# SENATE COMMITTEE ON APPROPRIATIONS
**Senator Anthony Portantino, Chair**
**2021 - 2022 Regular Session**

**SB 958 (Limón) - Medication and Patient Safety Act of 2022**

**Version:** April 18, 2022
**Urgency:** No
**Hearing Date:** May 2, 2022
**Policy Vote:** HEALTH 8 - 0
**Mandate:** Yes
**Consultant:** Samantha Lui

**Bill Summary:** Senate Bill 958 would enact the Medication and Safety Act of 2022, which would establish a framework for how, and whether, a health plan or health insurer, or its designee, can dispense an infused or injected medication directly to a patient.

**Fiscal Impact:**

- Department of Managed Health Care (DMHC). The DMHC estimates the total cost of this bill to be approximately $619,000 Managed Care Fund (MCF) and 2.9 PYs in FY 2022-23, $868,000 MCF and 3.3 PYs in FY 2023-24, $935,000 MCF and 3.5 PYs in FY 2024-25, $931,000 MCF and 3.5 PYs in FY 2025-26 and annually thereafter. All costs associated would be incurred by the Managed Care Fund (MCF) and covered through fees assessed on health plans.

- Department of Insurance (CDI). The CDI estimates $11,000 FY 2022-23, $20,000 FY 2023-24, $10,000 FY 2024-25 for CDI to revise policy forms, policies and procedures, and provider contracts, and to review the revised documents when submitted.

**Background:** 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. On February 18, 2021, the Pharmacy Board's Enforcement Committee 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.

**Proposed Law:** SB 958 would including the following provisions, among others:

- Prohibits a health plan or health insurer, or its designee, from requiring a vendor 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.

- Authorizes a health plan or health insurer, or its designee, to arrange for an infused or injected medication to be administered to an enrollee in the enrollee's

home when the treating health care provider and patient determine administration in the home setting is in the best interest of the patient. The treating health care provider must document the reasons in the patient's medical record.

- Prohibits a health plan or health insurer, or its designee from requiring, as a condition of coverage or payment, and must not offer an incentive for, an infused or injected medication to be supplied by a vendor specified by the plan or designee unless specified conditions are met.

- Requires a health plan or health 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.

- Prohibits a health plan or health insurer, or its designee, to interfere with the enrollee's right to obtain a covered, medically necessary infused or injected medication from a participating provider of the enrollee's choosing.

- Prohibits a health plan or health 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.

- Requires a health plan or health insurer, or its designee, to implement a patient-specific exception process if the plan or insurer opts to require the medication be supplied by a specified vendor, and submits 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. Requires the provider to document the reasons for their determination in the patient's medical record.

- Requires a health plan or health insurer, or its designee to conduct or arrange for a review by a pharmacist and a practicing physician, which must be completed within seven calendar days of the provider's submission of the relevant enrollee information.

    - The review must be completed within 24 hours if the enrollee's discharge from an inpatient facility will be delayed until the infused or injected medication is available.

    - If either the reviewing pharmacist or reviewing physician determines, or if the reviewing pharmacist and reviewing physician agree, that the enrollee is not likely to be able to be safely and appropriately treated with the drug from the plan's vendor within the time period needed by the enrollee, in

the treating health care provider's reasonable medical judgment, the plan or insurer, or designee, must reimburse the health care provider for the medication and its administration at the contracted rate.

- The bill requires the health care service plan and 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

- A health care service plan or designee that requires, as a condition of coverage or payment, prior authorization for an infused or injected medication shall provide written notification of approval or denial of the prior authorization request to the enrollee and the treating provider within specified time limits.

- A physician's office, clinic, infusion center, or hospital outpatient department that supplies and administers an infused or injected medication to an enrollee pursuant to this section shall obtain the enrollee's consent and disclose a good faith estimate of the enrollee's applicable cost-sharing amount.

- Provides that health plan or insurer is not required to cover any new or additional benefits.

**Staff Comments:**

CalPERS. Staff estimates unknown impact to CalPERS health plan premiums, as CalPERS spent approximately $10 billion in 2020 to purchase health benefits for approximately 1.5 million members. Of that, over $2 billion is spent on prescription drugs, including tens of millions annually for physician-administered infused or injected drugs.

DMHC. The bill's costs would be incurred by different units within the DMHC as described below.

- Office of Legal Services (OLS). $36,000 and 0.2 PY in FY 2022-2023 only for short-term workload to conduct legal research, issue a legal memorandum and draft an All-Plan Letter to clarify the bill's requirements.
- Office of Plan Licensing (OPL). $227,000 and 1.0 PY in FY 2022-23, $119,000 and 0.5 PY in FY 2023-24, $45,000 and 0.2 PY in FY 2024-25 and annually thereafter, for workload to review Evidence of Coverages, disclosure forms, policies and procedures, subscriber contracts, provider and "designee" contracts and other health plan documents for compliance with the requirements.
- Office of Plan Monitoring (OPM) $222,000 and 1.0 PY in FY 2022-23, $610,000 and 2.1 PYs in FY 2023-24, $638,000 and 2.1 PYs in FY 2024-25 and annually thereafter. These costs include consultant funding in the amount of $14,000 in FY 2022-23, $167,000 in FY 2023-24, $212,000 in FY 2024-25 and ongoing for additional workload to review health plan filings of utilization management process for infused and injected medications, work with other DMHC programs to develop all plan letters to provide guidance to health plans, revise various policies and procedures and revise existing survey methodology and tools.

- Help Center (HC). $65,000 and 0.4 PY in FY 2022-23, $68,000 and 0.4 PY in FY 2023-24, $65,000 and 0.4 PY in FY 2024-25 and annually thereafter for increased workload associated with increased volume of consumer complaints.
- Office of Enforcement (OE). $68,000 and 0.3 PY in FY 2022-23, $70,000 and 0.3 PY in FY 2023-24, $186,000 and 0.8 PY in FY 2024-25 and annually thereafter. These costs also include $1,000 annually for legal software licensing costs beginning in FY 2024-25 and ongoing. This workload assumes seven referrals from the Help Center in FY 2022-23 and FY 2023-24, and 15 referrals from the HC and OPM beginning in FY 2024-25 and ongoing.
- Office of Technology and Innovation (OTI). $1,000 in FY 2022-23 and the same amount annually thereafter for annual software licensing costs for access to the Necessary Infrastructure Modernization for Business Unified Services (NIMBUS) platform for employees.

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