SENATE COMMITTEE ON
BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT
Senator Richard Roth, Chair
2021 - 2022 Regular

Bill No:	SB 524	**Hearing Date:**	April 5, 2021
Author:	Skinner		
Version:	March 11, 2021		
Urgency:	No	**Fiscal:**	No
Consultant:	Dana Shaker		

Subject: Health care coverage: patient steering

SUMMARY: Prohibits a health care service plan or health insurer, including a self-insured employer plan, or the agent of a health care service plan or health insurer to engage in patient steering.

Existing law:

1) Under the Pharmacy Law, provides for the licensure and regulation of pharmacies, pharmacists and wholesalers of dangerous drugs or devices by the Board of Pharmacy. (Business and Professions Code (BPC) § 4000 *et seq.*)

2) Defines "carrier" as a health care service plan, as defined in Section 1345 of the Health and Safety Code, or a health insurer that issues policies of health insurance, as defined in Section 106 of the Insurance Code. (BPC § 4430(a))

3) Defines "health benefit plan" as any plan or program that provides, arranges, pays for, or reimburses the cost of health benefits. "Health benefit plan" includes, but is not limited to, a health care service plan contract issued by a health care service plan, as defined in Section 1345 of the Health and Safety Code, and a policy of health insurance, as defined in Section 106 of the Insurance Code, issued by a health insurer. (BPC § 4430(d))

4) 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 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. (BPC § 4430(g))

5) Provides that notwithstanding any other law, a contract that is issued, amended or renewed on or after January 1, 2013 between a pharmacy and a carrier or a PBM to provide pharmacy services to beneficiaries of a *health benefit plan* shall comply with the provisions of this chapter. (BPC § 4432)

6) Establishes the California Board of Pharmacy (the Board) administers and enforces The Pharmacy Law. (BPC § 4001)

7) Provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and the regulation of health insurers by the Department of Insurance. (California Health and Safety Code (HSC) § 1340 *et seq.*; California Insurance Code § 740 *et seq.*)

8) Requires a health care service plan contract or health insurance policy that provides coverage for outpatient prescription drugs to cover medically necessary prescription drugs. (HSC § 1342.71(c))

This bill:

1) Requires that a health care service plan or a health insurer, including a self-insured employer plan, or the agent of a health care service plan or health insurer shall not engage in patient steering.

2) Defines "patient steering" to mean either of the following:

   a) Communicating to an enrollee or insured, verbally, electronically, or in writing, that they are required to have a prescription dispensed at, or pharmacy services provided by, a particular pharmacy or pharmacies if there are other pharmacies in the network that have the ability to dispense the medication or provide the services.

   b) Offering or including in contract or policy designs for purchasers of group health care coverage provisions that limit enrollees' or insureds' access to only those pharmacy providers that are owned or operated by the health care service plan, health insurer, or plan's or insurer's agent, or owned or operated by a corporate affiliate of the health care service plan, health insurer, or plan's or insurer's agent.

3) "Patient steering" does not include directing an enrollee or insured to a specific pharmacy for a specific prescription due to the need for special handling or clinical requirements that cannot be performed by other pharmacies in the provider network of the health care service plan, health insurer, or plan's or insurer's agent.

4) Makes findings and declarations that:

   a) a health care service plan, health insurer, or pharmacy benefit manager that requires a patient to use a specific pharmacy provider for services that otherwise could be provided by any pharmacy in the provider network unjustifiably limits patient choice and may put the patient's health at risk;

   b) evidence demonstrates that limiting access to pharmacy providers is designed to eliminate competition and can result in higher costs for the patient and for the health care system as a whole, patients losing connection with trusted advisors, and being unable to get necessary advice and consultation; and

c) it is necessary to limit the practice of "patient steering" used by some health care service plans and health insurers, and their contracted pharmacy benefit managers, to those situations when it is used for established clinical or logistical reasons, and not for financial benefit to the plan or insurer, or their agents.

FISCAL EFFECT: Unknown. This bill has not been keyed fiscal by Legislative Counsel.

COMMENTS:

1. **Purpose.** The California Pharmacists Association (CPhA) is the Sponsor of this bill. According to the Author, "In a practice known as "patient steering," PBMs inform patients that they must have their prescriptions filled at a select pharmacy or pharmacies, even though there are other pharmacies in the network that the patient wishes to use and which are able to fill the prescription. Patients are told they will risk not having their prescription filled or have to pay more for their prescription if they do not use the PBM's selected pharmacy."

2. **Background.**

Pharmacy Benefit Managers (PBMs). PBMs have been around since the early 1970s. Initially, PBMs' functions were limited -- they served merely as fiscal and administrative intermediaries between health plans, plan members, and pharmacies. What remains the same of PBMs, both in the past and currently, is their role as claims processor. Claims processing requires a pharmacy to contact a PBM to verify that a consumer has coverage for a requested prescription, determine whether the customer's plan covers the drug, and how much copay is required. Once the prescription is filled, the pharmacy transmits patient details -- the health plan number, the physician's prescription, and the drug price -- to the PBM. The PBM responds by approving or disapproving the transaction, and then forwards the reimbursement from the health plan to the retail pharmacy.

Nearly every health plan, whether sponsored by an employer, a union, Medicare, or self-purchased, employs a PBM, and PBMs' functions have evolved over time from merely claims processing to include managing their clients' entire pharmacy benefit. The functions offered to clients may now include:

- Negotiating prices for drugs, including discounts, rebates, and other concessions, with pharmaceutical manufacturers;
- Conducting drug-utilization reviews (i.e., compiling information regarding the projected volume of plan members who use a given drug);
- Disease management (i.e., managing the chronic conditions of high-risk, high-cost patients);
- Determining the composition of pharmacy and wholesaler networks;
- Running mail-order and affiliated specialty pharmacies; and,

- Creating and managing formularies.

PBMs and Pharmacies. PBMs contract with pharmacies to create networks for their clients based on clients' needs and state laws, which may include geographic retail requirements and limitations on mail-order pharmacies. Because nearly every individual with a pharmacy benefit must interact with a PBM, it follows that joining PBMs' pharmacy networks is more than good business practice -- it is essential for pharmacies' survival. Pharmacies' revenues from drug dispensing are primarily derived from health plans' reimbursement for the drug's cost, a dispensing fee, and a patient's copay.

Contracts for inclusion in PBMs' pharmacy networks are extensive and frequently-updated. Common provisions include basic inventory requirements, professional codes of conduct, reimbursement amounts, reimbursement criteria, and applicable federal and state laws. Most contracts offered by PBMs to retail pharmacies are fairly boilerplate, meaning they consist of standardized terms and conditions that are routinely repeated with different parties. Disputes and grievances between PBMs and pharmacies are typically resolved through PBMs' in-house dispute committees or by mandatory arbitration. Pharmacies are also subject to periodic, routine audits from PBMs during which time a pharmacy's accounts are reviewed to reconcile reimbursements, fees, and ensure compliance with the contract terms.

While large pharmacies deal with PBMs directly, smaller pharmacies may contract with a pharmacy services administrative organization (PSAO) for leverage. A PSAO can represent the pharmacy in PBM contract negotiations and manage drug reimbursement claims, among other administrative offerings. PSAOs charge pharmacies fees for their services, and do not get any reimbursements from PBMs or other contract affiliates.

Pharmacy Benefit Managers (PBMs) and Health Plans. According to a 2005 Federal Trade Commission report on Pharmacy Benefit Managers (PBMs) and mail-order pharmacies, many health plan sponsors offer their members prescription drug insurance and hire PBMs to manage these pharmacy benefits on their behalf. As part of the management of these benefits, PBMs assemble networks of retail and mail-order pharmacies so that the plan sponsor's members can fill prescriptions easily and in multiple locations.

State Responses to Current PBM Practices. In response to current PBM practices, states are increasingly requiring PBMs to license or register with their Department of Insurance or Board of Pharmacy. Specifically, Maryland, Georgia, Mississippi, and Louisiana have all passed legislation to ban patient steering.

In California in recent years, Governor Brown signed AB 315 (Wood, Chapter 905, Statutes of 2018), which requires pharmacy benefit managers (PBMs) to register with the Department of Managed Health Care (DMHC), and to disclose, upon a purchaser's request, information with respect to prescription product benefits. The law also requires DMHC to convene a Task Force on PBM reporting to determine what information related to pharmaceutical costs, if any, it must report by health care service plans (health plan) or their contracted PBMs. Finally, the law established a pilot project in Riverside and Sonoma Counties to assess the impact

of health plan and PBM prohibitions that prohibit the dispensing of certain amounts of prescription drugs by network retail pharmacies.

Recent Relevant Court Cases. PBMs have traditionally argued that various state laws could not apply to them due to federal preemption under the Employee Retirement Income Security Act of 1974 (ERISA). However, a recent United States Supreme Court ruling provides clarity on this subject.

In 2015, Arkansas passed a law barring PBMs from setting the price they pay independent drug stores for medicines obtained for their contracted health insurers' customers. Arkansas and other states have held PBMs responsible for independent pharmacies and drug stores losing money on the medicines they dispense. Media reports note that PBMs who negotiate on behalf of health plans have contended in the past that they must be allowed to set prices to keep costs under control, and that their business model shouldn't have to account for independent pharmacies' financial viability. Most of the major health insurance companies each own PBMs.

In challenging the 2015 Arkansas law, PBMs argued that this law did not apply to them due to federal preemption under ERISA. The Supreme Court upheld the Arkansas state law, stating that, as a general rule, ERISA does not preempt "state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage."

Additionally, as the Sponsor notes in its letter, in December 2020 the Ninth Circuit Court of Appeals concluded that HIV Patients "adequately alleged that they were denied meaningful access to their prescription drug benefit under their employer-sponsored health plans because defendants' program prevented them from receiving effective treatment for HIV/AIDS." In the case, patients in the program were required to obtain their HIV medications by mail-order or pharmacy drop shipment service.

Patient Steering and Patient Letters from PBMs. At issue in this bill is the practice of patient steering. Generally speaking, patient steering occurs when a patient is required to receive their prescriptions from one particular pharmacy, whether or not that was the patient's choice. According to the Author, patients have routinely received letters from PBMs stating that prescriptions that they have previously received from their pharmacies of choice are no longer covered by their existing health plans. Instead, they must obtain those medications from another, oftentimes larger chain pharmacy or they have to utilize a mail order pharmacy.

In one such letter dated 1/20/2017, the company OPTUMRx, a PBM, writes to a health-insured patient denying coverage of COREG CR, a medication used to treat some heart conditions such as congestive heart failure and hypertension:

"Notice of Denial for a Medical Judgement

We reviewed all of the information you and/or your doctor sent to us, and we sent the information to an appropriate physical specialist if needed. Unfortunately, we must deny coverage for COREG CR.

Why was my request denied?

This request was denied because you did not meet the following clinical requirements:

Based on the information provided, you do not meet the established medication-specific criteria or guidelines for COREG CR at this time.

Coreg CR is denied for medical necessity. Medication authorization requires that you try the following alternative: Generic carvedilol.

Reviewed by: KRB, D.Ph.

The reason(s) OptumRx did not approve this medication can be found above. This denial is based on the COREG CR drug coverage policy, in addition to any supplementary information you or your prescriber may have submitted."

Another letter that is undated, but was written prior to January 1, 2017 states:

"OptumRx and Walgreens make it easy for you to get your maintenance medications and potentially save you money. The OptumRx Select90 Saver Program allows you to get 90-day supplies of your medication(s) at a Walgreens pharmacy or through OptumRx home delivery—the choice is yours. The program is equivalent to your existing retail 90-day maintenance medication program. **There will be no changes to your copays.**

Beginning January 1, 2017, the maintenance of medication(s) listed below will be part of the OptumRx Select90 Saver program.

- ATORVASTANTIN CALCIUM
- COREG CR
- LEVOTHYROXINE SODIUM
- LOSARTAN POTASSIUM"

The language in this bill seems to reflect the author's intention to stop the practice of patient steering. The language of the bill clearly states that patient steering means "communicating to an enrollee or insured, verbally, electronically, or in writing, that they are required to have a prescription dispensed at, or pharmacy services provided by, a particular pharmacy or pharmacies…." The bill even describes what patient steering does not include, thereby providing permissible alternatives of PBM and plan activity. At the heart of this bill is a desire to ensure that patients have every available option to fill their prescriptions—whether it's at the independent pharmacy down the street or the local CVS, whether it's by mail-order or pick-up, whether it's to work with a pharmacist they have a relationship with or not.

3. **Arguments in Support.** The Sponsor, the California Pharmacists Association (CPhA) writes in support: "Patient steering occurs when a PBM moves a patient's prescription to a different pharmacy without their consent and that new pharmacy happens to be owned by the PBM – either a physical location or a mail-order pharmacy. Patients are then given a "choice" of filling their covered prescriptions at the new pharmacy or pay full price out of pocket at the existing in-network pharmacy. The practice of patient steering is becoming increasingly problematic for patients who are losing their right to receive pharmacy services at locations convenient to them and/or where they have an established relationship with the

pharmacist. While this practice happens primarily in the independent setting, it is increasingly happening in smaller chain settings who are not owned by PBMs…

While opponents of this bill will state that patients are not "forced" to use specific pharmacies, recent court actions taken by patients directly counter that claim. Most notably, the Ninth Circuit Court of Appeals overturning a lower court's decision, holding that five "John Doe" HIV patients could pursue a discrimination claim against CVS Caremark for requiring HIV and AIDS patients to obtain their medications by mail-order or drop shipment to a CVS store.

"This decision is an important victory for HIV patients who sought to vindicate their health care rights and obtain their life-sustaining medications in medically-appropriate manner," said Jerry Flanagan of Consumer Watchdog. *Ninth Circuit Reinstates HIV Discrimination Claims Against CVS Prescription Drug Mail-Order Program, Says Consumer Watchdog.*

While CPhA believes there is a role for pharmacy benefit managers, the problem lies with the inherent conflict of interest when a PBM is steering patients to their own pharmacies. It is at that point we must question whether decisions are made for the benefit of the patient or simply to increase profit margins."

AIDS HealthCare Foundation writes in support that they are "particularly concerned about the impact of patient steering in three ways: The Pharmacy is a critical component of patient care, especially for those with chronic medical conditions like HIV who need a pharmacist who is familiar with the patient, the condition and the patient's specific needs; The cost of the patient may be higher when steered to a pharmacy controlled by the insurer. This is a particular concern to patients who are on a fixed income; and Many patients, again most notably those with chronic conditions, are unable to travel far to pick up their prescriptions. Neighborhood pharmacies provide convenience as well as the patient/pharmacist relationship that is frequently invaluable in maintaining the patient's treatment regimen."

The Consumer Attorneys of California (CAOC) write in support: "SB 524 will help ensure that patients can use their own in-network pharmacist by prohibiting "patient steering"—a practice whereby pharmacy benefit managers (PBMs) limit patients' ability to access the pharmacies in their network. PBMs inform patients that they must have their prescriptions filled at a select pharmacy or pharmacies—typically select retail and/or mail-order pharmacies owned by the PBM—even though there are other pharmacies in the network that the patient wishes to use and which are able to fill the prescription. Patients are told they will risk not having their prescription filled or have to pay more for their prescription if they do not use the PBM's selected pharmacy."

4. **Arguments in Opposition.** The California Association of Health Plans (CAHP), the Association of California Life and Health Insurance Companies (ACLHIC), and America's Health Insurance Plans (AHIP) write in opposition: "Health plans, insurers, and their contracted pharmacy benefit managers (PBMs) design pharmacy networks with the consumer in mind. They contract with chain, independent, and mail order pharmacies to provide consumers with the choice of services that best fit their needs. They design preferred networks that allow patients to have access to

high performing, lower cost options. All of this is done with the consumer's safety in mind – the pharmacy programs created by health plans, insurers, and PBMs are able to look across all of the patients' pharmacy activity to flag potential interactions, provide counseling for patients with chronic conditions, and suggest lower-cost alternatives. By focusing on pharmacies that provide cost-effective and high-quality care, health plans and insurers are ensuring consumers receive the best value for their health care dollars. SB 524 threatens these safety and cost saving measures. We are concerned that this bill would eliminate the use of "preferred" networks that provide patients with additional cost saving measures."

Kaiser Permanente writes in opposition unless the bill is amended: "Unfortunately, as written SB 524 would interfere with this extremely efficient and popular model of our care for our members. We understand that is not the intent of the bill, and we look forward to future conversations with the author and sponsor to ensure that the KP model and the 9.5 million KP members in California are not negatively impacted by this measure."

The Pharmacy Care Management Association (PCMA) writes with concerns: "SB 524 eliminates the ability of health service plans and insurers to develop plan designs that lower costs for their members. Further, it would restrict communications to members informing them about access to lower cost medicines. Health service plans and insurers design networks of independent, chain and mail-order pharmacies to provide patients with access to a range of high-quality pharmacies, while balancing savings for patients and payers. To achieve this goal, PBMs require pharmacies to compete on service, price, convenience, and quality to attract consumers within a particular health plan. This competition helps keep the rising costs of prescription drugs down, while also prioritizing patient's health and wellbeing. By building networks of pharmacies, patients have convenient access to prescriptions at discounted rates."

5. **Proposed Author's Amendments.** In response to concerns noted above, the Author plans to amend the bill as follows:

   Add to Section 4450: (d) Nothing in this chapter shall prevent a health care service plan, or health insurer, including a self-insured employer plan, or the agent of a health care service plan or health insurer from offering enrollees or insureds financial incentives to use a particular pharmacy, including, but not limited to, reductions in copays or other financial incentives given to the enrollee or insured when the prescription is dispensed.

   Clarify that Section 4450(b)(2) does not apply to a health plan or health insurer that performs its own pharmacy benefit manager service (i.e., that do not contract with outside pharmacies).

NOTE: ***This bill is double referred to the Senate Committee on Health, second.***

SUPPORT AND OPPOSITION:

Support:

The California Pharmacists Association (Sponsor)
AIDS HealthCare Foundation
The Consumer Attorneys of California

Opposition:

America's Health Insurance Plans (AHIP)
Kaiser Permanente
The Association of California Life and Health Insurance Companies
The California Association of Health Plans
The Pharmaceutical Care Management Association

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