



May 11, 2018

Massachusetts Health Policy Commission
50 Milk Street, 8th Floor
Boston, MA 02109

Re: A Review of Specialty Drug Dispensing and Patient Safety

Dear Health Policy Commission:

A practice has developed over the last five to ten years driven in large part by third party payers that creates an unnecessary patient safety risk regarding infusion therapies for cancer and other chronic diseases. Patients requiring medications that are too unsafe and complex for infusion in the home setting have those treatments at hospital based clinic sites. The treatments are ordered by a physician, reviewed, approved and compounded by a pharmacist and, monitored and administered by a nurse. The hospital has full resuscitative capacity should the patient have an adverse reaction to the medication, which is not an uncommon occurrence. These therapies are often biotechnology or oncology medications requiring special storage and handling, controlled environments for compounding, specialized equipment for administration, and they are often extremely expensive.

Third party payers are requiring members to procure these medications from designated pharmacies. These pharmacies, often called specialty pharmacies, may either dispense the medication(s) directly to their patients with instruction to bring the medications to the hospital or have the medication(s) dispensed by the specialty pharmacy to the hospital which in turn redispenses the medications to the patient. It has been estimated that while specialty pharmacy medications comprise only 1-2% of all prescriptions, these medications total 40% of all prescription costs in 2016, up from 18% in 2006. In 2014, the FDA had approved 39 new molecular entities and new therapeutic biologics in 2014, and approximately 50% of those fit the definition of a specialty pharmacy medication.

Patients with multi-drug treatment regimens may have one or more expensive biotechnology medications dispensed by the specialty pharmacy and other medications dispensed by the hospital pharmacy. This limits the ability to use decision support to

evaluate and act on potential allergies, interactions or contraindications. This practice also interferes with established drug distribution, drug pedigree assurance and other basic pharmacy drug preparation services designed to ensure patient safety, quality, and continuity of care. Further, we believe 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 redispense 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 redispensing 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.

The current and draft regulations make clear that the Board of Pharmacy does not support any form of medication redispensing.

Traditionally, a patient is seen by a physician and is determined to require treatment for cancer or any number of diseases requiring infusion medication treatment. The physician prescribes the medication(s) for the patient and determines the appropriate setting for safe medication administration. While some infusion medications may be safely administered in the home setting, many require patient monitoring that can only be provided in the hospital setting. The medications of this type have traditionally been prepared and dispensed from the hospital's pharmacy department. The medication is prescribed, dispensed and administered using all the safe guards available in the hospital setting. Providers enter the medication order into the computerized provider order entry system that has clinical decision support. Pharmacists medication review and approve the medication order assuring the regimen is safe and effective for the indicated treatment. The pharmacy department compounds the medication in a sterile environment to ensure it is free from microbial contaminants. The nurse administers the medication according to specific administration guidelines to reduce likelihood of an adverse reaction with close monitoring of the patient.

Medications that have been dispensed by a specialty pharmacy that is not operated by the hospital or health-system bypass several of these important safety measures incorporated by a hospital's medication use process. The medication may lack appropriate pedigree and not have been shipped and or stored under appropriate conditions. The medication may not be entered into the order entry system as the prescription has been sent elsewhere. The pharmacist review and approval to ensure safe and effective treatment may not occur as the order is not evaluated using the hospital information system. That review includes checking against the patient's known allergies and for potential interactions with other medications the patient is known to be taking. The patient's pertinent laboratory values are also checked to ensure the dose ordered is appropriate.

While the specialty pharmacy does have clinical decision support in their computer systems, they do not have the full medical, medication history and the patient's most recent clinical laboratory values. This fragmented care approach increases the risk of adverse events. While the nurse will be able to monitor the patient appropriately, the administration of the medication is part of the coordinated medication use process and information typically available to the nurse may be lost.

The hospital infusion service also maintains all the necessary equipment and medications to treat the patient should the patient develop a reaction to the medication. This includes physicians that are immediately available to respond to an adverse medication reaction and the availability of Emergency Medicine services. The hospital provides the appropriate pharmacy, nursing and physician services and the appropriate physical plant for the safe treatment of the patient at great expense. The patient's insurer reimburses the hospital for administering these medications in this setting. However, the insurer avoids reimbursing the hospital for preparing and dispensing the medication while also shifting costs to the patient who may often pay a co-pay for acquiring the prescription medication and for having the medication administered at the hospital. All told, the insurer is decreasing their own expenses and shifting costs to the patients and providers.

As noted above, this practice is barred by Board of Pharmacy regulations. However, hospital pharmacy is also required to be in compliance with The Joint Commission (TJC) hospital standards and the Center for Medicare and Medicaid Services (CMS) Conditions of Participation. The fact that the medication comes from a specialty pharmacy does not relieve the hospital from its obligations under TJC and CMS to ensure quality pharmaceutical care. The quality and safety practices of specialty pharmacies are not directly evaluated by the pharmacy director as are other contracted vendors of a hospital pharmacy as required by TJC Leadership Standard LD 04.03.09 (5), (6) & (7). A safety check of outsourced pharmacy service vendors which is considered vital by TJC is lost. Further, the CMS states the hospital governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services. 42 CFR 482.12 (e).

It is our goal to provide excellent pharmaceutical services to our patients and to do so in a manner compliant with regulation. We ask that you review this practice and ensure safe and effective treatment of patients with cancer and other debilitating chronic medical conditions requiring infusion treatments in the hospital setting. Should you require additional information, we are happy to supply this information.

Sincerely,



David Seaver, RPh, JD

Massachusetts Society of Health-System Pharmacists
Legislative Committee Chair