SENATE COMMITTEE ON HEALTH
Senator Dr. Richard Pan, Chair

BILL NO: SB 524
AUTHOR: Skinner
VERSION: April 19, 2021
HEARING DATE: April 28, 2021
CONSULTANT: Teri Boughton

SUBJECT: Health care coverage: patient steering

SUMMARY: Prohibits a health plan, insurer, self-insured employer plan and an agent of a health plan, health insurer, self-insured employer plan from engaging in specified activities that limit enrollees' or insureds' access to pharmacies that are part of the plan's or insurer's network, except if special handling or clinical requirements are necessary, and permits the use of financial incentives at network pharmacies.

Existing law:

1) Establishes the Department of Managed Health Care (DMHC) to regulate health plans under the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene Act) and the California Department of Insurance (CDI) to regulate health insurance. [HSC §1340, et seq., and INS §106, et seq.]

2) Establishes requirements for nongrandfathered health plans and health insurance policies that cover outpatient prescription drugs. [HSC §1342.7 and INS §10123.193]

3) Requires a plan or insurer that provides essential health benefits 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. [HSC §1367.42 and INS §10123.201]

4) Establishes a pilot project to assess the impact of health plan and pharmacy benefit manager (PBM) prohibitions on the dispensing of certain amounts of prescription drugs by network retail pharmacies. Applies the provisions to pharmacy providers located in the counties of Riverside and Sonoma. Prohibits a health plan from, or permitting any delegated PBMs 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. Requires on or before July 1, 2020, health plans subject to this pilot 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. Requires 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. [HSC §1368.6]

This bill:

1) Prohibits a health plan or a health insurer, including a self-insured employer plan, or the agent of a health plan or health insurer 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.

   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 self-insured employer plan, health plan, health insurer, or an agent of the self-insured employer plan, health plan or insurer; or are owned or operated by a corporate affiliate of the health plan, health insurer, or plan's or insurer's agent.

3) Permits 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 plan, health insurer, or plan's or insurer's agent.

4) Permits a health plan, health insurer, self-insured employer plan, or the agent of a health plan or health insurer to offer 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 this bill a health plan that is part of a fully integrated delivery system where enrollees, including enrollees 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, and the plan's enrollees, including enrollees in a self-insured employer plan administered by the health plan or its health insurer affiliate, may use any pharmacy in the health plan's network that has the ability to dispense the medication or provide the services.

6) Finds and declares when a health plan, insurer, or PBM requires a patient to use a specific pharmacy provider for services that otherwise could be provided by any pharmacy in the provider network, it unjustifiably limits patient choice and may put the patient's health at risk. Evidence shows that limiting access to pharmacy providers is designed to eliminate competition and can result in higher costs, patient losing connection with trusted providers, and getting advice and consultation they need. It is necessary to limit patient steering

FISCAL EFFECT: This bill has not been analyzed by a fiscal committee.

COMMENTS:

1) *Author's statement.* 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, pharmacy 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. 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. 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) *DMHC Task Force*. AB 315 (Wood, Chapter 905, Statutes of 2018), requires DMHC to convene a Task Force on PBM Reporting. PBMs are health care companies that contract with health plans to manage pharmacy benefits and negotiate manufacturer rebates. Throughout the Task Force meetings, various presenters discussed the role of PBMs in the complex pharmaceutical supply chain. It was noted that PBMs play no role in the physical distribution of prescription drugs. Rather, drugs move from the manufacturer, to the distributor, to the pharmacy, to the consumer. PBMs help health plans manage their drug benefits through negotiating or contracting with manufacturers and/or pharmacies on behalf of their contracted health plans. It was established there is a lack of transparency regarding the value PBMs bring to the health care industry and how they help to reduce prescription drug costs. There is also a lack of transparency regarding how PBMs make money and how much money they make. One Task Force recommendation is to require PBM reporting on the pharmacy source for each drug reported. Pharmacy source refers to the type of pharmacy used by enrollees to obtain a prescription drug. Pharmacy source includes integrated, chain, independent, specialty, and mail order pharmacies. PBM reporting on pharmacy source would demonstrate the volume of prescription drugs filled at different types of pharmacies, whether certain types of pharmacies are dominating the market and how these market dynamics ultimately impact costs. This data could also shed light on how enrollees access pharmacies and their relationships with pharmacists.

3) *Market concentration*. Among other issues of concern that came up at the DMHC Task Force was the issue of market concentration. 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.

4) *Self-insured employer plan*. While not defined in this bill, the term refers to state regulated self-insured plans as well as plans regulated under the Employee Retirement Income Security Act (ERISA). 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 regulation of self-insured plans. That regulation of a self-insured plan is one that binds the plan administrators in making determinations on eligibility or entitlement to certain benefits. So ERISA's primary concern is over laws that require providers to structure benefit plans in particular ways, such

as requiring payment of specific benefits or beneficiary determinations, or laws that force ERISA plans to adopt a certain scheme of coverage which was made clear in *Rutledge v. Pharmaceutical Care Management Association* (2020) 141 S.Ct. 474, 480. *Rutledge* generally allows states to regulate PBMs much more than originally expected under ERISA. Under *Rutledge,* the Pharmaceutical Care Management Association (PCMA) challenged a 2015 Arkansas law that includes mandates for pharmacy reimbursement for drug costs, new requirements for PBMs, updates to maximum allowable cost lists, and administrative appeal procedures. At issue in the Supreme Court ruling is whether or not provider reimbursement requirements are preempted by ERISA and the Supreme Court held that the Arkansas law is not preempted by ERISA. Specifically, Justice Sotomayor's opinion states "the Court holds that the Act has neither an impermissible connection with nor reference to ERISA and is therefore not pre-empted." With regard to patient steering, in *Tri-City Healthcare District v. Scripps Health, Inc.* (S.D. Cal 2010) 2010 WL 11509161, the health care district sued Scripps over Scripps patient steering practice. The district court found the claims of patient steering were unrelated to the benefits ERISA covered patients would receive under the ERISA plan.

5) *Double referral.* This bill was heard in the Senate Committee on Business, Professions and Economic Development on April 5, 2021 and passed with a vote of 11-0.

6) *Prior legislation.* AB 315 requires PBMs to register with 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 requirements that prohibit the dispensing of certain amounts of prescription drugs by network retail pharmacies.

   SB 1021 (Wiener, Chapter 787 Statutes of 2018) prohibits health plan contracts and health insurance policies from having utilization management policies or procedures which rely on a multitablet drug regimen over a single-table drug regimen for the prevention of HIV infection and AIDS; extends the January 1, 2020 sunset on law that caps cost sharing for a covered outpatient prescription drug at $250/$500 per 30-day supply, as specified, as well as other formulary requirements; and codifies a regulation that prohibits an enrollee or insured from being charged more than the retail price for a prescription drug when the applicable copayment or coinsurance is a higher amount.

   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 (HIV/AIDS), as specified. This bill places 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.

7) *Support*. The California Pharmacists Association, the sponsor of this bill, writes that the National Community Pharmacists Association conducted a survey which noted that, "A majority of community pharmacies have lost patients in the last six months due to unfair patient steering, and CVS Health is most often the culprit. "The AIDS Healthcare Foundation writes in support that patient steering is a concern because 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. Additionally, the cost to 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. Lastly many patients with chronic conditions are unable to travel far to pick up their prescriptions and neighborhood pharmacies provide convenience and patient-physician relationship that is frequently invaluable in maintaining a patient's treatment regimen. APLA Health writes that mail-order pharmacies can also result in significant privacy and safety issues for some clients, including youth and others living in congregate settings, people experiencing domestic violence, people living in rural areas and others who may need to protect their confidential medical information. If these individuals do not have the option to discreetly pick up their medication at their local pharmacy, medications arriving via mail-order may be intercepted by someone who is not aware of their medical condition – threatening their housing, employment or even physical security. These concerns are particularly salient for LGBTQ individuals, who may not be out to friends and family and could face stigma, discrimination, rejection and violence should their sexual orientation and/or gender identity be revealed. Mail-order pharmacy requirements have long been recognized to be inappropriate and even unlawful for people living with HIV. Numerous lawsuits have been successfully brought against insurance companies over mandatory mail-order requirements and subsequent impacts on people living with HIV. Most notably, the Ninth Circuit Court of Appeals overturning a lower court's decision, holding that five "John Doe" patients with HIV could pursue a discrimination claim against CVS Caremark for requiring people with HIV to obtain their medications by mail order or drop shipment to a CVS store.

8) *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 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. This bill threatens these safety and cost saving measures. CAHP, ACLHIC and AHIP are concerned that this bill would eliminate the use of "preferred" networks that provide patients with additional cost saving measures. Some health plans and insurers are part of vertically integrated systems – they may own or be owned by entities that also operate PBMs and/or pharmacies. CAHP, ACLHIC and AHIP are interested in the data that the author is relying on to show that these vertically integrated systems restrict patients' choice when data has shown the opposite. PCMA writes that this bill eliminates choices for employers and individuals to select a benefit plan that meets their needs. PCMA also believes this bill is not likely to apply to self-funded employer or union plans and the burden will fall on fully insured small businesses and individual who purchase coverage through Covered California. PCMA believes bill proponents are incorrectly interpreting *Rutledge*. PCMA cites *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.,* 514 U.S. 645 (1995) which concluded that the imposition of "rate regulation" did not violate ERISA's preemption clause for self-insured plans. PCMA believes this bill dictates plan choices for self-insured plans and believes it would be preempted under ERISA. PCMA writes restricting lower cost pharmacy network designs, and lower cost mail-order

pharmacies will raise costs and lower quality. The California Chamber of Commerce writes this bill intends to regulate self-insured employers, which falls squarely within the province of ERISA. This impermissible overreach is preempted by federal law and violates the objective of achieving national uniformity in self-insured benefit design.

9) *Policy comments.* Existing law already requires plans participating in Covered California and individual and small group market plans outside of Covered California to allow enrollees and insureds to access prescription drug benefits at an in-network retail pharmacy 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, so it is not clear how this bill's provisions would create a significant change in those plans as the opposition suggests.

10) *Amendments.* The author requests the committee adopt amendments requested by Kaiser Permanente Health Plan to clarify their exemption from this bill.

SUPPORT AND OPPOSITION:

Support: California Pharmacists Association (sponsor)
AIDS Healthcare Foundation
APLA Health
California Chronic Care Coalition
California Pharmacists Association
Consumer Attorneys of California

Oppose: America's Health Insurance Plans
Association of California Life and Health Insurance Companies
California Association of Health Plans
California Chamber of Commerce
Pharmaceutical Care Management Association

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