MASSACHUSETTS Health & Hospital ASSOCIATION

Principles for Specialty Pharmacy Utilization

The following principles were developed to address significant concerns that have resulted from requirements by health insurers that certain medications be moved from the medical to the pharmacy benefit and dispensed by a specialty pharmacy. The focus of these principles is not on oral and injectable medications that can be safely dispensed directly from the specialty pharmacy to the patient but on the subset of medications (primarily infusion and some injectables) that present significant clinical, operational, and patient concerns when an insurer requires that they be provided under the pharmacy benefit.

Guiding Principles

A health system that is able to offer a full range of safe and effective pharmaceutical care services to its patients should not be prevented from doing so by the creation of health insurer policies that restrict the place of service where medications can be safely dispensed. Insurers that move certain drugs from the medical benefit to the pharmacy benefit and require dispensing from a specialty pharmacy significantly restrict the ability of physicians and hospitals to provide their patients with the right care at the right time in the right setting.

Drugs should not be moved from the medical benefit 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 based on the drug characteristics, profile and stability of the medication, required storage and preparation conditions, side-effect management protocols, and/or patient characteristics.

Relevant clinical expertise must be used in making initial determination

When determining which medications can be safely dispensed by a specialty pharmacy, a health plan must use reviewers who are actively practicing healthcare professionals in the same or similar specialty who typically treat the medical condition or provide the treatment for which that particular medication would be used. For example, an oncologist, in conjunction with a pharmacist, would review a recommendation that an oncology medication be moved to the pharmacy benefit and dispensed by a specialty pharmacy.

Preparation/Dosage (excerpted from Massachusetts Society of Health System Pharmacists)

All patient specific medications provided by a specialty pharmacy to a Health System pharmacy must be received by the Department of Pharmacy in a ready to administer dosage form and clinically appropriate dosage. The medication must have a pedigree to assure the hospital pharmacy that the medication was handled appropriately through the supply chain.

1. Any medication requiring sterile compounding by the health system pharmacy staff is inappropriate for delivery through the specialty pharmacy channel.

2. Any medication with a patient specific dosage dependent on lab / test results on the day of the clinic visit is inappropriate for delivery through the specialty pharmacy channel.

Drugs requiring a Risk Evaluation and Mitigation Strategies (REMS) and Elements To Assure Safe Use (ETASU)

Drugs that require a REMS to manage known or potential serious risk associated with a drug or biological product and particularly those that require an ETASU should generally be excluded from any requirement that they be dispensed by a specialty pharmacy.

- For example: Tysabri (natalizumab): drug to treat multiple sclerosis and Crohn's disease. Prescribers, pharmacies and infusion sites must be specially certified and there must be evidence of documentation of safe use conditions.

IT Considerations - Loss of intraoperability

Hospitals have established sophisticated systems to insure safe administration of medications including computerized pharmacy systems with sophisticated clinical decision support that review medication doses, duplicate therapies, allergies, drug interactions, and other clinical criteria for appropriate use. Pharmacists and others responsible for processing drug orders should have routine access to appropriate clinical information about patients (including medication, allergy, and hypersensitivity profiles; diagnoses; pregnancy status; and laboratory values) to help evaluate the appropriateness of medication orders. Much of this technology is lost when drugs are required to be delivered for multiple individual patients from an unaffiliated specialty pharmacy. In addition:

- Technological innovations such as bar coding help identify patients, products, and care providers. Consistent barcoding of product used for compounding allows a health-system pharmacy to use technology such as bar-code medication preparation which guides the safety of the actual preparation of the medication specific to the patient's medication profile. This barcode guidance is often compromised if the health-system pharmacy is required to accept medication from an outside pharmacy to then prepare for a patient.

- Pharmacy-generated medication administration records or labels assist nurses in interpreting and documenting medication activities.

- Specialty pharmacies don't have access to patient medical records and therefore may not be able to adequately provide for medication reconciliation nor ensure that all necessary criteria have been met before treatment begins, potentially putting patients at risk.

Chain of Custody/Regulatory

Any medications which could result in compromising the chain of custody or non-compliance with state or federal regulations should not be required to be dispensed by a specialty pharmacy.

- The pharmacy department must be responsible for the procurement, distribution, and control of all drugs used within the organization. The pharmacy director and staff must ensure that all drug products used in the organizational setting are of high quality and integrity, stored in the appropriate manner and delivered timely, in unspoiled condition.

- When drug products are provided by an outside specialty pharmacy, which the hospital does not maintain a contractual relationship with, the hospital does not have access 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. Transfer of pedigree information is required of wholesalers and manufacturers under the federal Drug Quality and Security Act of 2013(DQSA). Pharmacies rely upon this transaction information to assure the medication is not counterfeit or otherwise from an illegitimate source. Pharmacies that transfer medications to other pharmacies for a specific patient need are not required to provide transaction information. (DQSA section 582 (d) (1) (A) (ii)). The lack of transaction information places the pharmacy in a position of dispensing medications for which it does not have a pedigree which is not the standard of pharmaceutical care which is applied to medications dispensed that are received through sources that do provide pedigree documentation.

- Board of Pharmacy regulation 247 CMR 9.01 (4) states: "Unless otherwise permitted by law, a pharmacist shall not re-dispense any medication which has been previously dispensed."

Patient Education and Provider Notification

Health insurers must notify providers at least 60 days prior to implementation regarding any of their patients who are affected by a transition in coverage from the medical to pharmacy benefit and requiring procurement from a specialty pharmacy. Patients must also be informed about this change at least 60 days prior to the effective date so that appropriate arrangements can be made for administration of the drug. Insurers must establish an expedited exception process for any provider who believes that his/her patient is unable to have the drug administered outside of the current clinical setting.

Clinical Waiver/Exception Process

Health plans should establish a patient-specific exemption process to be applied in cases where a provider certifies that it is unsafe for a patient to receive medication from a third party specialty pharmacy based on the drug characteristics, profile and stability of the medication, required storage and preparation conditions, side-effect management protocols, prior history of adverse reactions, and/or patient characteristics.