DANA-FARBER
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Health Policy Commission (HPC) Listening Session
Shifting Drug Distribution Channels / Brown & White Bagging
May 9, 2018

Good morning Commissioners - My name is Sylvia Bartel, and I'm the Vice President of Pharmacy and the co-chair of the Pharmacy & Therapeutics Committee at Dana-Farber Cancer Institute. I am a registered pharmacist with over 25 years of clinical experience specializing in oncology and currently serve on the Commonwealth's Pharmacy Advisory Committee within the Massachusetts Board of Registration in Pharmacy. On behalf of Dana-Farber, I appreciate the opportunity to comment on the significant patient safety concerns associated with the practices of brown and white bagging.

We'd like to thank the HPC for further examining these concerning practices and appreciate that HPC staff have reached out to us along the way in order to better understand the patient safety issues.

As you know, these practices are an evolving pharmacy trend among certain health plans and could significantly change the way we provide medication to our patients. This raises significant patient safety concerns for a subset of supportive care drugs used for oncology patients. The subset of drugs involved are non-self injectable medications. These medications must be administered by a licensed clinician and are not in ready to use form, but rather must be aseptically manipulated in a cleanroom and compounded for an individual patient based on their health status and lab results on the day of administration. This requires rigorous quality and safety protocols.

Specifically, the concerns associated with these practices include:

- **Chain of Custody / Drug Integrity:** The integrity of the affected prescription drugs, which have specific handling, storage, and temperature control requirements, may be compromised while in the custody of a patient.

- **Documentation & Medical Record:** Brown bagging precludes the provider care team from having a complete record of drugs administered to the patient which includes information such as the expiration date, drug specific lot numbers, documentation of side effects/adverse reactions, medication recalls etc.

- **Patient Confusion:** Brown bagging policies confuse patients who may not understand where or how to get their medication at a specialty pharmacy, which increases the risk of missed or delayed doses.

- **Supply & Drug Waste:** Specialty pharmacies typically dispense a 3-month supply of patient-specific medication, which may exceed the intended number of doses for treatment. As a result, a patient may continue to receive treatment when the medication has either been discontinued or the intended number of doses has been administered. This can also result in an increase in drug waste.

In addition, as part of Dana-Farber's rigorous quality and safety protocols, we typically batch order medications at a volume we anticipate necessary to accommodate all of our in-clinic patients. When drugs are brown or white bagged, an individual dose of injectable medication arrives labeled for a specific patient. This subverts our unique and specialized pharmacy systems, which incorporate state-of-the-art safety features that Dana-Farber has spent years developing. These systems simply cannot safely accept drugs and manage inventory for an individual patient from a third-party specialty pharmacy outside of our typical distributors. Given the complex medication regimens and toxicity of the treatments required by our oncology patient population, this threatens to compromise the safety and integrity of our patient care.

As a result of these concerns, Dana-Farber has elected not to accept any brown or white bagged medications from patients or external pharmacies. Regarding your first question about how widespread these practices are, we cannot comment because we do not allow them. We have continued to follow our policies and safety procedures when dispensing medications to our in-clinic patients. This has required us to obtain patient-specific waivers to ensure we can continue providing these drugs in a hospital clinic setting. We maintain concerns that brown and white bagging policies are emerging market trends that may become more widely adopted and/or may evolve into policies that restrict access to these drugs entirely, as has been done in other markets.

In response to your question about how many and which specific drugs have shifted, there is not a fixed list and it varies by health plan. While drugs are increasingly being transferred to the pharmacy benefit, it is important to note that we are only concerned with a specific subset of these drugs based on the profile of the medication and the patients' clinical condition.

One example is IVIG – Intravenous Immune Globulin – that is used to strengthen the body's immune system to lower the risk of infection in persons with a weakened immune system. It is routinely used for

patients with hematologic malignancies and post-bone marrow transplant patients, who represent one of the sickest oncology patient profiles. Even though IVIG therapy has been around for sometime, there are several key considerations to ensure safe, effective patient outcomes. These include:

Product selection: There are several IVIG formulations available and each can cause different side effects. Switching between formulations is not recommended.
Adverse reactions: There is the risk of serious adverse reactions, including severe allergic reaction as well as more common adverse reactions such as fever and chills.
Complete documentation of patient monitoring, adverse drug reactions experienced and the IVIG formulation administered is critical to avoid clinical consequences for the patient. This is especially important for cancer patients that have recently undergone a bone marrow transplant.
If IVIG is supplied by an outside pharmacy, this critical information will not be captured causing a gap in the medical record.

Brown and White bagging also negatively impacts the patient experience from a financial perspective as well as causing possible delays in treatment. When drugs are moved from the medical benefit to the pharmacy benefit, patients often pay for a percentage of the total cost of the drug, as opposed to a flat fee. For many patients, who already face a number of financial burdens, this results in a significant additional out of pocket cost. Patients may also experience a delay in treatment as a result of the patient waiting for the medication to arrive from an outside pharmacy instead of receiving the medication in the clinic.

In addition, we believe that brown and white bagging constitute "re-dispensing," which is a prohibited practice in accordance with the MA Board of Registration in Pharmacy regulations (247 CMR 9.01 (4), and should therefore not be permitted on the basis of existing state regulations.

In closing, I want to emphasize that these are incredibly complex and important issues, which truly warrant a regulatory response to ensure that pharmacy regulations keep pace in protecting patients. **Our hope and recommendation is for the Department of Public Health and the Board of Registration in Pharmacy to take regulatory action to prohibit and/or curb these unsafe pharmacy practices.** Thank you for the opportunity to provide testimony on this important patient safety issue. If you have any questions or would like additional information, please contact Anne Levine, Vice President of External Affairs at Dana-Farber, at 617-632-4433.