VAHP
VIRGINIA ASSOCIATION OF HEALTH PLANS

phone 804-648-8466 · address 1111 East Main Street, Suite 910, Richmond, VA 23219

email: info@vahp.org · website: www.vahp.org

May 18, 2021

The Honorable Scott White
Commissioner of Insurance
State Corporation Commission
1300 E. Main Street
Richmond, VA 23219

VIA EMAIL

Dear Commissioner White:

In response to the letter dated April 5 from the Virginia Hospital and Healthcare Association (VHHA) to the Bureau of Insurance regarding "white bagging," the Virginia Association of Health Plans (VAHP) would like to share the following information.

White bagging focuses on reducing the cost of certain specialty medications covered under a member's medical benefit and is part of health plan's long-term objective to reduce health care costs for the Virginian's we serve. Health plans cover the vast majority of these costs and play a vital role to help members who need specialty medications continue to receive the same high-quality drugs at more affordable costs. Some health plans have implemented white bagging programs through designated specialty pharmacy networks. Whatever the approach, the programs ultimately afford the member with significant cost savings while not impacting the site of service in which the specialty drugs are administered. Health plans help consumers access the right care, at the right time, and at the right place, while working to ensure the costs of health care are affordable.

The high costs of certain complex specialty medications administered in the office setting and hospital outpatient setting are the largest driver of rising costs for health plans and can cause members to reach quickly their deductible and out-of-pocket maximums. This creates a significant financial burden for patients. White bagging seeks to address the out-of-pocket costs members pay for certain specialty medications and allows for the out-of-pocket costs to be more spread out. Currently, the cost of certain specialty medications administered in the hospital outpatient setting can be approximately 200 to 300% more than when the same drug is administered in an office-based setting, with some providers charging over 500% more. Specialty drugs account for only 2% of drugs dispensed but represent nearly 45% of all prescription drug spending, a figure expected to rise to 52% by 2024, and over 60% of employers say drug and medical spending is unsustainable.

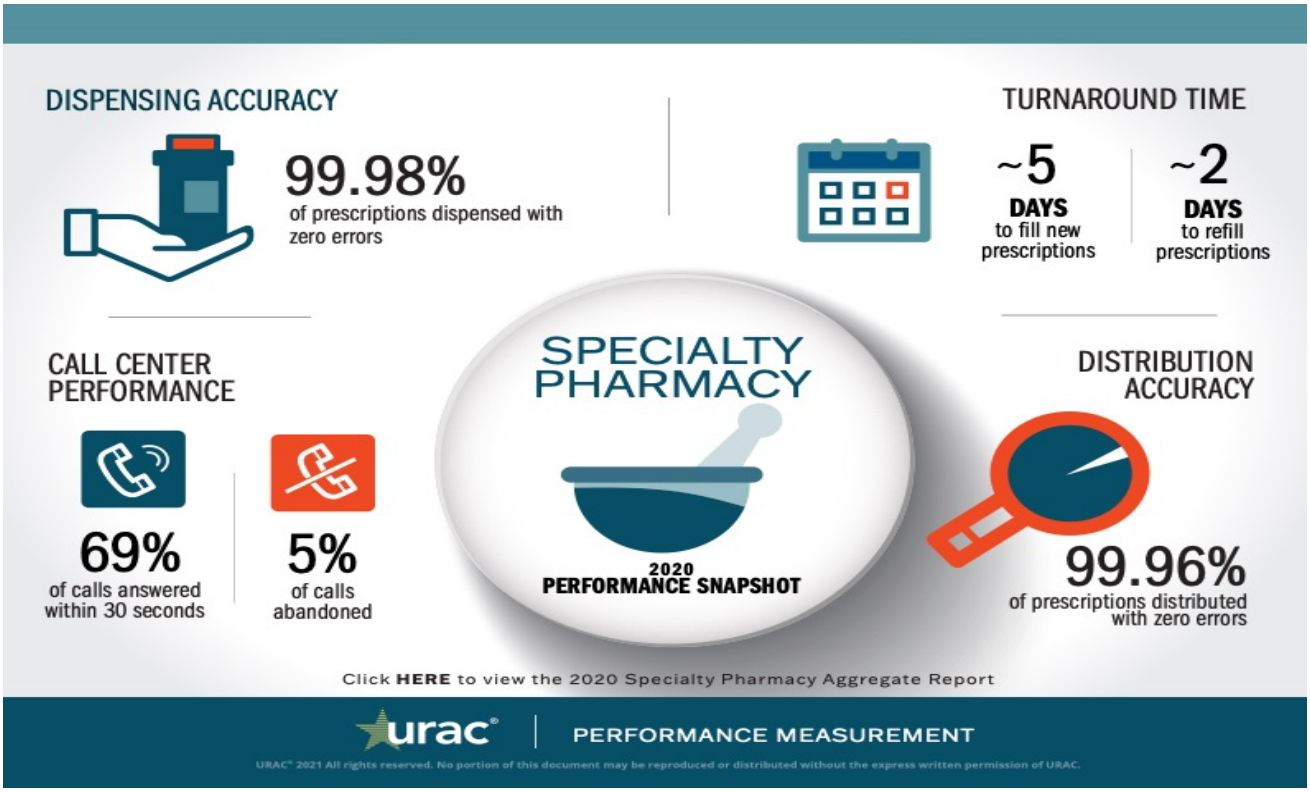
As background, the issue of "white bagging" has been discussed by the Board of Pharmacy for several years. In 2016 the National Association of the Boards of Pharmacy developed a definition for white bagging. In March 2016, a state workgroup developed to study pharmacy benefit manager practices, issued a report to the Secretary of Health and Human Resources. The workgroup recommended the Board of Pharmacy review the practice of white bagging and make any needed recommendations for patient safety. The Board of Pharmacy reviewed regulations adopted in other states, such as provisions from Oregon, which allow for white bagging with certain safeguards in place for reconstitution, labeling and accountability. In 2017, the Board of Pharmacy established a white and brown bagging workgroup. The workgroup developed and shared proposed regulations with the full Board, which were subsequently adopted by the Board.

In response to a comment suggesting that the Board of Pharmacy include language in the proposed regulations to establish "any willing provider" requirements in the regulations, the Board of Pharmacy responded "the Board (of Pharmacy) does not have the authority to regulate insurance companies or pharmacy benefit managers." The Board also commented that "…the Board recognizes that white bagging may assist patients access to medication when delivered in a restricted manner." Public documents also state that the "Board cannot prevent insurance companies or pharmacy benefit managers from requiring a patient to obtain the drug from a specialty pharmacy, but it can place requirements on the pharmacy for how those drugs must be delivered to the patient."

Regarding the comments made in VHHA's letter concerning pharmacy freedom of choice, our members believe the regulations are not being interpreted correctly. When a health plan sees the need to use white bagging to help reduce overall costs, including the member's out of pocket expense, through its specialty pharmacy, the health plan reaches out to the member to gain their consent. Health plans also notify members via a letter letting them know about changes to their programs, including any impending use of a specialty pharmacy and white bagging. Our members agree that the "pharmacy freedom of choice" statute was written to ensure patients could continue to access their pharmacy benefit at independent retail pharmacies. The statute was not written to apply to the outpatient hospital pharmacy. It is also the position of our members that currently patients do not have pharmacy freedom of choice when getting care in a hospital setting.

Responding to VHHA's suggestion that white bagging poses a patient safety risk because the hospital cannot track and therefore assure the drug was properly handled and maintained and delivered at the proper temperature; all health plan white bagging programs ensure specialty medications are handled appropriately during shipping and are safe to dispense. The majority of specialty medications stocked by specialty pharmacies require special handling. Specialty pharmacies have processes in place to ensure all medications are handled based on the manufacturer's recommendation. They work closely with manufacturers to determine the most effective method of shipping product and conduct FDA-approved storage tests to ensure stability at various temperatures. The specialty pharmacy uses the ambient temperature of the shipping and receiving destinations, along with the manufacturer's recommendation, to determine the optimal method and supplies for special handling and delivery. Additionally, in order to ensure product integrity for medications that require refrigeration during shipping, they have established standardized packaging and shipping guidelines for each of the product. These specifications have been validated and indicate handling requirements, such as the number of frozen gel packs and the type and size of the thermal shipping container. Packing specifications are adjusted for extreme temperatures in transit or at the destination location. Designated specialty networks work closely with one shipping company, like UPS, to ship a majority of the medications to

meet their handling requirements. Through partnerships with companies like UPS, designated pharmacy networks monitor the status of all medications scheduled for delivery, which includes monitoring for potential delays or lost packages. In the event the package is lost or mishandled, the designated specialty network works with the facility to ensure the members need is met. This is no different than what providers experience today. To ensure the medications are not tampered with packages are either self-sealing and require the recipient to pull a tab that tears open the package, or they are sealed with brown packing tape embedded with fibers. The tape must be cut in order for the recipient to open the box. In both instances, any tampering would be evident. Beyond required compliance with federal and state laws and regulations, health plans and their PBM's specialty pharmacies are all accredited by the Utilization Review Accreditation Commission (URAC). To become an accredited pharmacy, the specialty pharmacy must meet standards governing dispensing practices, including the storage, handling and distribution requirements. URAC accredited pharmacy standards are particularly rigorous and ensure the integrity of the medication regardless of whether the medication is shipped to a provider's hospital or to the health plan specialty pharmacy.



It is difficult for VHHA to argue that white bagging creates a breach of contract when their members significantly inflate the cost of specialty drugs year-over-year. White bagging is all about allowing Virginians to receive the same specialty drugs at reasonable rates. If a provider does not agree to afford Virginians with specialty drugs, the provider's claim for the specialty drug will be denied. Further, many hospitals opposed to white bagging and health plans use of specialty pharmacies acquire their drugs through the 340B program, a federal drug discount program offered to some hospitals. Hospitals purchase specialty drugs at the discounted 340B rate and then charge Virginians a marked-up price. While white bagging initiatives lower overall costs and especially patient costs, they still reimburse hospitals at rates that are generally greater than the cost these facilities pay to acquire the drug. Health plans use of specialty pharmacies and white bagging, prevents hospitals from continuing to

capture excessive margins on outpatient medications. Finally, our members ask that the Bureau remember that hospitals who wish to continue acquiring specialty drugs through their own suppliers may have an opportunity to do so if they agree to specific ASP price terms.

We want to assure the Bureau of Insurance that Virginia's health plans are in full compliance with existing laws and regulations regarding white bagging. Ultimately, the issues raised from the providers are not about patient safety or chain of control issues, they are about reimbursement. Provider's oppose the practice of white bagging because in inhibits their ability to increase their profit margin on specialty prescription medication. We respectfully ask that the Bureau take no action on the Virginia Hospital and Health Care Association's request that the Bureau assess whether or not "white bagging" is complaint with existing law and regulations.

We appreciate your attention to this matter.

Sincerely,

Doug Gray
Executive Director
Virginia Association of Health Plans