July 16, 2021

Kim Kirchmeyer, Director

Department of Consumer Affairs

1625 North Market Blvd., Suite N 112

Sacramento, CA 95834

**SUBJECT: White Bagging Concern**

Dear Director Kirchmeyer:

Maintaining quality of care and safety for patients and staff is a guiding principle for all California hospitals, every day. Hospitals exist to serve their communities and are committed to providing high-quality patient care that addresses the challenges and opportunities of the future. Because the Department of Consumer Affairs similarly protects and serves California consumers, the California Hospital Association (CHA) is compelled to call to your attention a recent change in third-party payer practices — known as white bagging — that may jeopardize Californians’ health, safety, and well-being.

White bagging is a commercial payer policy that prioritizes profits over patient safety by requiring alternative methods of distribution and payment for certain costly specialty drugs. The drugs subject to these policies are not those typically dispensed by a retail pharmacy directly to a patient, but instead are administered by a clinician to a patient through injection or infusion in an outpatient setting. Traditionally, acquisition and payment for these drugs has been termed “buy and bill,” where the hospital purchases and stores drugs for general use, and payers reimburse the providers for the cost and administration of the drug.

In a white bagging policy, the commercial payer contracts with a third-party specialty pharmacy to purchase drugs, removing the hospital from the drug acquisition process. The outpatient setting in hospitals is typically an ambulatory infusion center, where traditional pharmaceutical acquisition supports the compounding and titrating needs of, for example chemotherapy patients, at the time of service.

The changes introduced by white bagging upset this important established system, potentially sacrificing patient safety and quality of care. They also disregard many guardrails in the medication administration and handling process that assure our patients’ safety. These negative impacts include:

* Drug integrity safeguards that conflict with state dispensing, furnishing, and repackaging regulations
* Drug supply chain disruption that prohibits a pharmacist from full disclosure of transaction information necessary to assure drug integrity before administration
* Disruption of provider just-in-time dose modifications based on patient point-of-care services needs, which can be life threatening

To illustrate the gravity of white bagging policies, consider these actual examples of compromised patient care:

1. Patient with hepatocellular cancer: Provider requests for new therapy were denied and patient was admitted for disease progression.

* Order placed: 10/6/2020
* Prior authorization denied: 11/6/2020
* Reconsideration request sent: 11/13/20
* Denial received: 11/16/2020

**IMPACT:** 40-day delay in therapy with resultant disease progression

2. Expired drug shipped: Retail pharmacy noted medication wasn’t expired, but it was.

**IMPACT**: Potential administration of expired drug with treatment delay

3. Patient with liposarcoma pending discharge: Unable to get medications shipped from mandated specialty pharmacy

**IMPACT:** Patient discharge delay

4. Patient with a neuroendocrine tumor: Unable to affordtheir share of cost as a result of the conversion from medical benefit to pharmacy benefit

**IMPACT**: Two-month delay in therapy

CHA and our member hospitals have actively advocated against this policy at many levels over the past year when the policy was first introduced. We met with the Department of Managed Health Care (DMHC) and submitted a letter of concern to the department in January 2021. We have also met with other concerned associations such as the California Children’s Hospital Association, the California Medical Association, California America’s Physician Groups, Association of Northern California Oncologists, and the American Cancer Society California. Most importantly, we worked closely with the Board of Pharmacy (BoP), which held an informational session in February with all related constituents. The BoP subsequently recommended at its April board meeting that we continue to educate ourselves and the public on the topic, track other state and jurisdictional activity related to white bagging, and report consumer safety issues to them and to DMHC.

We are closely watching legislative activity in five other states with pending legislation and in Louisiana, which unanimously passed legislation last month prohibiting white bagging.

CHA and its member hospitals are committed to safe, timely delivery of life-saving drugs. We share our concerns so that you are fully aware of the risk to California patients, and we welcome additional conversation to further clarify any of these public safety issues. Please don’t hesitate to contact me at (916) 206-8714.

Sincerely,

BJ Bartleson, RN, MS, NEA-BC

VP Nursing & Clinical Services

CC: Mary Watanabe, Department of Managed Health Care

Anne Sodergren, Board of Pharmacy