Beth Israel Deaconess Medical Center

HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

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May 11, 2018

Mr. David Seltz, Executive Director
Ms. Lois Johnson, General Counsel
Dr. Stuart Altman, Chairman
Health Policy Commission
50 Milk Street
Boston, MA

Dear Mr. Seltz, Ms. Johnson, Dr. Altman and Members of the Commission,

On behalf of our doctors, nurses, and community of caregivers, we are writing to offer the following perspective in response to the increase in so-called "whitebagging" and "brownbagging" in Massachusetts and beyond. We offer our comments with particular focus on the impact on patients undergoing treatment for cancer and other serious chronic diseases who need life-saving and life-sustaining medications in the proper care setting.

By way of background, our interest in this practice intensified more than two years ago when we are alarmed by abrupt and unilateral changes in health insurance policies that ultimately prevented cancer and other infusion patients from receiving their infusions in a hospital outpatient setting.

We witnessed firsthand the negative impact on patients when their health insurer suddenly required a patient to "self-administer" an infusion drug, or to pursue a home infusion -- even when not clinically appropriate – and to obtain their infusion drugs from a third-party specialty pharmacy outside of the hospital. All of this occurred without notice to the patient, without conversation with the provider community, and without a clear and transparent clinical or cost justification.

These insurance changes, imposed without warning or notice to patients, abruptly disconnect patients from their providers, and force providers to seek waivers, special permissions, and "workarounds" in an effort to continue caring for these patients.

Many of our most complex patients experienced these insurance changes several years ago, which caused alarm, confusion and disruption for many, as well as poor

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health outcomes. This is particularly concerning given the serious illness impacting many of our infusion patients, including cancer; neurological disorders such as multiple sclerosis; autoimmune disorders such as lupus; immune deficiency disorders; and inflammatory bowel disease.

These insurance changes also shifts costs to patients because their infusions are no longer covered under a medical visit benefit and are moved instead to the pharmacy benefit.

Patients may also be encouraged to bring drugs that have been dispensed to them to the hospital for infusion ("brownbagging"), or to have their drugs sent to the hospital by an outside pharmacy for infusion ("whitebagging"). Both "brownbagging" and "whitebagging," however, present serious quality and safety concerns for hospitals, because we bear the responsibility for the integrity of the drug, the compounding of the drug, and administration of the correct dosage.

Hospitals must also ensure that any medications administered to our patients are obtained from reliable sources; are stored in the appropriate manner at all times; are delivered timely, in unspoiled condition; and are traceable in the event of recall or problem.

***Examples of Challenges and Concerns Related to "Whitebagging"***

*Drug Does Not Arrive*. In one local community hospital, we recently learned of an experience where a patient arrived for chemotherapy treatment, and the patient's pharmacy had not sent the drug for administration. Because the prescription was written directly to and only to the patient, the hospital was unable to supply the drug to the patient, and her treatment was interrupted and delayed until the following week. Health insurers will also require that the patient reschedule and delay therapy, rather than authorize the hospital to serve the patient with the hospital's medication.

*Dosages Changes*. In another example, the "whitebagged" drug was supplied to the patient, but the patient's dosage had been changed. Because the hospital is unable to correct the dosage in a "whitebagged" drug, the product was wasted and could not be used.

*Exclusive Requirements for "Brand Name" Drugs*. We are also seeing increasing relationships between insurers and specific manufacturers, such that the insurer will mandate that a brand name drug, such as Remicade, must be used and a biosimilar medication in this case that is a clinically appropriate alternative drug may not be substituted even though it is drastically less expensive for the patient and the insurer. Many brand name drugs are more than double the cost of such biosimilar and generic medications, which hospitals would otherwise use. Because of these exclusive arrangements, hospitals and patients are unable to utilize drugs that are

significantly lower cost to the patient or to the larger delivery system.

Finally, throughout the evolution of the increasing practice or "whitebagging" and "brownbagging" and an increasing number of "exclusive" relationships and requirements, hospitals have not been given any opportunity to discuss the clinical implications for the patient population impacted; to discuss pricing associated with hospital-supplied drug therapy; or to otherwise offer competitive alternatives to certain drug therapy regimens required by insures and specialty pharmacies, who are increasingly financially incented to process more prescriptions.

We welcome and appreciate the Commission's review of this complex and ongoing issue, and we urge the Commission to make recommendations for greater transparency and oversight of these practices as needed and appropriate.

We thank you in advance for your consideration and would welcome the opportunity to discuss the full range of our experiences with you in greater detail.

Very truly yours,

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