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HARVARD MEDICAL SCHOOL  
TEACHING HOSPITAL

May 10, 2018

David Seltz, Executive Director  
MA Health Policy Commission  
50 Milk Street  
8<sup>th</sup> Floor  
Boston, MA 021109

Re: White bagging comments

Dear Executive Director Seltz and Honorable Commissioners,

On behalf of Boston Children's Hospital, the Commonwealth's only acute freestanding pediatric hospital, thank you for allowing us the opportunity to submit this written testimony regarding our experiences with white bagging.

### **Background**

With regards to any health care policy evaluation, it is always important to remember that children are different than adults; issues pertaining to pharmacy related matters are no different. Pediatric pharmacy is very different from adult pharmacy; everything that the Boston Children's Hospital pharmacy dispenses is a unit dose, and all intravenous (IV) medications are drawn up in individual syringe/bags when ready to administer. The Boston Children's Hospital pharmacy works very closely with in an interdisciplinary care team of providers and nurses to ensure that administration of medications, especially biologics to children and adolescents which tend to have high rate of reactions are administered at very specific rate, a rate that is vastly different than the rate of administration in adults. At Boston Children's Hospital, safety and quality are at the forefront of everything we do and to that end we have developed specific, high reliability guidelines for the administration of medications to pediatric patients.

Boston Children's Hospital currently has a policy prohibiting the utilization of "brown bagging" or having our patient, parent/caregiver acquire specialty medication from a pharmacy and bring it to Boston Children's Hospital, one of our satellite locations or their home for administration.

### **White Bagging**

Boston Children's Hospital does not have a specialty pharmacy in house as a result the historical mechanism for securing medication was via the "buy and bill" process. In the "buy and bill" process we purchase, store, and administer the medication to a patient. After the patient receives the drug and any other medical care, we then submit a claim for reimbursement.

The term "white bag" was conceived about seven years ago to describe the way medications were procured, i.e. shipped from the specialty pharmacy directly to the site of care, and to differentiate from the term "brown bag" which refers to the medications dispensed by the specialty pharmacy and brought to the site of care by patients. The white bag practice has been slowly growing over the years because insurance companies and pharmacy benefits managers (PBM's) switched the infused medication reimbursements from the medical benefit to the pharmacy benefit, thus forcing home care administration for many infused medications that potentially have severe infusion reactions. This is a trend that we have seen both with our patients from Massachusetts as well as our out of state patients.

As pediatric providers, we advocate against certain medications being infused at home because the possibility of infusion reactions is high, this has resulted in the Boston Children's Hospital prohibition on "brown bagging". As a result we are forced to accept "white bag" medications provided from a third-party specialty pharmacy. Accepting "white bag" medications presents a number of safety, quality, operational and financial challenges to the patient/patient family and to the institution.

The process of approving infusion medications by insurance companies is handled by the team in our patient financial services department at Boston Children's Hospital. If a medication is approved as "buy and bill", the hospital pharmacy prepares and dispenses the medication to the infusion center directly. The process of approving a medication takes anywhere from five to 14 days. If the medication is not approved as "buy and bill" through the hospital pharmacy, it has to be shipped from a specialty pharmacy. A hospital pharmacy employee will have to contact the specialty pharmacy directly at that point to request that the medication is shipped to the hospital. The specialty pharmacy then needs to seek their own insurance approval for the medication, register the patient to the pharmacy, talk to the patient or in many of our cases, a parent/caregiver about the shipment of the medication, get patient/parent approval to ship the medication to the hospital pharmacy when the insurance approval is received, and collect copay before the medication is shipped. This process takes additional five to 14 days, therefore causing significant delays in the course of the patient's treatment. Most of the patients need their medications to be administered as soon as possible. Many patients carry a new diagnosis which needs to be treated immediately, and some may experience disease flair. In many cases, patients must be admitted to the hospital to be treated in a timely fashion.

It is the position of Boston Children's Hospital that the practice of "white bagging" is neither safe nor cost-effective for the following reasons:

**Clinical:**

- The administrative and operational burden that "white bagging" creates leads delays in treatment that in turn can result in avoidable emergency room visits, hospital admissions, disease flairs, and/or a discontinuation of the medication.
- When the hospital pharmacy is forced to deal with a third party (e.g. a specialty pharmacy), we have no control of when the medication is going to arrive. The specialty pharmacy doesn't communicate if there is a shipping delay. A scheduled medication may be delayed by the specialty pharmacy for a number of reasons, for example, when a Prior Authorization is expired, the patient did not authorize the shipping, or the patient did not pay the copay.
- In many situations, patients do not know that they have to use a specialty pharmacy and only find out about it when the specialty pharmacy contacts them to enroll and collect the copay. Since the patients don't expect to deal with a specialty pharmacy they do not respond to the calls.



- With certain medications, for example Infliximab, which is used to treat Crohn's Disease and Ulcerative Colitis, delaying scheduled treatment dose may lead to antibodies development which, in turn, may lead to a reaction during the medication administration and/or the patients may stop responding to the medication which in turn leads to a medication discontinuation.
- When utilizing the "buy and bill" method, a patient's weight is recorded before the scheduled appointment and, if the weight has significantly increased/decreased, the dose is adjusted right before the infusion. With "white bagging" the specialty pharmacy ships certain doses based on height and weight measurements that are not done in real time, so the patients may not be treated with the appropriate per weight dose and therefore undertreated or creating a delay in treatment to adjust the dose. In pediatrics this is a specific quality and safety concern as small fluctuations in the weight of a pediatric patient can have significant ramifications for medication dosing.

### **Operational & Financial**

- The Boston Children's Hospital pharmacy accepts medications from the specialty pharmacy and therefore accepts the responsibility to procure, store, and prepare the medication without being reimbursed.
- To procure a medication from the specialty pharmacy the Boston Children's Hospital pharmacy had to dedicate one new full time equivalent (FTE) to coordinate the medication shipment and arrivals in time for the patient's appointment.
- The "white bag" process creates double work for the providers who order medications for the patients. They have to provide an order to the hospital pharmacy to prepare the medication and a separate order to the specialty pharmacy to dispense the medication.
- The hospital pharmacy has to ensure that the patient's insurance is not billed during the medication verification/preparation process. This causes pharmacists and technicians to spend extra time making sure that the medication sent from specialty pharmacy is used and the patient is not billed.
- Medications sent from the specialty pharmacy are not stored with the hospital supply and therefore the Boston Children's Hospital pharmacy had to purchase an extra refrigerator to store the medications sent from specialty pharmacies.
- If a medication is discontinued for whatever reason and the medication is already received from a specialty pharmacy, the hospital pharmacy has to waste it. Biologic products are very expensive medications and therefore the waste is very costly.
- Further patient safety and quality concerns exists in that "white bagging" creates opportunities for medications to be lost or go to a clinic instead of the pharmacy - medication is then not refrigerated and cannot be used, creating unnecessary and costly medical waste.
- "White bagging" also creates weakness in the chain of command of medications. A specific example is most biologic medications are protein molecules and should be handled carefully, not shaken. During the additional shipment/transit that "white bagging" demands, medications like biologics may be agitated and thus become clinically suboptimal.
- A further example of a safety and quality issue occurs when a specialty pharmacy sends a different size vial than what we have in the Boston Children's Hospital system. When that happens, we have to prepare medication on paper bypassing DoseEdge (electronic system we have with scanning medications and walking a technician step by step during the preparation, as well as lets pharmacist see and verify every step of the preparation). Bypassing DoseEdge may contribute to the mistake during the preparation of the medication.

**Legislative Recommendations**

Boston Children's Hospital currently has a policy prohibiting the utilization of "brown bagging" or having our patient, parent/caregiver acquire specialty medication from a pharmacy and bringing it to Boston Children's Hospital, one of our satellite locations or their home for administration. We believe that prohibitions against both "white and brown bagging" are needed to be codified within state law in Massachusetts, if not for all patients then certainly for pediatric patients or classes of pediatric patients.

Thank you for allowing Boston Children's Hospital to submit this testimony on this important issue. If you have questions regarding this testimony please contact Kate Audette, Director of State Government Relations at 617-919-3062. We are also happy to meet with the staff and/or Commissioners of the Massachusetts Health Policy Commission to discuss this issue in further detail if that would be helpful.

Sincerely,



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Boston Children's Hospital



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