PIH Health Whittier - Hospital

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Acquisition of Drug

- Per California Board of Pharmacy regulation 1735.3 (b) and (c), Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products and components used in compounding. (c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration ("FDA").

- The Drug Supply Chain Security Act ("DSCSA"), effective July 6, 2015, requires dispensers to capture transaction information including transaction history, statements, and proof of authenticity.
  - This requirement ends once it becomes a patient specific drug, meaning that Hospital cannot compound a patient's own medication because Hospital does not have the acquisition history of the product since it did not purchase the drug. Hospital would be dispensing a drug without the DSCSA information.

Standardization of Delivery

- There has been no standardization of how/where to properly deliver the medications to Hospital's pharmacy and no way to ensure the integrity of the medications received.
- Hospital cannot accept medications delivered to a physician's office for office staff are not educated to the handling and storage requirements of these medications, which may lead to improper storage and compromise the integrity of the medication.
- Hospital cannot accept medications that are sent directly to the patient for the same reason. Hospital cannot ensure the integrity and storage condition of the medications.
- If these medications are not promptly delivered to the pharmacy, and storage temperature is compromised, Hospital risks exposing a patient to a compromised drug.
- If these medications are dropped by those not experienced with hazardous drugs, exposure to non-pharmacy staff and possibly the public is a concern.
- Chain of Custody of these hazardous medications is severely compromised. They are often dropped off at the front desk of the hospital or bundled together with other non-medication deliveries where they sit for hours on the dock. The lack of security makes these medications prime for diversion and raises questions as to the integrity of the medication The lack of timeliness to get the medications to the right departments is also a concern.

Standardization of Care

- There is no standardization as to which medications Hospital will and will not be responsible for (pre-meds, diluents, etc.).
  - Some deliveries may come with all medications, some with only one drug and no pre-meds. The process is unclear.
- Some medications come in a different dose sizes/concentrations from what the hospital carries.
  - If the medications delivered are inconsistent with the concentrations Hospital carries, there is a great risk for an error.
- All of the reasons above pose a serious patient safety concern including, but not to, compromised medication, delay in care, imposing the responsibility on a patient who is not clinically trained to obtain his/her medication and/or handle the medication, etc.

Scheduling

- Patient care is being compromised by delays in therapy.
  - Delivery of medications is frequently sent after the treatment date, causing delay in therapy and great anxiety for our gravely ill patients.
  - Patients are being expected to follow up with obtaining their medication and bring it with them for their treatment when they are not trained to handle their medication and/or may be to weak/tired from their treatment to remember to follow up.

Storage

- A pharmacy must be able to store and log each patient's medications safely and securely.
  - Hospital does not have the capacity to store a patient's medications separately and these medications cannot be co-mingled with Hospital's purchased stock.
  - Hospital has no level of confidence that courier delivered medications were stored properly in transit.

Safety

- Patient's own medications are entered in the Hospital Electronic Health Records ("EHR") as "non-formulary medications".
  - These must be distinct from medications carried by Hospital or a charge to the patient will be made.

- A Non-Formulary designation has the most risk associated with it as it increases the chances for order entry errors for it must be created from scratch rather than using standardized orders.
  - This can lead to compounding and dosing errors which places patients at risk.
  - Standardized orders are recommended by the Institute of Safe Medication Practice ("ISMP") as standard of care, especially in regards to hazardous medications. They ensure all appropriate warnings, compounding instructions, etc. are included on the label and on the eMAR.
  - Non-formulary medications are not cross referenced in the EHR for allergies or duplicates.
  - These "non formulary medications" (at the NDC level) will not be built out in Hospital's database to ensure errors are minimized during the admixing process utilizing the barcode scanning technology at the point of dispense prep and dispense check.

Variation from Prescription

- 1716. **Variation from Prescriptions**.
  - Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code. Authority cited: Section 4005, Business and Professions Code. Reference: Section 4040, Business and Professions Code

- Medications need to be dispensed in the final administrable form that is specified in the prescription. Specialty pharmacy is deviating from the prescription. The prescription is written for a compounded medication to be delivered intravenously, not vials that require **another pharmacy** to compound.

Hospital Policy

- It is against our hospital policy to accept a patient's own medications that can be provided by the hospital because it poses a patient safety concern.
- White-Bagging forces the hospital to assume unnecessary risk, and conflicts with BOP regulations.
- PIH Health Whittier - Hospital has made the decision to not accept these medications to ensure that our patients continue to receive high quality, safe care.

The End

Thank you for your time