminole*, 874 So. 2d 48, 53 (Fla. 5th DCA 2004), *review denied* 892 So. 2d 1015 (Fla. 2004); *City of Riviera Beach v. Barfield*, 642 So. 2d 1135 (Fla. 4th DCA 1994); *Williams v. City of Minneola*, 575 So. 2d 687 (Fla. 5th DCA 1991). If the Legislature designates a record as confidential and exempt from public disclosure, such record may not be released by the custodian of public records to anyone other than the persons or entities specifically designated in statute. *See* Attorney General Opinion 85-62 (August 1, 1985).
[48] S. 499.012(3)(c), F.S.

Drug manufacturing includes the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug.[49] A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.[50] Such manufacturer must comply with all state and federal good manufacturing practices. A permitted prescription drug manufacturer may engage in distribution of its own manufactured drug without requiring a separate permit.[51] The distribution of drugs includes the selling, purchasing, trading, delivering, handling, storing, and receiving of drugs, but does not include the administration or dispensing of drugs.[52]

Nonresident Prescription Drug Manufacturer Permit

A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs located outside of this state or outside the United States that engages in the distribution in this state of such prescription drugs.[53] Such manufacturer must comply with all of the same requirements as prescription drug manufacturers operating in the state. The permittee must also comply with the licensing or permitting requirements of the state or jurisdiction in which it is located and must comply with federal and Florida laws and regulations when distributing any prescription drugs in the state. If the manufacturer intends to distribute prescription drugs for which it is not the original manufacturer, an out-of-state prescription drug wholesale distributor permit is required.[54]

Effect of Proposed Changes

Pharmacy Benefit Managers – Reporting Requirements

The bill imposes additional reporting requirements that must be included in contracts between PBMs and health insurers and HMOs. A PBM must annually report the following to health plans with which it contracts:

- The aggregate amount of all rebates received from drug manufacturers in association with claims administered on behalf of the health plan, and the aggregate amount of those rebates that was not passed on to the health plan.
- The aggregate amount of administrative fees paid to the PBM by the health plan for administration of the health plan's drug benefit. The PBM must distinguish between fees paid by 340B covered entities, and fees paid by pharmacies which are not covered entities.
- The types and aggregate amount of any fees paid by pharmacies to the PBM.
- The aggregate amount of revenue generated by the PBM using spread pricing in administration of the health plan's drug benefit.
- The type and aggregate amount of any other fees collected by the PBM through administration of the health plan's pharmacy benefit.

Beginning June 30, 2021, each health plan will be required to provide this information to OIR as part of an annual report. The OIR is then required to publish the reports on its website, along with an analysis of the reported information.

The reporting of aggregate rebates, administrative fees, and spread pricing may provide additional insight on the nature of PBM revenues in the state. To date, this information has been largely unknown outside the industry.

State Group Insurance Program

[49] S. 499.003(28), F.S.
[50] S. 499.01(2), F.S.
[51] S. 499.01(2), F.S.
[52] S. 499.003(16), F.S.
[53] S. 499.01(2), F.S.
[54] S. 499.01(2), F.S.

The bill requires DMS to contract for an annual audit of any contracted pharmacy benefits vendor. This requirement ensures that a PBM providing services under the SGI program is fully compliant with contract terms related to prescription drug rebates and spread pricing. The audit must identify any noncompliance by the contracted PBM and make recommendations for corrective actions as necessary.

Medicaid

The bill requires AHCA to develop two distinct analyses of pharmacy benefits under the SMMC program. First, the Agency must contract for an independent analysis of pharmacy benefit management practices under SMMC. The analysis must identify the types of pharmacy benefits arrangements used by participating managed care plans. In particular, the analysis will include:

- An examination of fees paid by a managed care plan to a contracted PBM.
- An examination of fees charged to participating pharmacies by a managed care plan or contracted PBM.
- A determination of spread pricing revenues retained by a managed care plan or contracted PBM.

Second, the Agency must complete an analysis of pharmacy networks under the SMMC program. This effort will provide insight on the nature of the pharmacy networks maintained by each participating managed care plan. The analysis must determine the market share of large chain pharmacies, small chain pharmacies, and independent pharmacies in each managed care network to determine whether enrollees have adequate choice among participating pharmacies. The analysis must also indicate any financial relationships that exist between a managed care plan or its contracted PBM and pharmacies included in the managed care network. The analysis should provide some indication of whether managed care plans or PBMs are favoring some pharmacies over others.

The AHCA must submit both analyses to the Governor and the Legislature by June 30, 2020.

Pharmacy Audits

The bill reproduces several audit-related provisions of the Florida Pharmacy Act in the context of the Florida Insurance Code. Namely, the bill requires that an entity conducting an audit of a pharmacy licensed under ch. 465, F.S.:

- Must notify the pharmacy at least 7 calendar days before the initial onsite audit for each audit cycle.
- May only conduct an audit after the first 3 calendar days of a month unless the pharmacist consents otherwise.
- Must limit the audit period to 24 months after the submission or adjudication of a claim.
- Must provide a preliminary audit report to the pharmacy within 120 days of the conclusion of the audit.
- Must provide a final audit report to the pharmacy within 6 months of providing the preliminary report.

The OIR now has authority to enforce these provisions and respond to potential violations as necessary. This enforcement could provide pharmacies with additional predictability in their business relationships with PBMs and health plans.

The bill also specifies that these audit protections do not apply:

- In cases where fraud is suspected.
- When claims are paid by federally funded programs.
- Under concurrent reviews or desk audits that occur within three business days of claim transmission and where no recoupment is demanded.

- When a pharmacy is located within a federally designated high-fraud area and has been part of a provider network for less than 12 months.

Prescription Drug Manufacturers

The bill requires prescription drug manufacturers to provide notice of upcoming product price increases as a condition of receiving a permit from DBPR. A manufacturer must to notify all health plans at least 60 days in advance of a drug price increase, along with the amount of the forthcoming price increase. The bill requires health plans to establish a single point-of-contact for use by drug manufacturers in compliance with this notification requirement. The OIR must, in turn, publish and maintain a list of the contact points established by health plans.

Not all price increases trigger the notice requirement – only those meeting certain thresholds. Specifically, drug manufacturers must submit notification to health plans on:

- A price increase of 15 percent or greater for a brand-name drug with an acquisition cost of $50 or more for a 30-day supply; or,
- A price increase of 25 percent or greater for a generic drug or biosimilar drug with an acquisition cost of $25 or more for a 30-day supply.

The bill also establishes a new annual reporting requirement for prescription drug manufacturers. Each drug manufacturer must submit a report to both DBPR and the OIR on each drug price increase made during the preceding calendar year that meets the thresholds for notification. This report must include a list of all the affected drug products and both the dollar amount and the percentage increase of each drug price increase. Manufacturers must also describe the factors contributing to each drug price increase.

Under current law, information provided to the OIR may be designated as trade secret to shield proprietary information from public records requests.[55] Drug manufacturers providing information to the OIR in compliance with the drug price increase notification requirement may utilize this designation as appropriate.

The responsibilities placed on drug manufacturers may increase transparency in the pricing of prescription drugs, which could assist health plans in assessing actuarial risk. Advance notification of price increases will also allow health plans to make appropriate coverage adjustments as necessary. At present, manufacturers are under no obligation to justify price increases or notify health plans of anticipated price changes.

Health Plans

The bill requires a health plan to provide at least 30 days' notice to affected patients of any formulary change that results from a drug price increase notification provided by a drug manufacturer. If a health plan chooses to discontinue coverage of a drug, or cover a drug on a less favorable formulary tier, a patient will incur additional costs to obtain the drug. Accordingly, a health plan taking such an action as a result of a drug price increase notification is required to provide notice to a patient currently using the drug.

The bill takes effect upon becoming law.

B. SECTION DIRECTORY:

Section 1: Amends s. 110.12315, F.S., relating to prescription drug program.
Section 2: Amends s. 499.012, F.S., relating to permit application requirements.

[55] S. 624.4213, F.S.

Section 3: Creates s. 499.026, F.S., relating to prescription drug price increases.
Section 4: Creates s. 624.491, F.S., relating to pharmacy audits.
Section 5: Creates s. 627.42394, F.S., relating to formulary changes resulting from drug price increases.
Section 6: Amends s. 627.64741, F.S., relating to pharmacy benefit manager contracts.
Section 7: Amends s. 627.6572, F.S., relating to pharmacy benefit manager contracts.
Section 8: Creates s. 641.3131, F.S., relating to formulary changes resulting from drug price increases.
Section 9: Amends s. 641.314, F.S., relating to pharmacy benefit manager contracts.
Section 10: Requires the AHCA to contract for an independent analysis of pharmacy benefit management practices under the Statewide Medicaid Managed Care program.
Section 11: Requires the AHCA to conduct an analysis of managed care pharmacy networks under the Statewide Medicaid Managed Care program.
Section 12: Provides that the bill takes effect upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DBPR and OIR will need to collect, report, and analyze data from PBMs. Any additional workload or information technology programming modifications necessary to implement the bill can be accomplished within existing resources. AHCA and DMS may incur some expenses in compliance with the required audits and analyses, but these can also be absorbed within existing resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill may have a negative fiscal impact on PBMs, pharmaceutical manufacturers, and health plans due to compliance with the bill's notification and reporting requirements.

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:

DBPR and the OIR have sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 18, 2020, the Health and Human Services Committee adopted a strike-all amendment to the bill and two amendments to the strike-all amendment. The amended strike-all amendment:

- Requires insurer reports of PBM data to OIR to include aggregate information by PBM.
- Requires a PBM to report annually on the type and amount of all other fees collected, in addition to the specific fees outlined in the bill.
- Requires PBMs to distinguish between 340b program pharmacies and non-340b pharmacies when they report fees paid by pharmacies.
- Limits drug manufacturer reporting to significant price increases and sets thresholds for brand drugs, generics, and biosimilars.
- Requires health plans to establish a single point-of-contact for manufacturers to use when reporting drug price increases; requires OIR to maintain and publish a contact list.
- Requires health plans to give a 30-day notice to affected patients when a drug price increase leads to a formulary change.
- Specifies that pharmacy audit protections do not apply in cases of suspected fraud.
- Requires DMS to contract for an annual audit of the pharmacy benefits vender for the SGI program.
- Requires AHCA to conduct two analyses of pharmacy benefits in the SMMC program.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health and Human Services Committee.