Testimony of Karen Granoff,
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Before the Health Policy Commission's Public Listening Session
on Shifting Drug Distribution Channels
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The Massachusetts Health and Hospital Association (MHA), on behalf of its member hospitals, health systems and physician organizations, appreciates the opportunity to provide feedback to the Health Policy Commission (HPC) on the concerns inherent in health plan policies and benefit design that mandate shifting drug distribution channels from hospital pharmacies to specialty pharmacies and/or require that certain medications be administered in the patient's home.

Insurers have increasingly altered their benefit structures by moving certain injectable and infusion drugs out of the medical benefit and into the pharmacy benefit, requiring that these drugs be obtained from a specialty pharmacy and delivered to either the patient to bring to his provider (brown bagging) or directly to the physician or hospital outpatient department to be administered to a specific patient (white bagging). In some plans, in order to be covered, the patient must receive the medication from a home infusion company rather than in a provider's office or clinic.

The focus of MHA's concerns is on the growing subset of injectable and infusion medications that generally require special handling, storage, temperature control, and/or compounding prior to administration and may also have significant side effects requiring the presence of a physician when the drug is administered. When insurers mandate that these medications must be provided by specialty pharmacies and in some case administered in the patient's home, the result is the creation of significant clinical, operational, patient safety, access, and financial challenges.

In response to these troubling benefit and policy changes, MHA and its members developed Principles for Specialty Pharmacy Utilization (attached). This document highlights that health systems should not be prevented by restrictive health plan policies from offering a full range of safe and effective pharmaceutical services to its patients. Drugs should not be moved from the medical to the pharmacy benefit and obtained from a third party specialty pharmacy if they are not intended or approved by the FDA for self-administration and cannot be safely administered outside of a clinic setting. In addition, any medications which could result in compromising the chain of custody or in non-compliance with state or federal regulations should not be required to be dispensed by a specialty pharmacy.

Hospital pharmacies bear the responsibility of making sure that any medications administered to patients are obtained from reliable sources, are stored in the appropriate manner and delivered timely, in unspoiled condition. The integrity of the pharmaceutical supply chain must never be compromised. For these reasons, hospitals have many procedures in place to ensure the quality of the medications that are procured, stored, dispensed and administered, including prohibiting the procurement of medications from outside sources and/or

bringing them to the hospital for administration in an outpatient setting. Among the clinical, safety, and operational issues that are raised by these health plan benefit changes are:

- Many of the infusion drugs cannot be safely administered at home because they require preparation by a pharmacist, extensive clinical monitoring and may have side effects that require a clinical setting. In some cases, hospitals have continued to provide the infusions from their hospital pharmacies and have swallowed the costs in order to prevent disruption to care. However, this is not a sustainable model. In other cases, physicians have had to assist patients in finding alternative providers who can provide the infusions, resulting in dis-integration of care.

- Patients who are taking many drugs may have some dispensed by the hospital pharmacy while others may be supplied by the hospital pharmacy. This limits the potential for decision support software to recognize possible interactions or contraindications.

- When drug products are provided by an outside specialty pharmacy which the hospital does not maintain a contractual relationship with, the hospital may not have complete information about the drug product being given to the patient, including documentation of proper storage and handling or information about the drug's origin or pedigree, which may be important in tracking adverse reactions or drug recalls.

- The medication supply provided for a patient from an outside specialty pharmacy may exceed the number of doses intended for treatment or the treatment plan could change as the patient's medical status changes. This can necessitate changes in dosages, require reordering or changing the drug, and can also result in drug waste.

- Operational difficulties include receiving and tracking the medications, keeping separate each patient's medications while having separate hospital inventory of same products, creating separate billing processes, etc. Multiple patient specific medications and doses would need to be segregated within storage areas. In addition, these medications require refrigerated storage so would require additional costs to purchase a large pharmaceutical grade refrigerator as well as space to place this refrigerator in a pharmacy controlled environment.

In April 2018, the National Association of Boards of Pharmacy issued a report called "White and Brown Bagging: Emerging Practices, Emerging Regulation" (https://nabp.pharmacy/wp-content/uploads/2018/04/White-Bagging-and-Brown-Bagging-Report-2018_Final.pdf)

The study concluded that:

"… *white bagging and brown bagging are not without shortcomings. The boards must determine who is accountable for verifying the authenticity and integrity of the drug before administration. Furthermore, regulators must decide who is responsible when a delay in therapy, due to a lack of coordination between patient, prescriber, and pharmacy, leads to adverse outcomes for patients. These issues are left to the state boards of pharmacy to grapple with in an effort to protect the public. The control and responsibility for the integrity and timely delivery of the medications under each bagging practice are two of the issues most relevant to the role and responsibility of the boards of pharmacy.*

The specific questions to be considered are: Where, when, and from whom were the medications purchased? Were the medications manufactured abroad and not Food and Drug Administration-approved? A shipment of sensitive drugs sitting outside a pharmacy or patient's residence for hours may result in compromised contents and raises concerns about whether the medication was handled appropriately and safely at all times."

In Massachusetts, we are concerned that this practice directly violates Massachusetts Department of Public Health (MDPH) regulation, specifically Board of Registration in Pharmacy (BoP) regulation barring the re-dispensing of medications. In particular, the BoP regulations state, "Unless otherwise permitted by law, a pharmacist shall not re-dispense any medication which has been previously dispensed." 247 CMR 9.01 (4). This regulation is in the process of being updated. The current draft regulations on re-dispensing at 247 CMR 9.01 (5) & (6) state:

> (5) Unless otherwise permitted by law or regulation, a licensee may not re-dispense any medication which has been previously dispensed.
> (6) Unless otherwise permitted by law or regulation, a licensee may not accept, store, dispense, package, label, or compound any medication that was previously processed or dispensed by another pharmacy.

MHA appreciates that many of these new medications are expensive and that health plans are seeking ways to address these costly drugs while still allowing access. However, *mandating* that specialty pharmacies provide these often toxic medications with significant side effects (and, in some cases, prohibit these drugs from being administered in a hospital setting) raises multiple patient safety, clinical and operational concerns, increases the cost for patients, compromises the chain of custody, and results in regulatory issues that the state board of pharmacy must address in an effort to protect the public. We urge the HPC to consider each of these serious concerns and to develop a reasonable and clinically appropriate approach that does not compromise patient safety, create administrative complexity for patients and providers, add operational challenges to hospitals, make it more expensive for patients to obtain these medications, and put hospital pharmacists in the difficult position of not complying with state regulations that prohibit the re-dispensing of any medication which has been previously dispensed. The Organization of Nurse Leaders MA-RI-NH-CT-VT supports the position of the Massachusetts Health & Hospital Association with regards to insurer-compelled whitebagging and brownbagging practices.

Thank you for the opportunity to provide these comments. If you have any questions, please contact Karen Granoff, MHA's Sr. Director Managed Care at KGranoff@mhalink.org or 781-262-6035.