RANCHO LOS AMIGOS
NATIONAL REHABILITATION CENTER

**POLICY AND PROCEDURE MANUAL**
**PHARMACY SERVICES**

CODE: 1.26.0
DATE: 6/6/08
REVISED: 4/19/22
APPROVED: Thinh Tran, Pharm. D.
Page **1** of **4**

SECTION: **DEPARTMENT OF PHARMACY**

SUBJECT: **COMPOUNDED MEDICATIONS**

POLICY

This policy and procedure will address medication(s) that are ordered from a practitioner and is/are not supplied by a manufacturer in either the strength or formulation.

PROCEDURE

A. OUTSOURCED COMPOUNDED MEDICATIONS

1 The pharmacist will notify a Pharmacy Manager or designee, during normal working hours, upon receiving an order for a compounded extemporaneous medication.
2 Depending on the complexity, availability of: equipment, supplies, medication, resources, and references; the Pharmacy Manager or designee will determine whether to send the compounded extemporaneous medication(s) to an authorized Pharmacy vendor or compound it at the facility's Pharmacy.
3 If the decision is to send the compounded extemporaneous medication(s) to an authorized Pharmacy vendor, the Pharmacy Manager or designee will contact the vendor to assure: 1) that it is feasible, 2) the vendor has references and stability data, and 3) retrieve the references and stability data and keep it on file prior to placing the order.
4 The Pharmacy Manager or designee will instruct the Procurement Assistant to place an order to the authorized Pharmacy vendor for the sterile compounded extemporaneous medication(s).
5 The Pharmacy Manager or designee will instruct the pharmacist to call the practitioner and unit to inform the practitioner and unit of the estimated time of arrival of the sterile compounded extemporaneous medication(s).
6 Upon receipt of the sterile compounded extemporaneous medication(s), the Pharmacy Procurement staff will notify the Inpatient Pharmacy staff of its arrival and the Inpatient Pharmacy staff will apply a label with the patient's name and directions on the container assuring that vendor's product information is visible.
7 The Inpatient Pharmacy staff will notify the practitioner and unit of the sterile compounded extemporaneous medication(s)'s arrival and deliver it to the unit
8 This policy must be reviewed on an annual basis by the pharmacist-in-charge and updated whenever changes in process are implemented.
9 The pharmacist-in-charge is responsible for notifying staff assigned to compounding duties of any changes in process or to the policy and procedure manual.

Reviewed: 4/28/14bj; 12/14/16ll; 4/19/2022 TT
PIC signature_____Date:_____
Approved By: Ben Ando

B. COMPOUNDED MEDICATIONS

1 The pharmacy will not compound drug product prior to receipt of a valid prescription from a practitioner.

2 The pharmacy will not compound medication until it has prepared a compounding log for each individual compounded prescription. The master formula record is on-line. The compounding log will contain all of the following:

a. Name and strength of the compounded drug preparation,
b. the date the drug preparation was compounded,
c. the identity of any pharmacy personnel engaged in compounding the drug preparation,
d. the identity of the pharmacist reviewing the final drug preparation,
e. the quantity of each ingredient used in compounding the drug preparation,
f. the manufacturer, expiration date, and lot number of each component. If the manufacturer is unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy and the limitations in the Beyond Use Date Policy 1.51.0.

3 If a master formula is not on file, the pharmacist must make a manufacturing worksheet in accordance to accepted CA Board of Pharmacy standards (CCR 1735). The master formula must refer to the source of documentation being used to validate the preparation, expiration, and labeling of the compounded medication for quality assurance purposes.

4 Only pharmacy staff assigned to compounding duties may compound medications. These staff documented their compounding skills by passing the DHS Pharmacy Competency testing for their respective job descriptions. All pharmacy staff involved in any process of the compounding of a medication must initial the manufacturing sheet in the appropriate place. This includes the pharmacist performing the final check.

5 Any component of a compounded medication involved in a recall, would require that the entire compounded medication be recalled in accordance with DHS Pharmacy Recall Policy.

6 Testing Methodology

a. **Integrity** of the product will be according to the referenced article or the manufacturer's expiration date.

Reviewed: 4/28/14bj; 12/14/16ll; 4/19/2022 TT
PIC signature_____Date:_____

b. **Potency**: We will be compounding with USP products and in the event that the compounded product is outsourced, the outsourced vendor will provide the potency data.
c. **Quality**: The compounded product will be checked by a pharmacist to assure 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.
d. **Strength**: The compounded product will be checked by a pharmacist to assure that all active USP ingredients were according to the master formula.

7 Any event in which any compounded drug product is ever discovered to below minimum standards for integrity, potency, quality or labeled strength must be immediately reported to the pharmacist-in-charge. The pharmacist-in charge is required to enter into Safety Intelligence as a medication error for RLANRC QRM and P&T to evaluate.

8 The pharmacy maintains and retains all records required in a readily retrievable form for at least 3 years in accordance with CA Board of Pharmacy regulations.

9 This policy must be reviewed on an annual basis by the pharmacist-in-charge and updated whenever changes in process are implemented.

10 The pharmacist-in-charge is responsible for notifying staff assigned to compounding duties of any changes in process or to the policy and procedure manual. Notification may be through staff meetings, e-mail, or handouts. All personnel involved must read all additions, revisions, and deletions to the written policies and procedures. Each review must be documented by a signature and date. Any material failure to follow the Pharmacy's written policies shall constitute a basis for disciplinary action.

11. Pharmacies shall maintain records of proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

12. The Pharmacy shall acquire and retain certificates of purity or analysis for chemicals, bulk drug substances, and drug products used in compounding that are not FDA approved.

13. Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy.

Reviewed: 4/28/14bj; 12/14/16ll; 4/19/2022 TT
PIC signature_____Date:_____

14. All hazardous agents shall bear a special label which states "Chemotherapy-Dispose of Properly" or "Hazardous-Dispose of Properly."
    a. Any drug preparation that is compounded in a Primary Engineering Control (PEC) where hazardous drugs are prepared must be labeled as hazardous.

Reviewed: 4/28/14bj; 12/14/16ll; 4/19/2022 TT
PIC signature_____Date:_____