

SWEET MEDICAL CENTER POLICY & PROCEDURES MANUAL

CLINICAL

HANDLING OF DONATED PHARMACEUTICALS

It is the policy of Sweet Medical Center, Inc. to provide for the safety of its patients through appropriate policies and careful handling of pharmaceutical products.

In accordance with the Prescription Drug Marketing Act (PDMA) Sec. 203.39 Donation of Drug Samples to Charitable Institutions, the following requirements will be followed by all Sweet Medical Center, Inc. employees handling donated pharmaceuticals.

- All pharmaceuticals donated by a pharmaceutical company shall be received at Sweet Medical Center, Inc. in original, unopened packaging with labeling intact. If the packing is not intact, they will not be accepted.
- Delivery of donated pharmaceuticals will be by mail, common carrier, or an authorized agent of the donating pharmaceutical company.
- A donated drug sample shall not be dispensed to a patient until it has been examined by an Sweet Medical Center, Inc. employee designated by the Medical Director to confirm that the donation record accurately describes the drug sample delivered and that no drug sample is adulterated or misbranded for any reason, including, but not limited to, the following:
 - The drug sample is out of date;
 - The labeling has become mutilated, obscured, or detached from the drug sample packaging;
 - The drug sample shows evidence of having been stored or shipped under conditions that might adversely affect its stability, integrity, or effectiveness;
 - The drug sample is for a prescription drug product that has been recalled or is no longer marketed; or
 - The drug sample is otherwise possibly contaminated, deteriorated, or adulterated.
- Sweet Medical Center, Inc. shall dispose of any drug sample found to be unsuitable by destroying it or by returning it to the manufacturer.
- Sweet Medical Center, Inc. shall prepare at the time of collection or delivery of a drug sample a complete and accurate donation record, a copy of which shall be retained for 3 years, containing the following information:
 - The name, address, and telephone number of the donating company;
 - The brand name, quantity, and a lot or control number of the drug sample donated; and
 - The date of the donation.
- Sweet Medical Center, Inc. shall maintain complete and accurate records of donation, receipt, inspection, and dispensing sufficient for complete accountability and auditing of drug sample stocks.

Sweet Medical Center, Inc. Policy C - 4

- Sweet Medical Center, Inc. will store pharmaceuticals under conditions that will maintain the sample's stability, integrity, and effectiveness, and will ensure that the pharmaceuticals will be free of contamination, deterioration, and adulteration.
- Sweet Medical Center, Inc. shall notify the FDA within 5 working days of becoming aware of a significant loss or known theft of prescription pharmaceuticals.

In addition, Sweet Medical Center, Inc. has instituted the following guidelines for distribution of pharmaceuticals to patients.

- Providers will counsel patients concerning usage and side effects of pharmaceuticals which will be provided. Counseling will be documented in the medical record.
- Each sample dispensed to a patient will be labeled with the patient's name, provider's name, date dispensed, and instructions for use.
- Each sample dispensed will be documented in the patient record.

Approved: _____
(Date)

Chair, Board of Directors