Department of Pharmacy POLICY AND PROCEDURE

POLICY NUMBER: 911
VERSION: 4

SUBJECT: Non-Sterile Compounding Policy

PURPOSE:

To outline all processes related to non-sterile compounding at High Desert Regional Health Center Pharmacy.

DEFINITIONS:

"Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

1. Altering the dosage form or delivery system of a drug
2. Altering the strength of a drug
3. Combining components or active ingredients
4. Preparing a drug product from chemicals or bulk drug substances

PROCEDURE:

Training and Competency

Pharmacy staff authorized to compound non-sterile medication at HDRHC pharmacy will be limited to pharmacists. All pharmacists involved in compounding shall have the skill and training required to properly and accurately perform their duties in compounding.

The pharmacist-in-charge shall be responsible for documenting initial training and/or competence in compounding and compounding processes and procedures including recordkeeping. The pharmacist-in-charge shall be responsible for maintaining records of a yearly competence evaluation for all staff involved in compounding.

All documentation of compounding training and competency shall be retained for at least three years beyond the period of employment.

Compounding Limitations

Drug products that are commercially available *shall not* be compounded unless a change must be made for an identified individual patient.

If a commercially available drug is compounded to pharmacist must notify the provider and document the reason compounded (i.e. shortage, allergy, intolerance to dosage form)

Recordkeeping:

Prior to allowing any non-sterile drug product to be compounded at HDRHC pharmacy, the pharmacist-in-charge shall complete the first section of the compounding self-assessment form developed by the California Board of Pharmacy. The self-assessment shall subsequently be completed before July 1 of odd-numbered each year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license.

The pharmacy shall only prepare a compounded drug product with a valid prescription for an individual patient.

Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. Records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding and these records shall be readily retrievable for at least three years from the date the record was created.

A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes the following elements:

1. Active ingredients to be used
2. Inactive ingredients to be used
3. Process and/or procedure used to prepare the drug
4. Quality reviews required at each step in preparation of the drug
5. Post-compounding process or procedures required, if any
6. Expiration dating requirements

Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.

To prepare a compounded drug the following shall be documented:

1. The date the drug product was compounded
2. The identity of the pharmacist compounding and reviewing final drug product
3. The quantity of each component used in compounding the drug product

4. The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted
5. The equipment used in compounding the drug product
6. Prescription number
7. The expiration date of the final compounded drug product
8. The quantity or amount of drug product compounded

Expiration Dating

Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This “beyond use date” of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist. Beyond use dates will be found in the master formula record. **All pharmacy staff shall follow these dates.**

Labeling Requirements

A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

1. The generic name(s) of the principal active ingredients (s) and inactive ingredient(s) with quantity
2. Directions for the use of the drug
3. Patient name
4. Prescriber name
5. The date of issue
6. The name and address of the pharmacy
7. Prescription number
8. The strength of the drug or drugs dispensed
9. The quantity of the drug or drugs dispensed
10. The expiration date of the effectiveness of the drug dispensed

11. **A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.**

Facilities/Equipment

- Compounded medications shall be prepared on a clean disinfected surface.
- A graduated cylinder shall be used to compound any liquid compound with specific measurements. This graduated cylinder shall always be cleaned with hot, soapy water after each use and stored to dry on a cleaned disinfected surface.
- A mortar and pestle shall be used to grind or crush tablets used for compounding. This mortar and pestle shall be cleaned with hot, soapy water after each use and stored to dry on a cleaned disinfected surface.
- All equipment used to compound shall be cleaned with hot, soapy water after each use and stored to dry on a cleaned disinfected surface.
- Rubbing alcohol shall be used to disinfect and clean surfaces before and after compounding.

Compounding Policies and Procedures

- These policies and procedures shall be reviewed annually and updated whenever changes are implemented by the pharmacist-in-chart.
- Any change in compounding duties or policies and procedures shall be communicated to all pharmacy staff via a memo and a signed log shall be maintained to document this communication.

Compounding Quality Assurance

The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

- “Integrity” means retention of potency until the expiration date noted on the label.
- “Potency” means active ingredient strength within +/- 10% of the labeled amount.
- “Quality” means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.
- “Strength” means amount of active ingredient per unit of a compounded drug product

Pharmacy personnel authorized to compound at HDHS Pharmacy shall be limited to pharmacists.

To ensure that compounded products retain integrity, potency, and strength pharmacy personnel shall only use dated medication to compound these products. Pharmacy personnel shall ensure that the beyond use date used for the final compounded product does not come after any products used in compounding the final product have expired. Beyond use dates used for compounded drugs must be documented in the Master Formula Record. Beyond Use Dates for each compounded product shall be reviewed and researched before being implemented in the Master Formula Record. Pharmacy personnel compounding medications shall use a graduated cylinder to measure each liquid medication.

To ensure quality compounded products are dispensed from HDHS Pharmacy. Pharmacy staff shall ensure integrity, potency, and strength of these compounded products, as stated above. In addition all equipment must be cleaned in hot soapy water and stored on a disinfected surface. All compounded products shall be prepared on a disinfected surface.

To ensure integrity, potency, quality, and strength all compounded drug products shall only utilize drug products received by a reliable supplier and maintained in its proper storage conditions. All recalls for drug products used in compounded medication shall be handled following HDHS Pharmacy Policy and Procedure 2-58.

If it is discovered or expected that any compounded drug product is below minimum standards, pharmacist shall not dispense the product. If the product has been dispensed pharmacist shall follow procedures in “Pharmacy Quality Assurance Program: Medication Errors”

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