HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 555 Pharmacy
SPONSOR(S): Health Innovation Subcommittee; Gaetz
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	10 Y, 2 N, As CS	Tuszynski	Poche
2) Insurance & Banking Subcommittee			
3) Appropriations Committee			
4) Health & Human Services Committee			

SUMMARY ANALYSIS

Pharmacy benefit managers (PBM) provide a variety of services, including developing and managing pharmacy networks, developing drug formularies, providing mail order and specialty pharmacy services, rebate negotiation, therapeutic substitution, disease management, utilization review, support services for physicians and beneficiaries, and processing and auditing claims. Health plan sponsors contract with PBMs to provide these services, and payment terms are established in the contract.

In recent years, federal and state litigants and various stakeholders in the prescription drug industry have alleged that PBMs sometimes engage in unfair business practices that have resulted in excessive profits at the expense of health plan members, sponsors, or pharmacies. In response, PBMs have begun to offer health plan sponsors contracts that provide more transparency than traditional contracts. These contracts give health plan sponsors access to information about contractual and financial arrangements with drug manufacturers and pharmacies.

HB 555 builds on this trend of transparency in contracts between PBMs, plan sponsors, including employers and insurers, and contracting pharmacies. The bill requires that such contracts include specific terms related to disclosure of information, timeframes for providing such information, and providing notice of changes to the plan sponsor or contracting pharmacy. The bill establishes criteria that must be met for a PBM to place a generic drug on the maximum allowable cost (MAC) list, requiring at least three nationally available equivalent multiple-source generic drugs that meet certain requirements.

The bill requires that a contract between a PBM and a plan sponsor disclose the methodology used to establish MAC pricing for generic drugs and brand name drugs with generic equivalents. A PBM is required to promptly provide the plan sponsor with an updated list when MAC pricing changes. The contract must disclose if the PBM uses a MAC pricing list for drugs dispensed at retail, but not for drugs dispensed by mail order. The contract must also disclose whether the PBM uses the same MAC pricing list to bill the plan sponsor as it uses to reimburse a contracted pharmacy. If a PBM does not use the same MAC list to bill a plan sponsor and reimburse a contracted pharmacy, the bill requires the contract to disclose the pricing differences.

The bill requires that contracts between a PBM and a pharmacy contain a process for an appeal, investigation, and resolution of disputes relating to MAC pricing. If an appeal is denied, the PBM must provide the reason for denial and identify an alternative drug that may be purchased at a price at or below the MAC. If an appeal is upheld, the PBM must make an adjustment retroactive to the date the claim was adjudicated for all similarly situated contracted pharmacies.

There is an anticipated significant negative fiscal impact on the state group health plan. See fiscal comments.

The bill provides an effective date of July 1, 2015.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Pharmacy Regulation

Pharmacies and pharmacists are regulated under the Florida Pharmacy Act (the Act) in Chapter 465, F.S. The Board of Pharmacy (the board) was created within the Department of Health (DOH) to adopt rules to implement provisions of the Act and take other actions as required in the Act.[1]

Several pharmacy types are specified in law and are required to be permitted or registered under the Act:

- Community pharmacy[2] – A location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.
- Institutional pharmacy[3] – A location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medical drugs are compounded, dispensed, stored, or sold. The Act further classifies institutional pharmacies according to the type of facility or activities within the facility.
- Nuclear pharmacy[4] – A location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The Act excludes hospitals or the nuclear medicine facilities of hospitals.
- Internet pharmacy[5] – A location, whether within or outside the state, which uses the internet to communicate with or obtain information from consumers in order to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in Florida.
- Non-resident pharmacy[6] – A location outside the state, which ships, mails, or delivers, in any manner, a dispensed drug into the state.
- Special pharmacy[7] – A location where medicinal drugs are compounded, dispensed, stored, or sold and which provides miscellaneous specialized pharmacy service functions.

Each pharmacy is subject to inspection[8] and discipline[9] by DOH for violations of applicable state or federal laws relating to a pharmacy. Any pharmacy located outside of this state which ships, mails, or delivers, in any manner, a dispensed drug into this state is considered a nonresident pharmacy, and must register with the board as a nonresident pharmacy.[10,11]

Pharmacy Benefit Managers and Pharmacies

Advances in pharmaceuticals have transformed health care over the last several decades. Many health care problems are prevented, cured, or managed effectively using prescription drugs. As a result, national expenditures for retail prescription drugs have grown from $120.9 billion in 2000 to $271.1

[1] S. 465.005, F.S.
[2] S. 465.003(11)(a)(1), F.S.
[3] S. 465.003(11)(a)(2), F.S.
[4] S. 465.003(11)(a)(3), F.S.
[5] S. 465.003(11)(a)(5), F.S.
[6] S. 465.0156(1), F.S.
[7] S. 465.003(11)(a)(4), F.S.
[8] S. 465.017, F.S.
[9] S. 465.016, F.S.
[10] S. 465.0156, F.S.
[11] However, the board may grant an exemption from the registration requirements to any nonresident pharmacy, which confines its dispensing activity to isolated transactions. *See* s. 465.0156(2), F.S.

billion in 2013.[12] Health plan sponsors, which include commercial insurers, private employers, and government plans, such as Medicaid and Medicare, spent $222.6 billion on prescription drugs in 2013 and consumers paid $45.9 billion out of pocket for prescription drugs that year.[13]

Health plan sponsors contract with pharmacy benefit managers (PBMs) to provide specified services, which may include developing and managing pharmacy networks, developing drug formularies, providing mail order and specialty pharmacy services, rebate negotiation, therapeutic substitution, disease management, utilization review, support services for physicians and beneficiaries, and processing claims.[14] Payments for the services are established in contracts between health plan sponsors and PBMs.[15] For example, contracts will specify how much health plan sponsors will pay PBMs for brand name and generic drugs. These prices are typically set as a discount off the average wholesale price[16] for brand-name drugs and maximum allowable cost price for generic drugs, plus a dispensing fee.[17]

The shift to generic drugs has saved consumers more than a $1 trillion over a decade[18], but it has adversely affected independent pharmacists according to recent news articles. In 2000, about 50 percent of U.S. prescription drugs were generic. Now, generics represent about 84 percent of the market, according to IMS Health Incorporated.[19] The increasing use of generics is pushing the dollar volume of prescription-drug sales down. In response, drugstores want lawmakers to require the PBMs to share pricing information that would help drugstores negotiate bigger reimbursements and avoid dispensing drugs that are money losers.[20] Contracts also generally include fees for processing claims submitted by pharmacies (usually based on a rate per claim) and fees for providing services such as disease management or utilization review.[21] In addition, contracts generally specify whether and how the PBM will pass manufacturer rebates on to the health plan sponsors.[22] The contracts can also include performance guarantees, such as claims processing accuracy or amount of rebates received.[23]

Maximum Allowable Cost

Maximum allowable cost (MAC) price lists set the upper limit amount that a plan will reimburse a contracted pharmacy for generic drugs and some brand-name drugs with generic versions, known as multi-source brands. State Medicaid programs have utilized MAC pricing as a cost-control tool. States with MAC programs typically publish lists of selected generic and multi-source brand drugs along with the maximum price at which Medicaid will reimburse for those drugs. In general, pharmacies will receive payment no higher than the MAC price when billing Medicaid for drugs on a state's MAC list.[24] PBMs also use MAC price lists as a cost-control tool. The methodology of how the MAC prices are set by a PBM is generally considered proprietary.

---

[12] Centers for Medicare and Medicaid Services, *National Health Expenditure Data, Historical, available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ (last visited March 8, 2015).
[13] Id.
[14] Program Policy Analysis & Government Accountability. (Office of Program Policy Analysis & Government Accountability, *Legislature Could Consider Options to Address Pharmacy Benefit Manager Business Practices*, Report No. 07-08 (Feb. 2007), *available at* http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/0708rpt.pdf (last visited March 7, 2015).
[15] Id.
[16] Average wholesale price is the retail list price (sticker price) or the average price that manufacturers recommend wholesalers sell to physicians, pharmacies and others, such as hospitals.
[17] Supra. at FN 14
[18] Timothy W. Martin, *Drugstores Press for Pricing Data,* Wall Street Journal, March 27, 2013. *available at* http://www.wsj.com/articles/SB10001424127887323466204578382990730159644 (last visited March 4, 2015)
[19] Id.
[20] Id.
[21] If the PBM owns the mail order or specialty pharmacy, claims processing fees may not be applied.
[22] Contracts may specify a fixed amount per prescription or a percentage of the total rebates received by a PBM.
[23] Supra. at FN 14.
[24] Richard G. Abramson, M.D. et al., *Generic Drug Cost Containment in Medicaid: Lessons from Five State MAC Programs*, Health Care Financing Review, Spring 2004 Vol. 25 No. 3 available at https://www.cms.gov/FResearch-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/downloads/04springpg25.pdf (last visited March 10, 2015)

Federal Pharmacy Benefits Managers Transparency Requirements

On March 23, 2010, President Obama signed into law Public Law No. 111-148, the Patient Protection and Affordable Care Act (PPACA), and on March 30, 2010, President Obama signed into law Public Law No. 111-152, the Health Care and Education Affordability Reconciliation Act of 2010, amending PPACA. The law requires Medicare Part D plans and qualified health plan issuers who have their own PBM or contract with a PBM to report to the federal Department of Health and Human Services (HHS) aggregate information about rebates, discounts, or price concessions that are passed through to the plan sponsor or retained by the PBM. [25] In addition, the plans must report the difference between the amount the plan pays the PBM and the amount that the PBM pays its suppliers.[26] The reported information is confidential, subject to certain limited exceptions.[27]

Federal Study on Pharmacy Benefit Managers

Concerns have been raised that a PBM that owns a pharmacy (whether retail or mail) may have a greater ability to influence which drugs are dispensed under the plans it administers than a PBM that does not own a pharmacy. If plan sponsor contracts with PBMs do not properly align the incentives of PBMs with those of the plans, this lack of alignment could create a conflict of interest. Potential conflicts of interest should be rare, however, if competition among PBMs provides plan sponsors with alternatives. At the request of Congress, the Federal Trade Commission (FTC) collected aggregate data on prices, generic substitution and dispensing rates, savings due to therapeutic drug switches, and repackaging practices. The study examined whether PBM ownership of mail-order pharmacies served to maximize competition and lower prescription drug prices for plan sponsors. In its 2005 report based on the study, the FTC found, among other things, that the prices for a common basket of prescription drugs dispensed by PBM-owned mail order pharmacies were typically lower than the prices charged by retail pharmacies. The study also found competition affords health plans substantial tools with which to safeguard their interests.[28]

The 2005 study continued the FTC's ongoing review of PBMs. The PBM practices were a particular focus of hearings on health care markets jointly conducted by the FTC and the Department of Justice Antitrust Division in 2003.[29] In 2004, the FTC and DOJ issued a report based on the hearings, a Commission-sponsored workshop, and independent research.[30]

OPPAGA Study on Pharmacy Benefit Managers

Pursuant to a legislative request, the Office of Program Policy Analysis & Government Accountability (OPPAGA) reviewed pharmacy benefit managers in a report released in 2007.[31] The report addressed concerns relating to PBM business practices, actions by states, PBMs, and plan sponsors, and gave possible legislative options. Relevant portions of the report are summarized below.[32]

Concern with PBM Business Practices

In recent years, federal and state litigants and various stakeholders in the prescription drug industry have alleged that PBMs sometimes engage in unfair business practices that have resulted in excessive profits at the expense of health plan members, sponsors, or pharmacies. These include allegations that PBMs:

[25] 42 U.S.C. s. 1320b-23.
[26] Id.
[27] Id.
[28] Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* (August 2005). Available at: https://www.ftc.gov/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report (last visited March 3, 2015).
[29] *See* Hearings on Health Care and Competition Law and Policy, June 26, 2003, *available at* http://www.justice.gov/atr/public/health_care/204694.pdf (last visited March 4, 2015).
[30] *See* Federal Trade Commission, and Department of Justice, *Improving Health Care: A Dose of Competition* (2004), available at http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf (last visited March 4, 2015).
[31] Supra. at FN 14.
[32] Supra. at FN 14.

- Have excessively profited by accepting secret monetary incentives from drug manufacturers, such as incentives for increasing a manufacturer's drug sales that are not shared with health plan sponsors.
- Have increased rebates by changing patient prescriptions to drugs that receive higher rebates.
- Have excessively profited from the price spread created by the difference between pharmacy reimbursements and plan sponsor drug prices.
- Have realized high profits by charging health plan sponsors significantly higher drug prices than prices at which they reimburse pharmacies.
- Have not provided sponsors access to information on PBM transactions or negotiations with manufacturers and pharmacies.
- Prevented health plan sponsors and pharmacies from receiving a fair share of the profits realized by PBMs in their negotiations with drug manufacturers.

Response to Concerns with PBM Business Practices

As of December 2006, three states and the District of Columbia had passed legislation that addresses certain contractual issues.[33] In addition, two states had passed legislation to regulate PBMs by requiring licensure or oversight by state insurance departments or pharmacy boards. The PBMs, health plans sponsors, and other stakeholders have taken steps to change business practices and increase transparency.

To create more transparency in their business practices, PBMs have begun to offer health plan sponsors contracts that provide more transparency than traditional contracts. These contracts give health plan sponsors access to information about contractual and financial arrangements with drug manufacturers and pharmacies. Some PBMs negotiate contracts that establish drug prices for health plan sponsors equal to the price at which PBMs reimburse pharmacies. In addition to these voluntary steps, the provisions of settled lawsuits require defendant PBMs to adhere to specific transparency practices.[34]

Legislative Options for Concerns with PBM Business Practices

In 2007, OPPAGA suggested that prior to considering statutory actions, the Legislature may wish to give market forces time to further influence efforts by PBMs, health plan sponsors, and other stakeholders to change PBM business practices and establish contracts that are more transparent. If the Legislature wishes to enact statutory provisions to regulate PBMs, the OPPAGA suggested it could consider options adopted in other states such as establishing transparency guidelines or licensing or certifying PBMs.

Effect of Proposed Changes

HB 555 establishes contractual requirements between a PBM and a contracted pharmacy and between a PBM and a plan sponsor. The requirements include updating the MAC pricing information every seven calendar days and establishing a reasonable process for prompt notice of MAC pricing updates to the contracted pharmacy.

To place a prescription drug on a MAC pricing list, the bill requires a PBM to ensure that the drug has at least two or more nationally available, therapeutically equivalent, multiple-source generic drugs that:

- Have a significant cost difference;

[33] At least 21 states and the District of Columbia have now enacted laws imposing some form of regulation on pharmacy benefit managers, including Arkansas, Connecticut, Florida (Medicaid audits), Georgia, Indiana, Iowa, Kansas, Kentucky, Maryland, Mississippi, Missouri, New Mexico, North Carolina, North Dakota, Oklahoma, Rhode Island, South Dakota, Tennessee, Texas, Utah, Vermont, and the District of Columbia. (National Community Pharmacy Association, *Laws that Provide Regulation of the Business Practices of Pharmacy Benefit Managers*, available at http://www.ncpanet.org/pdf/leg/leg_pbm_business_practice_regulation.pdf (last visited March 5, 2015).

[34] For example, the settlement agreement between 20 state attorneys general against Medco arising from litigation in 2003 prohibits Medco from soliciting drug switches when the net drug cost of the proposed drug exceeds the cost of the prescribed drug. It also requires Medco to disclose financial incentives for switching drugs.

- Are listed as therapeutically and pharmaceutically equivalent or “A” or “AB” rated in the most recent version of Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations published by the United States Food and Drug Administration;
- Are available for purchase without limitations from national or regional wholesalers without limitation by all pharmacies in the state; and
- Are not obsolete or temporarily unavailable.

A contract between a plan sponsor and a PBM must disclose whether the PBM uses a MAC pricing list for drugs dispensed at retail, but not for drugs dispensed by mail order. Also, the contract must disclose whether the PBM uses the same MAC pricing list to bill the plan sponsor as it uses to reimburse a contracted pharmacy. If a PBM does not use the same MAC list to bill a plan sponsor and reimburse a contracted pharmacy, the bill requires the contract to disclose the pricing differences.

The bill requires that a contract between a PBM and pharmacy contain a process for the appeal, investigation, and resolution of disputes regarding MAC pricing. The right to appeal is limited to 30 days after an initial claim is filed by a contracted pharmacy. The PBM is then required to investigate and resolve the dispute within 14 days of receiving the appeal from the pharmacy. If an appeal is denied, the contract must require a PBM to provide the reason for denial and identify an alternative drug that may be purchased at a price at or below the MAC. If an appeal is upheld, the PBM must make an adjustment retroactive to the date the claim was adjudicated for all similarly situated contracted pharmacies.

The bill defines contracted pharmacy, MAC, pharmacy benefit manager, and plan sponsor.

The bill provides an effective date of July 1, 2015.

B. SECTION DIRECTORY:

Section 1: Creates s. 465.1862, F.S., relating to pharmacy benefit managers
Section 2: Provides an effective date of July 1, 2015.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The Division of State Group Insurance anticipates a negative fiscal impact of $3,000,000 to the state group health plan as a result of increased administrative costs and changes to MAC pricing required by the bill.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The changes to MAC pricing may impact the operations of PBMs and the terms of contracts with plan sponsors and contracted pharmacies.

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:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 10, 2015, the Health Innovation Subcommittee adopted a strike-all amendment and reported the bill favorable as a committee substitute. The amendment made the following changes:

- Deleted the requirement that a PBM promptly change the MAC pricing list to reflect any change in the marketplace that impacts the cost of a drug.
- Deleted the requirement that a PBM remove a drug from the MAC pricing list within 3 days of a change if the drug does not meet the requirements outlined in the bill.
- Required a drug have at least two, instead of three, nationally available equivalent multiple-source generic drugs that meet the criteria in the bill before it can be placed on a MAC pricing list.
- Clarified a reference to the rating of a drug in the Orange Book to satisfy the criteria for inclusion on a MAC pricing list.
- Deleted the requirement that a PBM disclose to a plan sponsor the methodology and sources used to create its MAC pricing list.
- Eliminated the duty of the PBM to provide an updated MAC pricing list any time a change is made to the list.
- Required that a contract between a PBM and pharmacy contain a process for the appeal, investigation, and resolution of disputes regarding MAC pricing.
- Reduced the appeal deadline from 90 calendar days to 30 calendar days after an initial claim is made by the contracted pharmacy, and increased the timeframe within which an investigation and resolution of an appeal must occur, from 7 days to 14 days.

The analysis is drafted to the committee substitute as passed by the Health Innovation Subcommittee.