SENATE COMMITTEE ON HEALTH
Senator Dr. Richard Pan, Chair

BILL NO: SB 958
AUTHOR: Limón
VERSION: March 31, 2022
HEARING DATE: April 6, 2022
CONSULTANT: Teri Boughton

SUBJECT: Medication and Patient Safety Act of 2022

SUMMARY: Restricts the ability of health plans/insurers, or their designated medical groups or pharmacy benefit managers, from requiring or incentivizing patients to have infused or injected medications supplied by a vendor to the patient, or to the patient's physician office, clinic, infusion center, or hospital outpatient department, rather than maintained at the location where the infused or injected medication will be administered.

Existing federal law:

1) Establishes the federal Food Drug and Cosmetic Act, which includes authorization for the importation of certain prescription drugs from Canada by pharmacists and wholesalers, under specified circumstances. [21 U.S.C. 384 (b-h)]

2) Authorizes, pursuant to regulation, Section 804 Importation Program (SIP) sponsors, which can be states, Indian Tribes, pharmacist or wholesale distributors to establish drug importation programs under 1) above, and requires approval by the U.S. Food and Drug Administration (FDA) under the U.S. Department of Health and Human Services (HHS). [85 FR 62094]

3) Establishes the federal Drug Quality and Security Act, including the Drug Supply Chain Security Act, which requires tracking and tracing of products and licensing standards for wholesale distributors. [21 U.S.C. 360eee]

Existing state 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 insurers. [HSC §1340, et seq., and INS §106, et seq.]

2) Establishes the California Department of Public Health (CDPH) and sets forth its powers and duties, including, but not limited to, licensing and regulating health care facilities, including acute care hospitals. [HSC §1250, et seq.]

3) Establishes the Board of Pharmacy within the Department of Consumer Affairs to administer and enforce the Pharmacy Law. [BPC §4000 - 4427.8]

4) Prohibits a health plan contract from requiring or allowing a health care service provider (but not other providers such as health facilities, hospices, or surgical centers) to assume or be at any financial risk for any specified covered injectable medications and adult vaccines that are administered in the office of a physician and surgeon or prescribed by a physician and surgeon for self-administration by the patient. Requires these items to be reimbursed on a fee-for-service basis at the negotiated contract rate or through an alternate funding

mechanism mutually agreed to by the health plan and the health care service provider, subject to any applicable copayment or deductible, by the health plan. [HSC §1375.8]

3) Permits a health care service provider to assume financial risk for the items described in #4 above after making the request in writing at the time of negotiating an initial contract or renewing a contract with a health plan. Prohibits a health plan from requesting or requiring as a condition of the contract agreement a health care service provider to assume the financial risk for any of those items. [HSC §1375.8]

This bill:

1) Prohibits a health plan/insurer or its designee (such as a medical group, pharmacy benefit manager, or other designee) from arranging for or requiring a vendor (pharmaceutical manufacturer, pharmaceutical distributor or pharmacy) to dispense an infused or injected medication directly to a patient with the intent that the patient will transport the medication to a health care provider for administration. Indicates a vendor is not an integrated health system's internal pharmacy that dispenses a patient's prescription medical and transports the product to the health system's location of drug administration.

2) Defines an infused or injected medication as an outpatient prescription medication or biologic, other than a vaccine, that cannot reasonably be self-administered by the patient or other individual assisting the patient, and is typically administered by a licensed health care provider acting within the scope of their professional licensure in a physician's office, clinic, infusion center, or hospital outpatient department.

3) Prohibits a health plan/health insurer or its designee from requiring as a condition of coverage or payment, or offering as an incentive for, an infused or injected medication to be administered to an enrollee/insured in the enrollee's/insured's home unless the treating health care provider determines administration in the home setting is safe and appropriate.

4) Prohibits a health plan/health insurer or its designee from requiring, as a condition of coverage or payment, or offering an incentive for, an infused or injected medication to be supplied by a vendor specified by the plan/insurer or designee unless all of the following are true:

   a) The choice of drug, strength, or dose does not depend on the enrollee's same-day clinical presentation, the drug does not require adjustment based on the enrollee's weight, and the drug does not otherwise require same-day adjustment;
   b) The enrollee receiving the drug is 18 years of age or older;
   c) The drug does not require sterile compounding;
   d) The drug does not contain controlled substances;
   e) The federal Food and Drug Administration does not require a risk evaluation and mitigation strategy to manage known or potential serious risk or elements to assure safe use for the drug;
   f) The vendor is able to, and does, deliver the drug within the time period needed by the enrollee/insured, in the treating health care provider's reasonable medical judgment;
   g) The vendor provides appropriate cold chain logistics or another ability to ensure that drugs remain at the appropriate temperature through all stages of supply, shipping, and storage;

h) The vendor complies with the federal Drug Supply Chain Security Act's product tracing requirements applicable to wholesale distributors and all other statutes, regulations, and guidance regarding drug tracking, dispensing, and redispensing;
i) The vendor is accredited by a nationally recognized accreditation organization and maintains 24-hour-per-day, 7-day-per-week pharmacist availability for health care providers and patients to ask questions;
j) The vendor notifies the receiving hospital pharmacy, clinic, physician's officer, or infusion center, as applicable, of the expected date and time of arrival of the drug and of any shipping delays;
k) If applicable, the plan/insurer notifies the enrollee/insured in advance that a vendor will call the enrollee/insured to obtain billing information for any cost-sharing amount; and requires the plan/insurer to provide the name of the vendor and the cost-sharing amount to the enrollee/insured;
l) The health plan/insurer or designee allows the treating health care provider to administer the medication to the enrollee/insured and reimburses the provider for the medication at the contracted rate. Requires reimbursement for the medication to be separate from the administration fee, which reimburses the provider for the services and other supplies needed to infuse or inject the medication;
m) Administration of a drug procured in this manner does not violate any state or federal law; and,
n) The health plan/insurer obtains the enrollee's/insured's, or the enrollee's/insured's legally authorized representative's, consent for the infused or injected medication to be supplied by a vendor selected by the plan/insurer.

5) Requires a health plan/insurer or designee that implements a policy requiring, as a condition of coverage or payment, that an infused or injected medication be supplied by a specified vendor to provide written notification to the treating health care provider, the entity authorized to contract for the provider's services, and the facility in which the provider administers the medication, at least 45 business days in advance of the effective date of the proposed change.

6) Permits the treating health care provider, the entity authorized to contract for the provider's services, and the facility in which the provider administers the medication the right to negotiate this material change to the contract. Requires, if the parties to the contract cannot agree, any party to have the right to terminate the contract before the implementation of the change.

7) Prohibits a health plan/insurer or its designee from interfering with the enrollee's/insured's right to obtain a covered, medically necessary infused or injected medication from a participating provider of the enrollee's/insured's choosing. Prohibits a health plan/insurer or its designee from refusing to authorize or approve, exclude coverage for, deny payment for, or offer an incentive for, an infused or injected medication administered by a participating provider based on the site of service, whether the site is a physician's office, clinic, infusion center, or hospital outpatient department.

8) Requires, if a health plan/insurer opts to require an infused or injected medication to be supplied by a specified vendor as permitted in 3) above to implement a patient-specific exception process. Requires this process to be initiated when the treating health care provider submits to the plan/insurer a letter stating that, in the provider's reasonable medical judgment, it is unsafe or inappropriate for the enrollee to receive the medication from the

plan or designee's vendor based on the drug characteristics, profile and stability of the medication, required storage and preparation conditions, side-effect management protocols, prior history of adverse reactions, or other patient characteristics.

9) Requires the health plan/insurer or designee to conduct or arrange for a review by a pharmacist and a practicing physician in the same or similar specialty who treats the medical condition or provides the treatment for which the particular medication is used. Requires the health plan's or designee's review to be completed within seven calendar days of the provider's submission of the relevant enrollee information, or within 24 hours if the enrollee's discharge from an inpatient facility will be delayed until the infused or injected medication is available.

10) Requires, if either the reviewing pharmacist or reviewing physician determines, or if the reviewing pharmacist and reviewing physician agree, that the enrollee/insured is not likely to be able to be safely and appropriately treated with the drug from the plan's/insurer's vendor within the time period needed by the enrollee/insured, in the treating health care provider's reasonable medical judgment, the plan/insurer or designee to reimburse the health care provider for the medication and its administration at the contracted rate. Requires the health plan/insurer to inform all contracting providers how to initiate the exception process, if the provider's scope of practice authorizes them to prescribe infused or injected medications.

11) Requires the plan/insurer or designee that requires, as a condition of coverage or payment, prior authorization for an infused or injected medication to provide written notification of approval or denial of the prior authorization request to the enrollee/insured and the treating provider within the limits prescribed in existing law related to prior authorization.

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

COMMENTS:

1) *Author's statement.* According to the author, this bill ensures that patients with complex and life-threatening illnesses who need specialty, infused or injected medications administered by a doctor or nurse, such as chemotherapy, can receive the necessary medication in a safe, timely manner. This bill does not prohibit the current practice of requiring hospitals and physicians to order specialty medications from a third-party pharmacy, but rather sets appropriate guardrails to ensure patient safety and medication integrity.

2) *Drug trends.* According to IQVIA's 2023 outlook report the global pharmaceutical market will exceed $1.5 trillion by 2023 growing at a 3−6% compound annual growth rate over the next five years. The key drivers of growth will continue to be the U.S. and pharmerging markets with 4−7% and 5–8% compound annual growth, respectively. In the U.S., overall spending growth is driven by a range of factors including new product uptake and brand pricing, while it is offset by patent expiries and generics. New products and losses of exclusivity will continue to drive similar dynamics across developed markets, while product mix will continue to shift to specialty and orphan products. An average of 54 new active substance launches per year are expected over the next five years and two-thirds of launches will be specialty products, lifting specialty share of spending to near 50% by 2023 in most developed markets. At the same time, the impact of losses of exclusivity in developed markets is expected to be $121 billion between 2019 and 2023, with 80% of this impact, or $95 billion, in the U.S. By 2023, biosimilar competition in the biologics market will be nearly three-times larger than it is today. This will result in approximately $160 billion in

lower spending over the next five years than it would have if biosimilars did not enter the market.

3) *Background on white bagging.* The National Association of Pharmacy Boards (NAPB) describes “white bagging” as the distribution of patient-specific medications from a pharmacy, typically a specialty pharmacy, to the physician’s office, hospital, or clinic for administration. It is often used in oncology practices to obtain costly injectable medications that are distributed by specialty pharmacies and may not be available in all non-specialty pharmacies. “Brown bagging” is the dispensing of medication from a pharmacy (typically a specialty pharmacy) directly to a patient, who then transports the medications to the physician’s office for administration. In a 2018 report on these topics, the NABP indicates that as the specialty pharmacy model becomes more prevalent more patient care will be subject to white and brown bagging under mandates by third party payers. The NAPB concluded that there is a legitimate patient protection issue when a specialty drug is distributed to an entity other than the patient.

   The Pharmaceutical Care Management Association (PCMA) explains five steps to white bagging dispensing:

   a) First, the prescription is received by the specialty pharmacy by the prescriber through a secure electronic hub. The prescription is reviewed for drug interactions and other clinical safety concerns;
   b) Second, the specialty pharmacy reaches out to the patient or caregiver to answer any questions, confirm the patient’s consent, affirm the manner of dispensing, site of administration, and appointment date, including any pre-testing and other clinical safety reminders, and discuss patient cost sharing and if needed, financial support;
   c) Third, once confirmed with the patient, the specialty pharmacy contacts the provider where administration will take place to confirm patient details, the date of administration, and when the provider is available to receive the package;
   d) Fourth, the specialty pharmacy mails the prescription to the provider or hospital overnight using temperature-controlled or sensitive packaging in line with U.S. Pharmacopeia guidelines. The provider receives the shipped package and signs a receipt to ensure chain of custody, pursuant to federal Drug Supply Chain Security Act requirements; and,
   e) Fifth, the prescription is administered by the provider to the patient.

4) *California Pharmacy Board.* On February 18, 2021, the Enforcement Committee of the California Board of Pharmacy met to hold a public discussion on white and brown bagging. Presenters at this meeting raised many concerns that white bagging and brown bagging were in conflict with hospital and pharmacy regulation and provided examples of delays in care to patients. A representative of DMHC also attended this meeting and indicated that DMHC does not have the authority to prohibit white bagging as long as the practice does not harm enrollees or impact enrollees’ ability to receive medically necessary care.

5) *Double referral.* Should this bill pass out of this committee it will be referred to the Senate Committee on Judiciary.

6) *Support.* This bill is sponsored by the California Hospital Association (CHA), which writes that some health plans require physicians and hospitals to order medication from a third-party vendor contracted with the health plan, on a patient-by-patient basis, instead of using

medication the hospital or physician's offices have in stock. As such, these policies threaten patient and medication safety since they are not part of a hospital's or physician's office's quality control protocols, the provider has no way of assuring drug integrity. In addition, if medications are not delivered in a timely manner or have to be re-ordered due to same-day clinical presentations, patient care can be delayed, causing them unsafe and undue stress. For more complex medications, to ensure the highest quality product, increased care and attention are crucial to ensuring product quality control is required. Specialty drugs that are compounded, or that require a clinical assessment before infusion to ensure proper strength and dosage, are especially difficult to order from a third-party vendor because what was ordered may not be what is needed at the point of care. Instead of administering available medication from their stock, providers must request them from these third-party vendors. If the vendor is unable to deliver the medication, the patient must return on a different day for the infusion. Delaying treatment may put the patient's health at risk because many complex treatment plans involving infused medications are time sensitive, will likely lead to patient distress, and may impact the patient's overall treatment plan. CHA writes white bagging may present an initial cost savings to health plans, increased costs for hospitals and physician's offices to manage inventory on a patient-by-patient basis, plus the real patient costs of delayed care and disease progression both outweigh and potentially cancel any savings to the health care system. The California Council for the Advancement of Pharmacy writes too often, and for cost effective purposes, pharmacy benefit managers and/or health insurers require medically fragile patients to take their injectable/infused medicines to their appointment with a physician's office or outpatient hospital facility for treatment. This practice, known as white bagging, puts the patient in jeopardy because there is no quality assurance during the transport of the meds (for example, temperature sensitive drugs); however, if the same medication is already stored properly at the outpatient facility or doctor's office, then quality is not compromised for both the patient and the drug. White bagging is not necessarily a bad option for oral medications, but in the instance of injectable and infused specialty drugs, the practice of white-bagging puts the patient in a potentially health-compromised position. The Children's Specialty Care Coalition writes many patients with serious and life-threatening diseases need medications that are infused or injected at an outpatient hospital facility or in a doctor's office. Health care providers keep these specialty medications in stock, so that they are available in the form and dose whenever needed by a patient, and take primary responsibility for patient and medication safety. For more complex medications, to ensure the highest quality product, increased care and attention are crucial to ensuring product quality control is required. Specialty drugs that are compounded, or that require a clinical assessment before infusion to ensure proper strength and dosage, are especially difficult to order from a third-party vendor because what was ordered may not be what is needed at the point of care. Instead of administering available medication from their stock, providers must request them from these third-party vendors. If the vendor is unable to deliver the medication, the patient must return on a different day for the infusion. Delaying treatment may put the patient's health at risk because many complex treatment plans involving infused medications are time sensitive, will likely lead to patient distress, and may impact the patient's overall treatment plan.

7) *Oppose.* The California Association of Health Plans, Association of California Life and Health Insurance Companies, America's Health Insurance Plans (AHIP) and PCMA (opponents) write that the drugs to which this bill applies are high-priced medications that treat complex, chronic, or rare conditions (e.g., cancer, multiple sclerosis, rheumatoid arthritis) and cannot be safely administered by a patient or their caregiver. They can have special handling and/or administration as these include most biologic drugs. Both the number

and price of specialty drugs have rapidly increased in recent years, and specialty drugs are a leading contributor to drug spending growth. The price of a specialty drug can range from thousands to ten thousands of dollars per regimen. An AHIP study found that costs per single treatment for drugs administered in hospitals were an average of $7,000 more than those purchased through pharmacies. Hospitals, on average, charged double the prices for the same drugs, compared to pharmacies. Physician offices charged 22% higher prices for the same drugs on average. Specialty pharmacies are different from traditional "brick and mortar" pharmacies because they focus on dispensing drugs that retail pharmacies are not equipped to dispense. Specialty pharmacies typically ship products directly to clinicians just like a manufacturer or wholesaler would. They must abide by all state and federal legal and regulatory requirements, including chain of custody tracking in addition to meeting extra safety requirements for specialty drugs imposed by the FDA and drug manufactures. According to the opponents, specialty pharmacies are used only for prescription drugs that may be safely delivered this way, and they are on the hook for the cost of these very expensive drugs due to spoilage, delays, mishandling and therefore have every incentive not to waste any products. Delays can occur for individual patient deliveries in the same way delays can occur for hospitals or physician office deliveries. Health plans build additional safety features to avoid patient harm. Health plans always have exception processes in place to address circumstances of quality, safety, medical necessity, and/or care interruption. Often times medications are shipped with enough additional supply so that facilities can adjust a dose as needed at the time of administration. Opponents also write this bill allows a provider to unilaterally initiate the patient-specific exception process to white bagging without notice to or approval from the patient. Because of the great cost differential between drugs provided by a specialty pharmacy and those provided by the hospital or physician's office opponents strenuously object to this provision that allows the provider to make unilateral requests to protect their profits. Furthermore, opponents have concerns about the provision in the exception process that requires a health plan or insurer to arrange for the request to be reviewed by a pharmacist and a practicing physician in the same or similar specialty who treats the medical condition or provides the treatment for which the particular medication is used. While health plans typically involve specialty physicians in their decision-making process (either through physician advisory committees or similar outreach) it may not be reasonable, nor may it be necessary, to have a physician certified in the same specialty available to review these requests.

SUPPORT AND OPPOSITION:

Support: California Hospital Association (sponsor)
Adventist Health
Alliance of Catholic Health Care
American Academy of Pediatrics
California Children's Hospital Association
California Council for the Advancement of Pharmacy
California Life Sciences
California Pharmacists Association
California Rheumatology Alliance
California Society of Health System Pharmacists
Cedars-Sinai
Centinela Hospital Medical Center
Children Now
Children's Specialty Care Coalition

City of Hope National Medical Center
Coast Plaza Hospital
Dignity Health
District Hospital Leadership Forum
Encompass Health Rehabilitation Hospital of Bakersfield
Henry Mayo Newhall Hospital
Huntington Hospital
John C Fremont Healthcare District
John Muir Health
Kaweah Delta Healthcare District
Lucile Packard Children's Hospital
Marshall Medical Center
PIH Health
Rady Children's Hospital San Diego
Sacramento Behavioral Healthcare Hospital
Santa Rosa Behavioral Healthcare Hospital
Sierra View Medical Center
Stanford Health Care
Tahoe Forest Health System
Tenet Health
The Association of California Healthcare Districts
United Hospital Association

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

-- END --