

Date of Hearing: April 18, 2017

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS

Rudy Salas, Chair

AB 315 (Wood) – As Amended April 5, 2017

**SUBJECT:** Pharmacy benefits management.

**SUMMARY:** Requires pharmacy benefit managers (PBMs) to be licensed by the state Board of Pharmacy (Board); require a PBM to periodically disclose to a purchaser certain information such as drug acquisition cost, rebates received from pharmaceutical manufacturers, and rates negotiated with pharmacies; and applies these provisions to a contract or contractual relationship between a PBM and a purchaser that is entered into, issued, amended, renewed, or delivered on or after January 1, 2018.

**EXISTING LAW:**

- 1) Provides for the licensure and regulation of pharmacists and pharmacies by the Board. (Business and Professions Code (BPC) § 4000 et seq.)
- 2) Imposes requirements on audits of pharmacy services provided to beneficiaries of a health benefit plan. (BPC § 4430)

**THIS BILL:**

- 1) Defines “pharmacy benefit manager” (PBM) as a person, business, or other entity that, pursuant to a contract or under an employment relationship with a carrier, health benefit plan sponsor, or other third-party payer, either directly or through an intermediary, manages the prescription drug coverage provided by the carrier, plan sponsor, or other third-party payer, including, but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to prescription drug coverage, contracting with network pharmacies, and controlling the cost of covered prescription drugs.
- 2) Requires that within 30 days after a change of address of record with the board or a change of name according to law, a pharmacist, intern pharmacist, technician, designated representative, or pharmacy benefit manager shall notify the executive officer of the board of the change of address or change of name.
- 3) Specifies that a person or entity shall not act as PBM for any dangerous drug or dangerous device unless he, she, or it has obtained a license from the board.
- 4) Requires a PBM to disclose to the Board the location, names, and titles of all of the following:
  - a) Its agent for service of process in this state.
  - b) All pharmacists of the PBM who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state.

- 5) This information shall be made disclosed on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.
- 6) Requires the Board, upon approval by the board and the payment of the required fee, to issue a license to the applicant.
- 7) Defines “labeler” as a person or entity that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and who has a labeler code from the federal Food and Drug Administration.
- 8) Defines “pharmacy benefit manager” as a person, business, or entity described in Section 4037.5.
- 9) Defines “proprietary information” as trade secrets and information on pricing, costs, revenue, taxes, market share, negotiating strategies, customers, and personnel that is held by a private entity and used for that entity’s business purposes.
- 10) Defines “purchaser” as health benefit plan sponsor or other third-party payer with whom a PBM contracts to provide the administration and management of prescription drug benefits.
- 11) States that a PBM has a fiduciary duty to a purchaser and shall discharge that duty in accordance with all applicable laws.
- 12) Requires that a PBM notifies a purchaser in writing of any activity, policy, or practice of the pharmacy benefit manager that directly or indirectly presents a conflict of interest that interferes with the discharge of the pharmacy benefit manager’s fiduciary duty to the purchaser.
- 13) Requires, beginning in the second fiscal quarter after the effective date of a contract between a pharmacy benefit manager and a purchaser, the PBM to, on a monthly basis, disclose the following information to the purchaser with respect to prescription product benefits specific to the purchaser:
  - a) The aggregate acquisition cost from a pharmaceutical manufacturer or labeler for each therapeutic class of drugs.
  - b) The aggregate amount of rebates received by the pharmacy benefit manager for each therapeutic class of drugs. The aggregate amount of rebates shall include any utilization discounts the pharmacy benefit manager receives from a pharmaceutical manufacturer or labeler.
  - c) Any administrative fees received from a pharmaceutical manufacturer or labeler.
  - d) The aggregate of rates negotiated by the PBM with pharmacies with respect to each therapeutic class of drug.
  - e) Prescription drug utilization information for the purchaser’s enrollees or insureds that is not specific to any individual enrollee or insured.
- 14) Specifies that the information disclosed shall include all retail, mail order, specialty, and compounded prescription products.

- 15) Specifies that a therapeutic class shall include at least two drugs. If there are fewer than two drugs in a therapeutic class, the required information shall be reported by therapeutic category.
- 16) States that except for utilization information, a pharmacy benefit manager need not make the required disclosures unless and until the purchaser agrees, in writing, to maintain as confidential any proprietary information.
- 17) Requires the bill to apply to a contract or a contractual relationship between a PBM and a purchaser that is entered into, issued, amended, renewed, or delivered on or after January 1, 2018.
- 18) Declares that these provisions do not apply to:
  - a) A health care service plan or health insurer, if the health care service plan or health insurer offers or provides PBM services and if those services are offered or provided only to enrollees, subscribers, policyholders, or insureds who are also covered by health benefits offered or provided by that health care service plan or health insurer.
  - b) An affiliate, subsidiary, related entity, or contracted medical groups of a health care service plan or health insurer that would otherwise qualify as a pharmacy benefit manager but offers or provides services only to enrollees, subscribers, policyholders, or insureds who are also covered by health benefits offered or provided by the health care service plan or health insurer.

**FISCAL EFFECT:** Unknown. This bill is keyed fiscal by the Legislative Counsel.

**COMMENTS:**

**Purpose.** This bill is sponsored by the author. According to the author, “After a series of informational hearings on drug pricing, the author believes that the only way to fully understand and attempt to address the issue of escalating drug prices is to increase information available from the variety of players in the supply chain. There is existing discussion and legislation calling for greater transparency and disclosure from drug companies. While this information is critical without similar disclosure on the part of pharmaceutical benefit managers, purchasers and policymakers will not have a complete picture.”

**Background.** *PBMs.* In the 1960’s PBMs were utilized to assist insurance companies who were overwhelmed with processing claims. However, PBMs have evolved from basic claims administrators to more complex organizations offering a wide range of prescription drug managed tools, like drug utilization review, disease management, and consultative services. PBMs can also assist clients with establishing their benefit structure, including developing and maintaining a prescription drug formulary; developing a network of pharmacy providers; and, providing mail order fulfillment services.

According to the Pharmaceutical Care Management Association, PBMs administer prescription drug plans for more than 266 million Americans. PBMs may achieve savings for their customers by negotiating discounts and through cost containment programs, including use of formularies and cost sharing. In 2015, the three largest public PBMs were Express Scripts, CVS Health (formerly CVS Caremark), and United Health/OptumRx/Catamaran.

*The Department of Managed Health Care (DMHC) and the Department of Insurance (DOI) Regulatory Jurisdiction.* In California, the health plans, which PBMs contract with, are regulated by the Department of Insurance and the Department of Managed Health Care. Though originally the DOI regulated PPOs and the DMHC regulated Knox Keene health plans, the distinction has faded as a result of the standardized benefits provisions of the Affordable Care Act. Currently, the DMHC regulates the majority of the insurance market.

Health plans regulated by the DOI and the DMHC have mechanisms by which patients can contact the health plan if the patient has a problem with the PBM. The DMHC also has a “help line” that patients can utilize to report complaints, and there is a process in place for DMHC to review patient appeals to the Independent Medical Review panel if, for example, coverage is denied for specific drugs.

The DMHC receives some indirect information about PBMs. For example, whenever a health plan contracts with a PBM, the DMHC reviews the contract to ensure there is compliance with the Knox Keene Act. The DMHC also examines how health plans delegate functions to PBMs.

*Board of Pharmacy Regulatory Jurisdiction.* In California, pharmacists and pharmacies are regulated by the State Board of Pharmacy. There are 42,691 pharmacists and 70,624 pharmacy technicians with active licenses in the state. There are 7081 pharmacies regulated by the Board. Of these, 513 are hospital pharmacies. The Board reported it also regulates 506 non-resident pharmacies which generally include mail order pharmacies. The board has additional licenses for those pharmacies that perform sterile compounding and are located in California (890) and ship into CA from another state (91).

*Other States.* Eighteen states have specific statutes or regulations requiring certain disclosures from PBMs. Twelve states have requirements for audits and disclosures between pharmacies and PBMs. Oversight in other states is typically handled by the insurance commissioner. According to information from the Federal Trade Commission, Mississippi is the only state to have their board of pharmacy regulate PBMs.

*Scrutiny of PBMs.* In recent years, there has been much attention focused on the role that PBMs play. Many have criticized PBMs accusing them of being middlemen that make profits as they deal with pharmacies, insurers and drug manufacturers.

In December of 2016, the United States Senate Special Committee on Aging held a hearing entitled: *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System.* In the Committee report they state “PBMs, for example are tasked with negotiating back and forth between hospitals, employers, and pharmaceutical companies, to reportedly get the best deal. But it is unclear who the parties are that are getting the best deal as well as how much PBMs charge for these negotiations. There is good reason to suspect that the patient may not be getting the best deal.” Subsequently, multiple lawsuits in Missouri and New York were filed against Express Scripts, CVS Health Corporation, Optum Rx, Inc., and Prime Therapeutics, LLC.

In January of 2017, the Centers for Medicare & Medicaid Services reported that rebates that drug companies and pharmacies pay are growing, but PBMs are benefiting as the rebates are not lowering costs for patients or government health care programs. In March of 2017, Anthem announced that it was suing Express Scripts Holding Company for \$15 billion dollars in

damages, alleging that the PBM violated their contract through excessive charges and failures in its operations.

*CalPERS and PBM Disclosure Requirements.* According to information obtained from the CalPERS, for more than eight decades, CalPERS has built retirement and health security for state, school, and public agency members. The pension fund serves more than 1.8 million members in the CalPERS retirement system and administers benefits for more than 1.4 million members and their families in the health program, making CalPERS the largest defined-benefit public pension in the United States.

In March of 2016, CalPERS selected a new PBM- OptumRx. Contract terms require that the PBM provide drugs of the highest quality and value, based on sound clinical evidence. It also requires transparency and full disclosure of the financial relationships between the PBM and drug manufacturers. The Chair of the CalPERS Pension and Health Benefits Committee stated,

*We placed a lot of emphasis in this solicitation on the company's ability to deal with the increasingly high cost of prescription drugs, and OptumRx presented a very strong proposal. In addition to being concerned about the health and safety of our members, we wanted to ensure the company we selected would be as committed as we are to continually develop strategies to mitigate the impact of those rapidly rising costs on our members.*

*Federal Trade Commission (FTC) Comments.* According to a 2011 letter from the FTC to Mississippi Representative Mark Formby, Mississippi is the only state to have their Board of Pharmacy regulate PBMs. Further, this oversight was deemed problematic by the FTC. In the letter the FTC staff writes:

*Although we offer no specific recommendations on the ideal structure for regulation of PBMs, ...because pharmacists and PBMs have a competitive, and at times, adversarial relationship, we are concerned that giving the pharmacy board regulator power over PBMs may create tensions and conflicts of interest for the pharmacy board. Indeed, the antitrust laws recognize that there is a real danger that regulatory boards composed of market participants may pursue their own interest rather than those of the state. We urge the Mississippi legislature to consider this concern.*

In August of 2014, the FTC staff wrote a letter to Larry Good, the Executive Secretary of the Employee Retirement and Income Security Act (ERISA) Advisory Council. In the letter the FTC staff writes:

*The Council asked whether the FTC has conducted further study of the PBM industry since 2005. FTC staff has analyzed a number of state legislative proposals involving mandatory transparency requirements and their likely effect on competition. These FTC staff comments have highlighted two particular types of concerns:*

- 1) *Mandatory disclosure requirements may hinder the ability of plans to negotiate an efficient level of disclosure with PBMs; and*
- 2) *If such disclosures publicly reveal previously proprietary and private information about discounts negotiated with PBMs, disclosure may result in less aggressive pricing by, or even collusion among, pharmaceutical manufacturers.*

*We encourage the ERISA Advisory Council to consider whether harm may result if plan sponsors are denied the ability to choose the level of transparency that best suits them within the context of their overall plan design...we encourage the council to consider whether and how mandatory disclosure requirements might be tailored narrowly to present useful and meaningful information.*

**Current Related Legislation.** AB 29 (Nazarian) of the current Legislative Session requires, except as provided, a pharmacy benefit manager to disclose certain information to a purchaser or prospective purchaser, including, among other things, the aggregate amount of rebates, retrospective utilization discounts, and other income that the pharmacy benefit manager would receive from a pharmaceutical manufacturer or labeler in connection with drug benefits related to the purchaser or prospective purchaser. The bill would excuse a pharmacy benefit manager from making these disclosures unless the purchaser or prospective purchaser agrees to keep any proprietary information disclosed to it pursuant to these provisions confidential, as specified. *STATUS: This bill is scheduled to be heard in this Committee.*

**Prior Related Legislation.** AB 1960 (Pavley) 2004 would have required a PBM to make specified disclosures to its purchasers and prospective purchasers, including specified information about the pharmacy benefit manager's revenues and its drug formularies, and to make specified disclosures to the public upon request. The bill would have established certain standards and requirements with regard to PBM contracts and the provision of certain drugs. The bill would have imposed certain requirements on the membership of a pharmacy and therapeutics committee for a PBM. The bill would have required a PBM to meet certain conditions before substituting a prescribed medication. *NOTE: this bill was vetoed by Governor Schwarzenegger. In his veto message he stated, "I share the authors concerns with the rising cost of prescription drugs and generally, her interest in disclosure of information to consumers. However, this measure would have the unintended consequence of increasing drug costs to health plans, the Medi-Cal Program and other purchasers, without providing any real consumer benefit. Studies, including one from the Federal Trade Commission, have shown that enactment of this legislation will limit competition and significantly increase the cost of prescription drugs."*

## **IMPLEMENTATION CONCERNS:**

The goal of this measure appears to be consumer protection. This is accomplished via requirements for PBMs be more transparent about their business practices. The BOP is enlisted to assist in providing oversight of PBMs to support this goal. Considering the points raised by the FTC regarding the appropriateness of a licensing board providing oversight of PBMs, the Committee may wish to consider if this entity is the most appropriate regulatory entity to carry out this function. Alternatively, should the existing oversight the DMHC has over health plans be expanded to require a registration program for PBMs? Additionally, should more direct consumer protection measures be included to ensure patients have information about drug costs? For example, the American Consumer Institute suggests the following:

- Patients paying coinsurance and/or deductibles should pay the negotiated price and not pay the full price for drugs;

- Pharmacies should be allowed and encouraged to disclose to patients when lower cost generics or over-the-counter medications are available outside of patients' drug plans; and,
- Pharmacists should be allowed and encourage to disclose to patients when out-of-pocket costs are lower – if prescriptions are paid in cash instead of using insurance benefits.

**REGISTERED SUPPORT:**

Board of Pharmacy  
California Medical Association  
California Pharmacists Association  
Consumers Union  
Health Access California  
Independent Pharmacy Cooperative  
Project Inform

**REGISTERED OPPOSITION:**

Anthem Blue Cross  
America's Health Insurance Plans  
Association of California Life & Health Insurance Companies  
California Association of Health Plans  
Pharmaceutical Care Management Association

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