HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 617 Insurance Administrators
SPONSOR(S): Insurance & Banking Subcommittee; Beshears and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 580

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Insurance & Banking Subcommittee	12 Y, 0 N, As CS	Lloyd	Luczynski
2) Government Operations & Technology Appropriations Subcommittee			
3) Commerce Committee			

SUMMARY ANALYSIS

Third party administrators in life and health insurance are regulated by the Office of Insurance Regulation (OIR) as insurance administrators. They must obtain a certificate of authority from OIR to participate in the administration of life and health insurance benefits and are subject to auditing requirements and penalties for violations. Florida has enacted regulation of third party administrators consistent with guidelines adopted by the National Association of Insurance Commissioners (NAIC). Requirements of insurance administrators include: keeping records available for examination for five years, annual filing of financial statement, maintaining written agreements with insurers containing specified provisions, and deferring benefit determinations and claims payment procedures to the insurer. Pharmacy benefit managers (PBMs) are not included in the regulation of insurance administrators under Florida law or NAIC guidelines.

PBMs are entities that contract to administer or manage prescription drug benefits on behalf of a health insurer. The Florida Pharmacy Act requires PBM contracts with pharmacies to provide for updating of maximum allowable cost (MAC) pricing lists at least every seven days and the maintenance of a process that will, in a timely manner, eliminate drugs from MAC lists or modify drug prices to remain consistent with changes in pricing data used in formulating MAC prices and product availability. There is no provision of law that expressly provides for enforcement of compliance with the required contractual terms.

The bill regulates PBMs under s. 465.1862, F.S., as an insurance administrator under part VII of ch. 626, F.S. It requires them to:

- Comply with licensing requirements for the first time,
- Obtain a certificate of authority from the OIR, upon application and payment of a $100 fee, in order to operate as a PBM, and
- Submit to quarterly auditing for violations of s. 465.1862, F.S., which requires certain contract provisions in agreements with pharmacies, and performance in updating MAC lists and prices in compliance with those contract provisions (this auditing is at a higher frequency than for other insurance administrators).

The bill limits OIR's authority to discipline a PBM during the first 180 days after the bill becomes law.

The bill has a minimal positive impact on state government revenues and a negative impact on state expenditures. It has no expected impact on local government revenues and expenditures. It has positive and negative impacts on the private sector.

The bill is effective upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Insurance Administrators

An "administrator,"[1] more commonly referred to as a third party administrator or TPA, must be licensed by the Office of Insurance Regulation (OIR). Third party administrators provide various administrative services for life and health insurers, health maintenance organizations (HMOs), self-insurance programs, and other types of insurers. Some of the services provided by TPAs include soliciting and making effective insurance coverage, collecting premiums, and adjusting and settling claims.

Administrators are placed under various regulatory requirements pursuant to part VII of ch. 626, F.S. For example, an administrator must make its books and records available to the OIR for examination, audit, and inspection and must maintain its business records for five years.[2] Administrators are also required to file annual financial statements with OIR.[3] Administrators must have a written agreement with an insurer containing specified provisions. The insurance company, and not the administrator, must be responsible for determining the benefits, rates underwriting criteria, and claims payment procedures.[4] A payment to the administrator of any premiums on behalf of the insured are deemed to have been received by the insurer and all premiums collected by an administrator on behalf of an insurer must be held by the administrator in a fiduciary capacity. If an administrator is collecting premiums for more than one insurer, the administrator must keep records clearly recording each insurer's accounts.

The National Association of Insurance Commissioners (NAIC) is a voluntary association of insurance regulators from all fifty states.[5] They were created to coordinate regulation of multi-state insurers, provide a forum for addressing major insurance issues, and promote consistent laws among the states.

NAIC also has a national accreditation program of reviewing state insurance departments,[6] serves as a national insurer information clearinghouse, provides a structure for interstate cooperation in examining multi-state insurers, and develops model laws and guidelines. Many of the NAIC model laws have been adopted in whole or in part by Florida, including parts of NAIC Guideline GDL-1090,[7] Registration and Regulation of Third Party Administrators. Pharmacy Benefit Managers are not included in NAIC Guideline GDL-1090 or part VII of ch. 626, F.S.

Pharmacy Benefits Managers

Health plans contract with pharmacy benefits 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

[1] "…[A]n "administrator" is any person who directly or indirectly solicits or effects coverage of, collects charges or premiums from, or adjusts or settles claims on residents of this state in connection with authorized commercial self-insurance funds or with insured or self-insured programs which provide life or health insurance coverage . . . or any person who, through a health care risk contract as defined in s. 641.234 with an insurer or health maintenance organization, provides billing and collection services to health insurers and health maintenance organizations on behalf of health care providers . . . ." s. 626.88(1), F.S.
[2] s. 626.884, F.S.
[3] s. 626.89, F.S.
[4] ss. 626.8817 and 626.882, F.S.
[5] NAIC members also include the District of Columbia and four U.S. territories.
[6] Florida was the first state to be accredited by the NAIC.
[7] NATIONAL ASSOCIATION OF INSURANCE COMMISSIONERS, PRODUCTS AVS, DATA & PUBLICATIONS, http://www.naic.org/store/free/GDL-1090.pdf (last visited Mar. 24, 2017).

claims.[8] Payments for the services are established in contracts between health plans and PBMs.[9] For example, contracts will specify how much health plans will pay PBMs for brand name and generic drugs. These prices are typically set as a discount off the average wholesale price[10] for brand-name drugs and maximum allowable cost price for generic drugs, plus a dispensing fee.[11]

The shift to generic drugs has saved consumers more than $1 trillion over a decade.[12] In 2000, about 50 percent of U.S. prescription drugs were generic. Now, generics represent about 84 percent of the market.[13] The increasing use of generics is pushing the dollar volume of prescription-drug sales down. In response, drugstores have requested that PBMs be required to share pricing information that would help drugstores negotiate bigger reimbursements and avoid dispensing drugs that are money losers.[14]

Maximum Allowable Cost

Maximum allowable cost (MAC) price lists set the upper limit amount that a PBM 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.[15] PBMs also use MAC price lists as a cost-control tool.

PBM MAC Law

In 2015, the Legislature created s. 465.1862, F.S.[16] It defines the terms "pharmacy benefit manager" and "maximum allowable cost."[17] Contracts between PBMs and pharmacies must include requirements that the PBM update MAC pricing at least every seven days and maintain a process that will, in a timely manner, eliminate drugs from MAC lists or modify drug prices to remain consistent with changes in pricing data used in formulating MAC prices and product availability. While the Department of Health, in conjunction with the Board of Pharmacy, is responsible for administration and implementation of ch. 465, F.S., there is no enforcement authority applicable to PBMs and MAC pricing lists. This is because the law requires the existence of contract provisions, not adherence to them. The enforcement authority resides with the parties to the contract holding each other accountable for violations and applying the terms of the contract to actual performance.

Effect of the Bill

The bill regulates PBMs under s. 465.1862, F.S., as an insurance administrator under part VII of ch. 626, F.S. It requires them to:

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[8] OFFICE OF PROGRAM POLICY ANALYSIS & GOVERNMENT ACCOUNTABILITY, *Legislature Could Consider Options to Address Pharmacy Benefit Manager Business Practices*, Report No. 07-08 (Feb. 2007), http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/0708rpt.pdf (last visited Mar. 24, 2017).
[9] *Id*.
[10] 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.
[11] *Supra*, note 8
[12] Timothy W. Martin, *Drugstores Press for Pricing Data,* WALL STREET JOURNAL (Mar. 27, 2013), http://www.wsj.com/articles/SB10001424127887323466204578382990730159644.
[13] *Id*.
[14] *Id*.
[15] 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, https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/downloads/04springpg25.pdf (last visited Mar. 24, 2017).
[16] ch. 2015-127, Laws of Fla.
[17] "Pharmacy benefits manager" means a person or entity doing business in this state which contracts to administer or manage prescription drug benefits on behalf of a health insurance plan, as defined in former s. 627.6482, to residents of this state. "Maximum allowable cost" means the per-unit amount that a pharmacy benefits manager reimburses a pharmacist for a prescription drug, excluding dispensing fees, prior to the application of copayments, coinsurance, and other cost-sharing charges, if any. s. 465.1862(1), F.S.

- Comply with licensing requirements for the first time,
- Obtain a certificate of authority from the OIR in order to operate as a PBM subject to a $100 application fee, and
- Subjects them to the requirements for insurance administrators under part VII of ch. 626, F.S.,[18] which includes:
  - Quarterly auditing by OIR for violations of s. 465.1862, F.S.,[19] which is a higher frequency than for other insurance administrators, and performance in updating MAC lists and prices in compliance with those contract provisions.
  - Keeping their books and records available for OIR examination for five years.
  - Making annual financial statement filings with OIR, subject to a $250 fee per filing.
  - Having written agreements with insurers containing specified provisions.
  - Yielding benefit determinations and claims payment procedures to the insurer.

The bill limits OIR's authority to discipline a PBM during the first 180 days after the bill becomes law, if the PBM has applied for a certificate of authority in the first 90 days after the bill becomes law and the certificate is received within those first 180 days.

B. SECTION DIRECTORY:

Section 1. Amends s. 626.88, F.S., relating to definitions.

Section 2. Amends s. 626.8805, F.S., relating to certificate of authority to act as administrator.

Section 3. Amends s. 626.891, F.S., relating to grounds for suspension or revocation of certificate of authority.

Section 4. Amends s. 626.894, F.S., relating to administrative fine in lieu of suspension or revocation.

Section 5. Provides for the limited application of the bill during the first 180 days of its effectiveness, in certain circumstances.

Section 6. Directs the Division of Law Revision to insert the effective date, where referenced.

Section 7. Provides an effective date of upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Minimal. OIR will receive licensing and filing fees and may collect fines as audits reveal or PBMs self-report violations.

2. Expenditures:

   OIR estimates that implementing the regulation of PBMs will require expenditures of $550,000.[20]

[18] Violations are subject to fines from $5,000 to $10,000 per violation for operating without the certificate. s. 626.894, F.S.
[19] Violations of s. 465.1862, F.S., can lead to suspension or revocation of the certificate or an administrative fine not to exceed $1,000 per nonwillful violation (maximum $5,000 for all nonwillful violations) or $5,000 per willful violation (maximum $25,000 for all willful violations). If restitution is due to an affected person, it must be paid with interest at 12 percent per year. Failure to make restitution is a willful violation. *Id.*
[20] Email from Caitlin Murray, Legislative Affairs Director, Office of Insurance Regulation, RE: bill analysis - HB 617, Insurance Administrators, by Representative Beshears (Mar. 13, 2017).

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Indeterminate. Pharmacies may experience more accurate billing and reimbursement due to increased timely updating and maintenance of MAC pricing lists by PBMs. PBMs will incur costs associated with regulatory compliance, including quarterly auditing, and possible administrative penalties for willful and nonwillful violations of law. Drug purchasers such as group health insurers may see prices or contract costs affected as pharmacies and PBMs experience and pass along changes in costs to their customers.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill neither authorizes nor requires administrative rulemaking.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill will result in two agencies, the Department of Health and OIR, regulating portions of ch. 465, F.S.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 27, 2017, the Insurance & Banking Subcommittee adopted one amendment and reported the bill favorably as a committee substitute. The amendment requires the Office of Insurance Regulation to audit pharmacy benefit managers for their performance under contract provisions required under s. 465.1862, F.S. (i.e., timely updating and maintenance of maximum allowable cost lists), rather than just for the existence of the required contract provisions in their agreements with pharmacies.

The staff analysis has been updated to reflect the committee substitute.