Whenever standard therapeutic modalities are tried and failed or when there is no established treatment for a medical illness, the need may arise to try an investigational agent or an approved formulary drug for un-approved indication (Off-label). The ethics committee as well as the pharmacy and therapeutics committee could allow such practice by developing policies and procedures. Clear justification of drug need, dose, duration, and route of administration, therapeutic and toxic monitoring parameters must be clearly documented and approved by the prescriber and department head. Approval of such treatment must be limited to one individual patient at a time. Close monitoring and outcome reporting must be made by the treating physician to the concerned committees.

MM.25 The hospital has a system for reviewing the appropriateness of medication orders before medication is dispensed.

MM.25.1 The hospital maintains an updated and complete medication profile (electronic or paper record) for each patient in the pharmaceutical care department.

MM.25.2 A trained pharmacist reviews all medication orders or prescriptions before dispensing (except in emergencies, lifesaving situations, or diagnostic imaging where the prescriber is physically present).

MM.25.3 All medication orders are reviewed for:

MM.25.3.1 Patient's allergies or sensitivities.

MM.25.3.2 Approved indications for use.

MM.25.3.3 Therapeutic duplications.

MM.25.3.4 Existing or potential interactions (drug-drug and drug-food interactions).

MM.25.3.5 Appropriateness of the medication dose, frequency, and route of administration.

MM.25.3.6 Contraindications.

MM.25.4 All issues, concerns, or questions regarding medication order or prescription are clarified with the prescriber and documented before medication dispensing.

Standard Intent:

Patients are prescribed different medications at different times during their hospital stay. Maintaining and updating the drug profile allows pharmacy to monitor for drug allergy, indications, dosing, and route of administration, therapeutic duplication, drug interactions, adverse drug reactions and contraindications.

Allergy to prescribed medication constitutes a major patient safety issue. It is the responsibility of admitting physician to take drug history for any known allergies and communicate it in writing to the pharmacy. Pharmacy should not dispense any

medication without knowing and documenting drug allergy in the patient drug profile. The pharmacy is authorized to stop dispensing any medication the patient is allergic to until clarification is made with the prescriber. A qualified and licensed pharmacist reviews each prescription or order new to the patient for appropriateness except in emergency situations. This occurs prior to dispensing by a pharmacist or a technician. When questions arise, the individual who prescribed or ordered the medication is contacted for verification. Any changes in medication order shall be documented in patient's medical record. To prevent dispensing errors, dispensed medicine must be double checked by another pharmacist before leaving the pharmacy. As authorized by the pharmacy and therapeutics committee, the pharmacist is allowed to dispense generic substitution without consulting the prescriber unless the prescriber specifies "dispense as written".

MM.26 The hospital has a system for safe preparation of sterile compounded preparations.

MM.26.1 The hospital has a manual for proper aseptic technique and intravenous admixture (e.g., the guidelines of the Saudi Food and Drug Authority, the American Society of Health-System Pharmacists, United States Pharmacopoeia USP).

MM.26.2 Sterile compounded preparations are performed by the pharmaceutical care except during emergency or urgency situations in which a delay could harm the patient or when product stability is short.

MM.26.3 Sterile compounded preparations are performed in the clean room by pharmaceutical care staff, qualified in intravenous admixture and aseptic technique.

MM.26.4 The hospital provides and documents training and competency assessment of non-pharmaceutical care staff involved in compounding sterile preparations outside the pharmaceutical care department during emergency or urgency situations.

MM.26.5 There is full compliance with aseptic technique in all medication preparation areas all over the hospital.

MM.26.6 Visual inspection is performed for all compounded sterile products by a trained individual for particulate, discoloration, or evidence of loss of integrity.

MM.26.7 The pharmaceutical care has a clean room that is a functionally separate facility to maintain product sterility.

MM.26.8 The design of the clean room is guided by the professional organizations' standards (e.g., the American Society of Health-System Pharmacists, United States Pharmacopoeia USP).

MM.26.9 The pharmaceutical care uses ISO Class 5 laminar airflow hood for preparing sterile injectable preparations and all other sterile preparations.