

Date of Hearing: June 22, 2021

ASSEMBLY COMMITTEE ON HEALTH
Jim Wood, Chair
SB 524 (Skinner) – As Amended June 14, 2021

SENATE VOTE: 39-0

SUBJECT: Health care coverage: patient steering.

SUMMARY: Prohibits a health care service plan (health plan), a health insurer, and a self-insured employer plan, or agent from engaging in patient steering, as specified. Defines patient steering as communicating to an enrollee or insured that they are required to have a prescription dispensed at, or pharmacy services provided by, a particular pharmacy, as specified, or offering health care coverage contracts or policies that include provisions that limit access to only pharmacy providers that are owned or operated by the health plan, health insurer, self-insured employer plan, or agent. Specifically, **this bill:**

- 1) Prohibits a health plan, health insurer, or self-insured employer plan, or agent from engaging in patient steering.
- 2) Defines patient steering as 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; or,
 - b) Offering or including in contract or policy designs for purchasers of health care coverage provisions that limit enrollees' or insureds' access to only those pharmacy providers that are owned or operated by the health plan, health insurer, or self-insured employer plan or agent, or owned or operated by a corporate affiliate of the health plan, health insurer, or self-insured employer plan or agent.
- 3) Specifies that 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, as specified.
- 4) Provides that nothing in bill prevents a health plan, health insurer, or self-insured employer plan or the agent 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.
- 5) Exempts from the requirements of this bill, a health plan, health insurer, or self-insured employer plan administered by a health plan or its health insurer affiliate, that is part of a fully integrated delivery system in which enrollees or insureds, including enrollees or insureds in a self-insured employer plan administered by the health plan or its health insurer affiliate, primarily use pharmacies that are entirely owned and operated by the health plan, as specified.

- 6) Makes various finding and declarations, including that evidence shows 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 and can result in patients losing connection with trusted providers and being unable to get the advice and consultation they need.

EXISTING LAW:

- 1) Establishes, pursuant to federal law, the Employee Retirement Income Security Act of 1974 (ERISA), which sets minimum standards for most voluntarily established pension and health plans in private industry, including Taft-Hartley Multi-Employer Health and Welfare Plans. Exempts these plans from state insurance regulation.
- 2) Establishes, pursuant to federal law, the Patient Protection and Affordable Care Act and mandates the 10 federally required essential health benefits (EHBs) in the individual and small group market and establishes the Kaiser Small Group health plan as California's EHB benchmark plan, including prescription drug benefits, as specified, and incorporates by reference state law and regulations related to outpatient prescription drug coverage.
- 3) Establishes the Department of Managed Health Care (DMHC) to regulate health plans under the Knox-Keene Health Care Services Plan Act of 1975 in the Health and Safety Code; the California Department of Insurance (CDI) to regulate health insurers under the Insurance Code.
- 4) Requires health plans that provide prescription drug benefits to provide coverage for all medically necessary outpatient drugs, except as specified.
- 5) Requires health plans to maintain the following:
 - a) Complete drug formulary or formularies, including a list of prescription drugs on the formulary of the plan by major therapeutic category with an indication of whether any drugs are preferred over other drugs;
 - b) Records developed by the pharmacy and therapeutic committee of the health plan that fully describe the reasoning behind formulary decisions; and,
 - c) Health plan arrangements with entities that are associated with activities of the health plan to encourage formulary compliance or otherwise manage prescription drug benefits.
- 6) Requires a plan or insurer that provides EHBs to allow an enrollee or insured to access prescription drug benefits at an in-network retail pharmacy unless the prescription drug is subject to restricted distribution by the United States Food and Drug Administration (FDA) or requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy. Permits a nongrandfathered individual or small group health plan contract or insurance policy to charge an enrollee or insured a different cost sharing for obtaining a covered drug at a retail pharmacy, but requires all cost sharing to count toward the annual limitation on cost sharing.
- 7) Requires pharmacy benefit managers (PBMs) to register with the DMHC, to exercise good faith and fair dealing, and to disclose, upon a purchaser's request, information with respect to prescription product benefits, as specified.

- 8) Establishes a pilot project in Riverside and Sonoma Counties, effective January 1, 2020, to assess the impact of health plan and PBM prohibitions on the dispensing of certain amounts of prescription drugs by network retail pharmacies. Specifies the following:
 - a) Prohibit a health plan, pursuant to the pilot project, from prohibiting, or permitting any delegated PBM to prohibit, a pharmacy provider from dispensing a particular amount of a prescribed medication if the plan or PBM allows that amount to be dispensed through a pharmacy owned or controlled by the plan or PBM, unless the prescription drug is subject to restricted distribution by the FDA or requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy.
 - b) Require health plans subject to the pilot project, on or before July 1, 2020, to report annually to DMHC information and data relating to changes, if any, to costs and utilization of prescription drugs attributable to the prohibition of contract terms in a) above. Require DMHC to solicit and receive any additional information relevant to changes in costs or utilization attributable to the pilot project from other interested stakeholders. Require DMHC to summarize data received and provide the summary to the Governor and health policy committees of the Legislature on or before December 31, 2022. Sunsets the pilot project on January 1, 2023.
- 9) Provides for the licensure and regulation of pharmacists and pharmacies by the Board of Pharmacy.
- 10) Imposes requirements on audits of pharmacy services provided to beneficiaries of a health benefit plan.
- 11) Requires a pharmacy to inform a customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug, unless the pharmacy automatically charges the customer the lower price.
- 12) Requires a PBM that reimburses a contracting pharmacy for a drug on a maximum allowable cost basis to do the following, among other provisions related to maximum allowable cost:
 - a) Include in a contract, initially entered into, or renewed on its scheduled renewal date, on or after January 1, 2016, with the contracting pharmacy information identifying any national drug pricing compendia or other data sources used to determine the maximum allowable cost for the drugs on a maximum allowable cost list; and,
 - b) Make available to a contracting pharmacy, upon request, the most up-to-date maximum allowable cost list or lists used by the PBM for patients served by that pharmacy in a readily accessible, secure, and usable Web-based format or other comparable format.
- 13) Defines PBM as a person, business, or other entity that, pursuant to a contract with a health plan, manages the prescription drug coverage provided by the health plan, 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. Exempts from definition a health plan or its contracting provider, as specified.

FISCAL EFFECT: According to the Senate Appropriations Committee, the DMHC anticipates the total cost of this bill to be approximately \$95,000 and 0.5 personnel year (PY) in fiscal year

(FY) 2021-22, \$301,000 and 1.6 PYs in FY 2022-23, \$288,000 and 1.6 PYs in 2023-24, and \$72,000 and 0.4 PY in FY 2024-25 and ongoing annually thereafter (Managed Care Fund). A breakdown of DMHC's anticipated costs is as follows:

- 1) Office of Legal Services short-term workload costs to conduct legal research and issue legal memorandums to clarify requirements: \$226,000 and 1.2 PYs in FY 2022-23 and \$216,000 and 1.2 PYs in FY 2023-24.
- 2) Office of Plan Licensing workload costs to address review health plan documents, including Evidence of Coverages, provider contracts, and other disclosure forms: \$44,000 and 0.2 PY in FY 2021-22, \$22,000 and 0.1 PY in FY 2022-23, \$21,000 and 0.1 PY in 2023-24 and ongoing annually thereafter.
- 3) Office of Enforcement workload costs to address referrals: \$51,000 and 0.3 PY in FY 2021-22, \$53,000 and 0.3 PY in FY 2022-23, \$51,000 and 0.3 PY in FY 2023-24 and ongoing annually thereafter.

CDI anticipates costs of \$29,000 in FY 2021-22, \$65,000 in FY 2022-23, and \$53,000 ongoing (Insurance Fund) to address a potential increase in enforcement workload.

COMMENTS:

- 1) **PURPOSE OF THIS BILL.** According to the author, patients are safer and better served when they can fill their prescriptions with pharmacists they know, who are familiar with their unique medical history, and who speak their language and have cultural competency. However, through a practice known as patient steering, PBMs inform patients that they must have their prescriptions filled at a select pharmacy or pharmacies, usually a retail or mail order pharmacy owned by the PBM or health plan, even though there are other pharmacies in the network that the patient wishes to use and which can safely fill the prescription. The author states that patients risk not having their prescription filled or having to pay out-of-pocket if they do not use the PBM's selected pharmacy. Requiring patients to use a select retail or mail order pharmacy can harm patients, including those who do not live near the retail pharmacy and those who cannot get their prescriptions delivered due to logistical reasons or privacy concerns if their package is intercepted. The author concludes that this bill prohibits patients from being required to use a particular pharmacy when there is no clinical reason they must do so and ensures that patients can access whichever pharmacy in their network they prefer.

- 2) **BACKGROUND.**

- a) **Existing PBM law.** PBMs play a major role in negotiating the prices of prescription drugs, creating and managing formularies, and several other functions key to the management of pharmacy benefits for millions of Californians. However, despite a PBM's interaction with most major players, including drug manufacturers, health plans and insurers, and pharmacies, very little is known about those relationships. AB 315 (Wood), Chapter 905, Statutes of 2018, establishes a regulatory structure for PBMs, and provides for the registration of PBMs to the DMHC. AB 315 requires DMHC, by July 1, 2019, and in collaboration with other agencies, departments, advocates, experts, health plan representatives, and other entities and stakeholders that it deems appropriate, to convene a Task Force on PBM Reporting to determine what information related to

pharmaceutical costs, if any, it should require to be reported by health plans or their contracted PBMs, in addition to reporting required in existing law.

- b) **2020 AB 315 Task Force Report.** From July to December 2019, the DMHC facilitated a series of public Task Force meetings to develop the recommendations contained in this report. The report noted that the PBM marketplace appears to be highly concentrated, with the top three PBMs representing approximately 75% of covered lives in California. Some suggest that this concentration is evidence of a stable and functioning market, whereas others believe it is evidence that the largest PBMs have a stranglehold on the market and therefore wield too much negotiating power. Stakeholders attending the Task Force meetings asserted that dominant PBMs may negotiate higher rebates only to keep the bulk of the rebate. By not passing the rebate on to health plans, consumers may be adversely affected by higher costs. Market concentration is seen not only across the marketplace, but also vertically within the supply chain. Some PBMs own their own pharmacies, referred to as an “integrated pharmacy.” This may result in misaligned incentives, as a PBM may favor an integrated pharmacy even if competing pharmacies have lower costs. Additionally, the Task Force heard from pharmacy representatives who stated PBMs may improperly utilize prescription information to steer patients who are prescribed high-cost drugs to the PBM’s integrated pharmacies. Some PBMs and health plans have common ownership which could lead to PBMs increasing drug costs to rival health plans. The Task Force recommended gathering data to increase transparency and understand how PBMs impact the cost of prescription drugs, including gathering information on PBMs, including revenue and expense information, to determine PBM market impact and the value PBMs provide to consumers.
- c) *Rutledge v. Pharmaceutical Care Management Association.* An ERISA plan is established by an employer or employee organization and arranges (whether through insurance or otherwise) for certain benefits, including medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability, death or unemployment, among others. ERISA preempts state laws that “relate to” employee benefits, including health benefits. According to a December 2020 *Health Affairs* article, this extraordinarily broad provision has bedeviled courts and preempted scores of state health care regulations. In 2020, the Supreme Court ruled in *Rutledge v. Pharmaceutical Care Management Association*, that ERISA did not preempt Arkansas’s law regulating PBMs and held that a state law requiring PBMs to pay pharmacies no less than their acquisition costs for prescription drugs was not preempted by ERISA. At issue was whether ERISA preempts an Arkansas statute dictating rate floors for PBMs in reimbursing pharmacists, on the grounds that the statute was related to employee benefit plans governed by ERISA rather than state law which regulates traditional health plans. The Court concluded, “ERISA does not pre-empt state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage.” The article notes that *Rutledge* clarifies that states may regulate plans’ contractors, and that cost-control regulation is presumptively beyond ERISA’s preemptive scope. It intimates that states may regulate in the vast “vacuum” of issues on which ERISA offers no federal law, but it does not go so far as to significantly renovate ERISA preemption jurisprudence. Still, the article notes that this is welcome latitude for states seeking to regulate health care costs in a myriad of ways. The decision opens up further avenues beyond PBMs to broader state health reforms aimed at

reigning in the costs of health services and prescription drugs, protecting consumers, and expanding affordable access to more people.

The proponent and opponents of this bill acknowledge that this bill apply to self-funded plans, however, disagree as to the preemption issue.

- 3) **SUPPORT.** The California Pharmacists Association (CPhA), sponsor of this bill, writes that 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. CPhA notes that while this practice happens primarily in the independent setting, it is increasingly happening in smaller chain settings who are not owned by PBMs. The U.S. Centers for Medicare & Medicaid Services has expressed concern that PBMs are using pharmacy contracts “in a way that inappropriately limits dispensing of specialty drugs to certain pharmacies” and in ways that have nothing to do with patient health. While CPhA believes there is a role for PBMs, 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.
- 4) **OPPOSITION.** Pharmaceutical Care Management Association writes that this bill removes Californians’ ability to make cost effective decisions for themselves and reduces convenient options that not only make it easier to receive medications but also reduces patient adherence. The California Association of Health Plans (CAHP), the Association of California Life and Health Insurance Companies (ACLHIC), and America’s Health Insurance Plans (AHIP) contend that this bill takes away vital tools that health plans and insurers use to ensure patient safety and lower health care costs for consumers. CAHP, ACLHIC, and AHIP state that this bill limits benefit designs focused on lowering costs for consumers as plans design preferred networks that allow patients to have access to high performing, lower cost options. Additionally, the Federal Trade Commission has found that vertical integration can provide benefits and lower costs. Finally, this legislation may open the state to litigation because it attempts to regulate ERISA plans and overreaches as it tries to regulate self-insured employer plans and may put the state at risk of litigation.
- 5) **PREVIOUS LEGISLATION.**
 - a) AB 1803 (Committee on Health), Chapter 114, Statutes of 2019, requires a pharmacy to inform a customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug, except as specified, and, if the customer pays the retail price, requires the pharmacy to submit the claim to the customer’s health plan or health insurer beginning January 1, 2020.
 - b) AB 315 (Wood), Chapter 905, Statutes of 2018, requires PBMs to register with the DMHC, to exercise good faith and fair dealing, and to disclose, upon a purchaser's request, information with respect to prescription product benefits, as specified. Requires DMHC to convene a Task Force on PBM reporting to determine what information related to pharmaceutical costs, if any, it should require to be reported by health plan or their

contracted PBMs. Establishes 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.

- c) SB 17 (Hernandez), Chapter 603, Statutes of 2017 requires health plans and insurers that offer commercial products and file rate information with the DMHC or CDI to annually report specific information related to the costs of covered prescription drugs.
- d) AB 2752 (Nazarian) of 2016 would have required a health plan or a health insurer to annually notify an enrollee or insured that the enrollee's or insured's drug treatment or provider is no longer covered by the plan or policy. AB 2752 was held in Assembly Appropriations Committee.
- e) AB 2400 (Nazarian) of 2016 would have required health plans and health insurers to comply with a shortened internal grievance review process for formulary drugs. AB 2400 was held in Assembly Appropriations Committee.
- f) AB 374 (Nazarian), Chapter 621, Statutes of 2015, authorizes a request for an exception to a health plan's or health insurer's step therapy process for prescription drugs to be submitted in the same manner as a request for prior authorization for prescription drugs. Requires the health plan or insurer to treat, and respond to, the request in the same manner as a request for prior authorization for prescription drugs.
- g) AB 339 (Gordon), Chapter 619, Statutes of 2015, requires health plans and health insurers that provide coverage for outpatient prescription drugs to have formularies that do not discourage the enrollment of individuals with health conditions, and requires combination antiretrovirals drug treatment coverage of a single-tablet that is as effective as a multitablet regimen for treatment of Human immunodeficiency virus infection and acquired immune deficiency syndrome, as specified. Codifies in state law, federal requirements related to pharmacy and therapeutics committees, access to in-network retail pharmacies, standardized formulary requirements, formulary tier requirements similar to those required of health plans and insurers participating in Covered California and copayment caps of \$250 and \$500 for a supply of up to 30 days for an individual prescription, as specified.

- 6) **DOUBLE REFERRAL.** Upon passage from this committee, this bill will be referred to the Assembly Business and Professions Committee.

REGISTERED SUPPORT / OPPOSITION:

Support

California Pharmacists Association (sponsor)
 Advocating for Access Specialty Pharmacy Coalition
 Afa Specialty Pharmacy Association
 Aids Healthcare Foundation
 Apla Health
 California Chronic Care Coalition
 California Dental Association
 California Medical Association

California Nurses Association
Consumer Attorneys of California
National Community Pharmacists Association
National Multiple Sclerosis Society, Ms-can
United Nurses Associations of California/union of Health Care Professionals

Opposition

America's Health Insurance Plans (AHIP)
American Gi Forum Education Foundation of Santa Maria, CA
Association of California Life & Health Insurance Companies
Black Chamber of Orange County
California Association of Health Plans
California Chamber of Commerce
California Hispanic Chambers of Commerce
NAACP of Santa Maria- Lompoc
National Association for The Advancement of Colored People
National Latina Business Women Association of Los Angeles
Orange County Hispanic Chamber of Commerce
Pharmaceutical Care Management Association
San Diego County Hispanic Chamber of Commerce

Analysis Prepared by: Kristene Mapile / HEALTH / (916) 319-2097