HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 7045 PCB HMR 20-02 Prescription Drug Price Transparency
SPONSOR(S): 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			

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.

The bill 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, and spread pricing revenues 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 would authorize OIR to enforce the pharmacy audit provisions.

Pharmaceutical manufacturers are regulated by a combination of 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.

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.

The bill provides an effective date of July 1, 2020.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

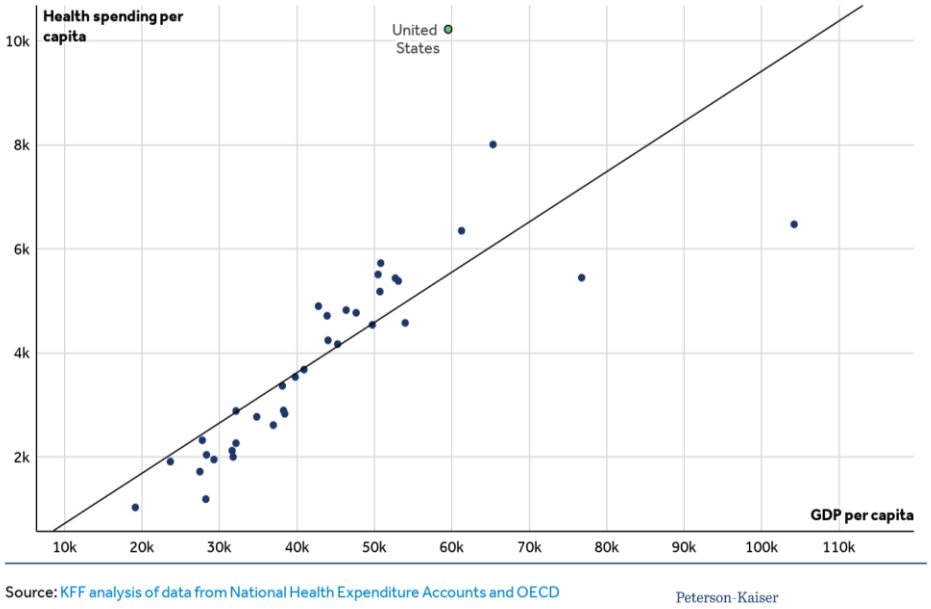
A. EFFECT OF PROPOSED CHANGES:

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] Relative to the size of its wealth, 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 and 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, and 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.

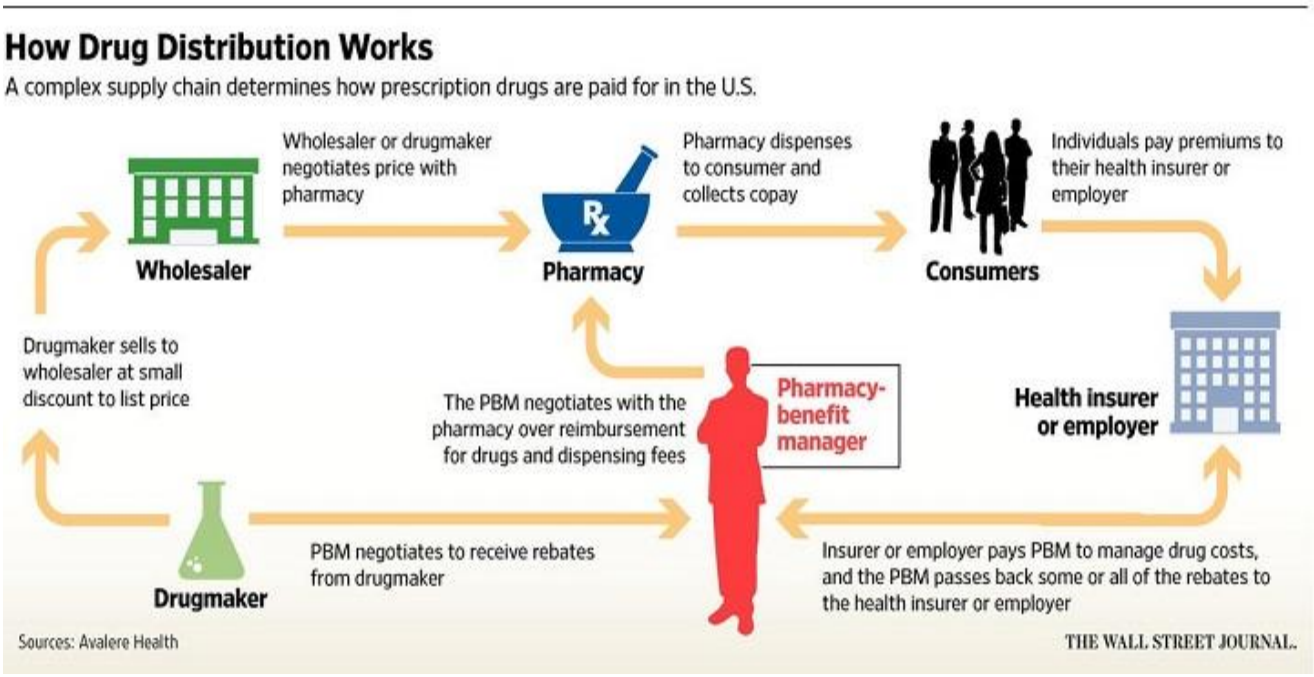
premiums, or coinsurance.[6] Insurers and other health plan sponsors increasingly rely on pharmacy benefit managers to restrain spending on prescription drugs.

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 negotiation process 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 very 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] At present,

[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).

PBMs 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

Broadly, PBMs generate revenue from the following sources:

- 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.

While the details of contractual agreements between PBMs and their clients are rarely made public, 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]

Health plan sponsors with sufficient resources can negotiate with PBMs to reach contract terms that may limit the PBMs ability to collect certain revenues. Florida's Division of State Group Insurance (DSGI)[19], which provides health benefits to state employees and their dependents, has negotiated contract language that prevents its chosen PBM – 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 DSGI.[20] Private health plan sponsors may also use these types of contract clauses to define which types of revenue may be earned by contracted PBMs.

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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] The state group insurance program is governed by Ss. 110.123 through 110.125, F.S.
[20] See *Pharmacy Benefit Management Services*, Contract between CaremarkPCS Health, L.L.C. and Florida Department of Management Services, available at

In a similar vein, the Florida Agency for Health Care Administration (AHCA) recently contracted with a consulting firm to undertake an analysis of PBM practices in the Florida Medicaid program.[21] Managed care plans providing coverage to Medicaid recipients have some flexibility to contract with PBMs, but it is unclear how PBMs may be generating revenues by virtue of serving the Medicaid population.

PBMs assert that their services result in significant savings for both insurers and patients.[22] 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.[23] 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 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".[24] In addition, PBM contracts with health plan sponsors have been criticized for being confidential and complex in nature.[25]

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 has passed laws to prohibit specific practices by PBMs.[26] Both the Legislature[27] and Congress[28] 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.[29] 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.[30] According to OIR, 42 PBMs were registered to operate in Florida during calendar year 2019.[31]

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 at the pharmacy. Each contract must specify that a patient's cost share shall equal the lower of the following prices:

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https://www.dms.myflorida.com/content/download/107930/607791/2015_PBM_Contract_REDACTED_FINAL.pdf (last accessed January 22, 2020).

[21] 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.

[22] 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).

[23] "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).

[24] 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).

[25] Supra note 18.

[26] 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).

[27] Ch. 2018-91, L.O.F. Ss. 627.64741, 627.6572, and 641.314, F.S.

[28] Public Law No.115-263.

[29] Ch. 2018-91, L.O.F.

[30] S. 624.490, F.S.

[31] E-mail correspondence from Grant Phillips, Florida Office of Insurance Regulation, September 9, 2019 (on file with staff of the Health Market Reform Subcommittee).

- The applicable cost sharing obligation under a patient's insurance; or,
- The retail (or "cash") price of the drug prescribed.[32]

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

Pharmacy Audits

The audit process is one means used by PBMs and health plan sponsors 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.
- Investigative audit – occurs where there is a suspicion of fraud or abuse.[33]

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[34] 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.

[32] Ss. 627.64741, 627.6572, and 641.314, F.S.
[33] 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).
[34] S. 465.1885, F.S.

- 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.[35]

Prescription Drug Manufacturers

Federal Regulation of Drug Manufacturers

The United States Food and Drug Administration (FDA) is the federal agency responsible for ensuring that foods, drugs, biological products, and medical devices are effective and safe for public consumption.[36] The FDA regulates these areas under the authority of the Federal Food, Drug, and Cosmetic Act (FDCA).[37] 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.

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 together 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, as applicable. 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.[38]

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.[39] 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.[40]

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.[41] 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.[42]

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[35] 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.
[36] U.S. Food & Drug Administration, *What We Do*, available at https://www.fda.gov/AboutFDA/WhatWeDo/default.htm (last accessed January 7, 2020).
[37] 21 U.S.C. § 355(a).
[38] Ss. 499.067 and 465.023, F.S.
[39] 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).
[40] S. 499.01, F.S.
[41] 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.
[42] Ss. 499.051, 499.062, 499.065. 499.066, 499.0661, and 499.067, F.S.

Prescription Drug Manufacturer Permit

Drug manufacturing includes the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug.[43] 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.[44] 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.[45] 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.[46]

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 and that engages in the distribution in this state of such prescription drugs.[47] 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.[48]

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. On an annual basis, a PBM will be required to 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 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.

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.

Pharmacy Audits

[43] S. 499.003(28), F.S.
[44] S. 499.01(2), F.S.
[45] S. 499.01(2), F.S.
[46] S. 499.003(16), F.S.
[47] S. 499.01(2), F.S.
[48] S. 499.01(2), F.S.

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.:

- Notify the pharmacy at least 7 calendar days before the initial onsite audit for each audit cycle.
- Occur after the first 3 calendar days of a month unless the pharmacist consents otherwise.
- Limit the audit period to 24 months after the submission or adjudication of a claim.
- Provide a preliminary audit report to the pharmacy within 120 days of the conclusion of the audit.
- Provide a final audit report to the pharmacy within 6 months of providing the preliminary report.

The OIR would have 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.

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 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.

The bill also establishes a new reporting requirement for prescription drug manufacturers. On an annual basis, each drug manufacturer must submit a report to both DBPR and the OIR on each drug price increase made during the preceding calendar year. 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.

The responsibilities placed on drug manufacturers may increase transparency in the pricing of prescription drugs, which could assist health plans in assessing actuarial risk. At present, manufacturers are under no obligation to justify price increases or notify health plans of anticipated price changes.

The bill provides an effective date of July 1, 2020.

B. SECTION DIRECTORY:

Section 1: Amends s. 499.012, F.S., relating to permit application requirements.
Section 2: Creates s. 499.026, F.S., relating to prescription drug price increases.
Section 3: Creates s. 624.491, F.S., relating to pharmacy audits.
Section 4: Amends s. 627.64741, F.S., relating to pharmacy benefit manager contracts.
Section 5: Amends s. 627.6572, F.S., relating to pharmacy benefit manager contracts.
Section 6: Amends s. 641.314, F.S., relating to pharmacy benefit manager contracts.
Section 7: Provides an effective date of July 1, 2020.

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.

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 and pharmaceutical manufacturers due to compliance with the bill's 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