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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

To: Board Members

Agenda Item IV: Discussion and Consideration of Senate Bill 958 (Limon) Medication and Patient Safety Act of 2022

Version: As Amended April 18, 2022
Status: Referred to Assembly Health Committee
Committee Analysis: Senate Floor Analysis
Summary: Provides legislative findings and declaration surrounding patient care issues involving practices of health care service plans, indicating that certain practices inappropriately restrict Californian's access to critical medications including high-quality infusion and injection services. This bill addresses both "brown bagging" and "white bagging". The bill states that it is the intent of the Legislature to ensure that infused and injected medications and related services remain available to all Californians who need them. This bill is entitled the Medication and Patient Safety Act.

In the "brown bagging" area, the bill would:

1. Prohibit a health care service plan from arranging with 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.
2. Prohibit a health care plan or its designee from requiring as a condition of coverage or payment, or offer any incentive for an infused or injected medication to be administered at the enrollee's home unless the treating health care provider determines that administration in the home setting is safe and appropriate.

In the "white bagging" area, the bill would prohibit a health care service plan or its designee from arranging for or requiring as a condition of coverage, for an infused or injected medication to be supplied by a vendor specified by the plan unless several conditions exist. The conditions include:

1. The medication does not require adjustment based on the enrollee's weight and the drug does not require adjustment based on the enrollee's weight and the drug does not require same-day adjustment.
2. The enrollee is at least 18 years of age.

3. The drug does not require sterile compounding.
4. The drug does not contain controlled substances.
5. The FDA does not request a risk evaluation and mitigation strategy to manage known or serious risk or elements to assure safe use for the drug.
6. The vendor is able to deliver the drug within the time period needed to treat the patient and provides appropriate cold chain logistics.
7. The vendor complies with the federal drug tracing requirements applicable to wholesale distributors and all other statutes, regulations and guidance regarding drug tracking, dispensing and redispensing.
8. The vendor is accredited by a nationally recognized accreditation organization and maintains 24 hour/day, 7 day-per-week pharmacist availability.
9. The vendor notifies the receiving hospital of the expected date and time of arrival and identification of any shipping delays.
10. The Plan or designee allows the treating health care provider to administer the medication and reimburses the provider for the medication.
11. Administration of the drug received in this manner does not violate any state or federal law.
12. The Plan obtains the enrollee's consent to receive the medications in this manner.

The bill also would prohibit a plan or its designee from interfering with the insured's right to obtain a covered, medically necessary infused drug or injected medication from a participating provider of the insured's choosing. It also would prohibit a plan or its designee from refusing to authorize, approve or exclude coverage for an infused or injected medication administered by a participating provider based on the site of the service. In addition, the bill provides several definitions including "vendor." Vendor is defined as a pharmaceutical manufacturer, pharmaceutical distributor, or pharmacy. "Vendor" does not mean an integrated health system's internal pharmacy that dispenses a patient's prescription medication and does not transport the product to the health system's location of drug administration.

Board Position: Watch

Prior Discussion: As part of the April 2022 Meeting, members noted that In February 2021, the Enforcement and Compounding Committee convened an informational hearing on "White Bagging." During this

hearing stakeholders shared challenges with the practice of white bagging and its negative impacts to patient care.

The Legislation and Regulation Committee offered a recommendation to establish a support if amended position, with amendments related to costs and establishment of a threshold after which a confirmed number of violations are identified by a particular vendor, that a Plan may not longer use that vendor. The Committee noted that the Board's primary jurisdiction is medication safety, patient safety and consumer protection.

However, during the Board Meeting, in response to public comments about potential unknown costs, members established a watch position on the measure. Since that time, the Senate Appropriations Analysis was released which indicates the Department of Managed Care and the Department of Insurance will incur costs to implement the provisions which appear to be about $1,000,000 annually. The measure passed out of the appropriations committee and ultimately referred to the Assembly.

Further, subsequent to the meeting, written comments were received in support of the measure. Included in the written comments are examples of patient safety issues that arise from white bagging including suboptimal therapy due to care delays and compromised drug integrity as well as cost information.

For Member Consideration:
Given the significance to the Board's consumer protection mandate, and in light of the available fiscal information, it appears appropriate to allow the Board an opportunity to determine if a change from the established Watch position, to one of support or support if amended is consistent with the Board's consumer protection mandate.

Following this memo is a copy of the written comments received.

May 2, 2022

Seung Oh, PharmD, President
Anne Sodergren, Executive Officer
California State Board of Pharmacy
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Re: SB958 – The Medication and Patient Safety Act

Dear Dr. Oh and Ms. Sodergren,

Regretfully, I was unable to attend the recent Legislation/Registration Committee and Full Board meetings due to meeting conflicts. As a result, I was not present for the discussions surrounding the potential impact of SB958 – The Medication and Patient Safety Act. However, I was informed of the discussion this past week including the comments by my colleague, Steve Gray, Pharm.D., and would like to provide my perspective on the issues raised.

With respect to Dr. Gray's comment that white bagging has been associated with minimal issues over the years, I have provided examples of patient safety issues reported by 6 healthcare institutions in California, including 2 children's hospitals. I don't believe these issues can be described as having a minimal impact on patient safety, since as the examples below illustrate, white bagging poses a significant threat to patient outcomes. These issues persist despite providers/hospitals' continued efforts to educate payors and collaborate on cost-effective practices that would provide high quality patient care.

Patient Safety Concerns	**Brief Summary**
Suboptimal Therapy due to Care Delays	Patient with brain cancer and melanoma had a one-week gap in treatment while waiting for white bagged medication to arrive, resulting in physician changing treatment from infusion to oral therapy to avoid further therapy delay.
	Patient with a white bagged medication arrived for treatment but medication was not delivered, causing treatment delay.
Patient and/or Caregiver Burden	Patient who has been receiving maintenance treatment with a white bagged medication had to spend considerable time coordinating with outside pharmacy for the prescribed medications. Patient treatment was delayed by 2 weeks.
	Patient with developmental delay has been maintained on a white bagged medication for treatment of his complex conditions. Patient's mother spends a considerable time coordinating with specialty pharmacies for timely delivery of medications each month.

	Patient with neuroendocrine tumor medication on a white bagged medication had a two-month gap in treatment due to the inability to afford their share of cost after conversion from medical benefit to pharmacy benefit per payer mandate.
	Patient with liposarcoma on a white bagged medication for treatment was pending hospital discharge after chemotherapy treatment. Patient was unable to receive medication from a payor-contracted specialty pharmacy causing delays in discharge. The prescription was sent 2-3 weeks prior to discharge.
Compromised Drug Integrity	67 yo patient diagnosed with ulcerative colitis needing vedolizumab (Entyvio), a white bagged medication that was delivered to a hospital pharmacy expired.
	72 yo patient with bone metastases from solid tumors taking denosumab (Xgeva), a white bagged medication that was delivered to the wrong site within the hospital. The unlabeled boxes were left outside a warehouse unrefrigerated, with no label to indicate the intended receiving department. Medication was wasted and the patient had to wait for approval and delivery of a new shipment.
	64 yo patient with rheumatoid arthritis needing infliximab (Remicade), a white bagged medication that was delivered with no label to indicate the intended receiving department. Medication administration was delayed, and patient had to be rescheduled.

White bagging conflicts with patients' rights since patients may not be aware that the drugs being administered don't come from the hospital and the integrity of the drugs cannot be verified. Additional patient safety challenges associated with white bagging include:

1. Delays in care: diseases and conditions that require drug infusions require same day treatment decisions due to the critical condition of the patients. Hospitals and providers' offices have medication readily available to support timely and safe treatment as delays can be life threatening (e.g., transplant organ rejection, cancer progression or hospitalization).
2. Disruptions in the medication ordering process: White bagging introduces risks of errors as evidence-based drug therapy plans are built into the electronic health records (EHRs) to support patient safety. These drug therapy plans are not available when prescriptions are e-prescribed. As a result, each therapy for cancer and complex diseases needs to be ordered in both the EHR and from the specialty pharmacy increasing the burden on physicians and increasing the risk of errors
3. Inability to manage drug recalls.
4. Approximately 70% of white-bagged medications are intravenous infusion requiring sterile compounding prior to administration. Per California State Board of Pharmacy law, a written master formula must be prepared prior to compounding every medication for each patient.
5. Inability to leverage safety technologies (e.g., barcode scanning) to ensure safety.

Dr. Gray also commented that SB958 would result in "billions of dollars" in increased expenditures "across all aspects of healthcare". We were unable to find the source for this information.

Dr. Gray's also stated that white bagging has been the process for years. The white bagging practice has substantially expanded over recent years and the COVID-19 pandemic appears to have accelerated this shift from the traditional buy-and-bill practice. Health plans are moving the management of these drugs to specialty pharmacies as part of newer vertically integrated health care delivery business models. The share of medications required by payors to be white bagged has grown significantly. For example, UnitedHealthcare® has expanded the number of specialty and oncology supportive drugs by almost 50% under their UnitedHealthcare®'s Medication Sourcing Expansion Policy in 2021.[1]

With respect to Dr. Gray's statement that SB958's goal is to allow hospitals to charge payors "whatever markup they decide" and that hospitals are using these medications as "profit center/cash cows" to cover other hospital costs. The goal of the bill is patient safety and not profit. The final reimbursement amounts paid to hospitals and providers for services rendered are based upon negotiated rates within contractual agreements with health plans. These rates are much less than hospital charges.

One of the reasons health plans have moved to white bagging is because specialty drugs are expensive with an average cost of $7,000/month and also represent a new source of revenue**.** Over recent years, health plans and specialty pharmacies have become part of an integrated strategy to manage patient care and increase profitability. For example, UnitedHealth Group®'s Optum® business unit which includes their specialty pharmacy program and CVS Health® which is the parent of Aetna®. UnitedHealth Group®'s posted increased profit for the first quarter of 2022 and double-digit revenue growth of 18.9% from Optum®, which operates its specialty pharmacy.[2] In 2021, UnitedHealth Group® grew more than $30 billion (11.8%) to $287.6 billion year-over-year, Optum® has attributed specialty pharmacy as a driver of its increased profitability.[3] CVS Health® also reported double-digit revenue and net operating income in 2021, representing 10.1% and 20.6% respectively in the 4th quarter, citing growth in specialty pharmacy as a contributing factor. CVS® total revenue in 2021 was over $290 billion.[4]

This record profit has not resulted in decreased patient out of pocket costs. Many patients struggle with high copays and forgo getting essential medications to treat cancer and other diseases. Additionally, white bagging creates additional burden to patients to schedule essential treatment around when the medications will be delivered.

In contrast to health plans which generate double-digit revenue and profits, California hospitals continue to experience financial losses each year, with as much as $8 billion lost in 2021.[5] Hospitals across the nation have reported spending an estimated $310 million due to white and brown bagging payor practices alone.[6] The vast majority of hospitals in California are non-profit/governmental organizations[7] providing care for:

- A growing number of uninsured and underinsured patients,
- Over 160,000 experiencing homelessness,

- An aging population that is projected to increase three times faster than the total population with almost half of adults over 60 years old expected to have at least one chronic disease,[8,9]
- An increasing number of patients with complex diseases requiring hospitalization and
- A significant increase in hospital patients who also have behavioral health issues with limited places where they can be treated.[8,9]

These complex patients tend to stay in the hospital longer and have significantly increased costs which hospitals absorb. The recent workforce shortages as a result of the COVID-19 pandemic have also significantly increased hospital expenses. Furthermore, regulatory requirements to support patient care such as mandatory nursing ratios, construction and maintenance of sterile compounding facilities are funded by hospitals. Therefore, it would be inaccurate to state that the difference between what hospitals pay for outpatient specialty medications and what they charge is "profit".

Dr. Gray further reported that the conditions under which white bagging would be permitted under SB958 are "so lopsided that the payors would not be able to meet them". These conditions focus on 4 important aspects of patient care: 1) patient consent to the white bagging practice, 2) medication availability at the right dose and at the right time to safely treat patients, 3) safe coordination of care, and 4) patient and medication safety. These conditions remain centered around the quality and safety of care for our patients. It is unclear why Dr. Gray refers to these as "lopsided".

In summary, after careful review of Dr. Gray's comments, I must respectfully disagree with his determination of the impact of SB958. Dr. Oh often reminds us during Board meetings that the goal of the State Board of Pharmacy is to protect the health and safety of Californians. SB958 aims to eliminate the numerous safety issues experienced with white and brown bagging practices that payors instituted to increase their profitability. I am available to answer any questions you or other Board members or staff may have on SB958. I hope that this important safety bill will receive the Board's full support after considering its benefits to Californians. Thank you for your time.

Sincerely

Rita Shane, PharmD, FASHP, CSHP

Vice President and Chief Pharmacy Officer

Cedars-Sinai Health System

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