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Comments of the Massachusetts Society of Clinical Oncologists
Before the Health Policy Commission
Re: Section 130 of Chapter 47 of the Acts of 2017 Public Listening Session regarding shifting drug distribution channels, commonly referred to as "brown-bagging and "white-bagging"

May 11, 2018

These comments are submitted on behalf of the Massachusetts Society of Clinical Oncologists (MSCO) which represents oncologists throughout the Commonwealth. Oncologists are responsible for providing and improving the quality of care of cancer patients.

MSCO appreciates the Health Policy Commission's (HPC) decision to open its review of insurer practices relating to drug distribution channels for certain cancer and chronic disease drugs by inviting comments from interested parties. Our comments below reflect our overall concerns and we would welcome an opportunity to respond to questions the commission may have as you continue your analysis.

There is an emerging practice among insurers to alter their policies to force cancer patients to get their injectable or infusion drugs from third party specialty pharmacies, which results in the specialty pharmacy dispensing the drugs for a specific patient and sending it to the oncologist (commonly known as "white-bagging"), or having the patient bring the drugs to the physician's office for administration or be forced to receive the infusion at home (commonly known as "brown-bagging").

While efforts by some insurers to require white-bagging or brown-bagging have been attempted recently in Massachusetts and later altered, MSCO is very concerned that this practice could become a policy of insurers here. MSCO welcomes the Legislature's charge to the HPC to study this issue and make recommendations to the Legislature.

The relatively new insurance policy of requiring pre-ordered cancer drugs be obtained from a specialty pharmacy and delivered either to the patient or oncologist raises serious questions of safety and quality, and interferes with the ability of an oncologist to alter the dose based on the patient's condition. These infusion drugs for cancer patients and patients with serious blood and immune disorders can have serious and toxic side effects, and the insurance policy undermines our ability to ensure that the medication administered to the patient has followed known quality and safety channels. It increases the potential for dose delays and having patients return repeatedly for the proper timing and dosing of their medication. It puts undue burden on hospital pharmacies to store and dispense drugs separate from institutional policies and practice, increasing the chances for error. This shift can invariably lead to increased patient expenses at a time when patients are already under significant financial strain from health care costs.

The immediate challenge the white-bagging and brown-bagging insurance policies bring to having cancer patients receive appropriate and adequate care include:

- **Quality**: when medications do not follow known quality and safety channels and are presented to the infusion center for administration (from a specialty pharmacy outside of the institution pharmacy or picked up by a patient from a pharmacy), a physician is faced with administering a medication of an unknown or unproven content. We do not know whether the medication was stored or transported properly. We cannot be assured of the integrity of the drug. For example, temperature can affect drug efficacy. Refrigeration in cancer centers or physician offices that stores drugs is monitored on a daily basis with an official log and an alarm that signals if the temperature has gone even several degrees out of range. This alarm is monitored 24/7. This way, oncologists can be assured that the drugs we give our patients have not been compromised in any way. Under the practice of white and brown bagging, this same level of quality assurance is not possible. We have no way of knowing whether the drug sat on someone's porch for several days or if it was placed on a radiator overnight before it was brought into clinic for administration.

- **Appropriate Patient Care**: when a medication is pre-ordered through a specialty pharmacy, the ability to change the dose based on the patient's condition is compromised. This can result in reordering or changing the drug and result in delayed treatment, patient inconvenience and added cost. On the other hand, drug waste is inherent in a pre-ordered patient specific drug prior to care. Patients will prepare mentally and physically for the day of chemotherapy. They arrange rides and babysitters and family members arrange schedules to be with them. Most of all, patients count on therapy as a means to control or cure their cancer. To tell a patient when they arrive that the dose needs to be changed and therapy will be delayed while we work through your insurance company to get the proper dosage is unfair, especially when the means to properly give therapy exists in the cancer center, but we are prohibited from using our own stock of drugs for insurance reasons.

- **Safety**: many of the medications used in cancer medicine have very serious and toxic side effects. They are administered in a dedicated infusion center where specialty trained and certified nurses manage the side effects and reactions of such medications regularly. Increased awareness of the risks of these drugs, potential hypersensitivity reactions, and the need for concurrent laboratory and patient physical assessment with each dose of these medications also necessitates greater, and not less, physician supervision of dosing. At a minimum, this policy will create yet another burden and delay for cancer and immunocompromised patients as they will, in this circumstance, be required to first visit the physician's office to undergo the appropriate evaluation and laboratory tests, wait for the results, and only then have their provider send a prescription to the specialty pharmacy for filling, come back when the drug is received, or picked up by the patient, and then receive treatment—rather than receiving monitored treatment during the same visit as is currently the case without white-bagging or brown-bagging.

We would also note that insurers' shifting to brown-bagging and white-bagging also shifts the patient's insurance medical benefit to their pharmaceutical benefit, which often forces patients to incur significantly increased out of pocket costs in the form of additional deductibles, co-insurance and co-payments.

Finally, in contrast to hospital and physicians maintaining practice-based inventories of drugs or supportive care agents for immediate administration and treatment as necessary for their patients, there is

no assurance that a needed drug will be available in a timely fashion through the specialty pharmacy distribution channel. This lack of treatment or delay in treatment could lead patients, who are already compromised by very serious illnesses such as cancer, to worse outcomes.

The practice of brown-bagging and white-bagging, which we believe raise real issues of patient safety and appropriate care for cancer patients, needs to be carefully reviewed. MSCO would be pleased to provide additional information and respond to questions as you conduct your study.

Respectfully submitted,

Patrick J. Gagnon, M.D.
President