RANCHO LOS AMIGOS
NATIONAL REHABILITATION CENTER

POLICY AND PROCEDURE MANUAL
PHARMACY SERVICES

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SECTION: **INPATIENT PHARMACY SERVICES**

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SUBJECT: **REPACKAGING**

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POLICY

The basic function of all pharmacy repackaging operations is to provide a safe and adequate supply of medications in convenient quantities. Any repackaging operation tends to obscure the source and identity of the materials processed, therefore it is essential that a system of controls be implemented to insure the integrity of the finished product of the repackaging operation.

PROCEDURE

Records

The following records shall be maintained to facilitate identification and tracing of any of the materials or ingredients used in the repackaging process.

1. Dispense Report is used as record keeping for any unit-dose repackaging operation via Talyst Autopack system (jv-240bx6).
2. Each drug to have separate file sheet.

RECORD DESCRIPTION

The repackaging control number sheet file shall be a permanent record containing the following entries:

1. Date of repackaging
2. Facility Lot number.
3. Name and strength of drug or preparation repackaged.
4. Dosage Form
5. Manufacturer of repackaged drugs.
6. Lot number of manufacturer of repackaged preparations.
7. Expiration date of repackaged preparation.
8. Quantity of packages made.
9. Pills per package
10. Initial of technician or individual performing repackaging operation.
11. Initial of pharmacist for the pre-check and final check.

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Approved By:

SELECT DRUG

Select drug to be repackaged and place in a designated holding area until the repackaging takes place. Pharmacist checks to ascertain correctness of the drug and strength.

Repackaging Procedure

Refer to repackaging workflow diagram

1. Packaging Medication with canister method.
2. Packaging Medication with STS method.

MIXED LOTS

Not more than one drug or a single lot of a given drug may be processed at one time.

QUARANTINE AND LABELING

Immediately after bottling and capping is completed, the repackaged drug shall have the Rancho Los Amigos National Rehabilitation Center control or lot number, with the expiration date affixed to each container of repackaged drug. The control number, expiration date and barcode may be a permanent part of the primary label or may be applied as an accessory label. If for any reason the labeling is not completed in a single operation, the repackaged drugs with control number, expiration date and barcode applied to the containers shall be placed in a quarantine area, along with the original drug containers, until the labeling is complete. In-so-far as possible, the repackaging and labeling operation shall be completed on the same shift or work as started. Labeling for the primary label shall conform to the labeling requirements of the Pharmacy Policy and Procedures Manual, Section 1.31.0, Labeling Medication Containers.

When a manufacturing sheet is **not** used, the pharmacy technician and pharmacist will initial the label.

CERTIFICATION

The pharmacist supervising the repacking and labeling operations will do a pre-check by signing or initialing the Dispense Report and also during the final check after determining the repacking and labeling procedures have been properly carried out to certify the repackaged drugs.

Labels for repackaged medications using this format include the following entries:

1. The generic/commercial name of the medication

2. Strength
3. Dosage form
4. Manufacturer
5. Package date
6. Manufacturer lot number
7. Drug expiration
8. Barcode identifier
9. Name of individual performing the repackaging operation.

Inpatient repackaging to unit-dose format is accomplished using Talyst's AutoPack system, (JV-240BX6). The drug name (generic/commercial), strength, manufacturer's name and lot number are used to identify repackaged items. The expiration date is not to exceed one year from the date of repackaging or the manufacturer's expiration date, whichever is less (28 days for liquid medications). The Euclid Cadet7 with Computer Printing & Sensors repackaging machine are as backup. Only sufficient amounts of drugs are repackaged at any time. The label and contents are then checked by a pharmacist prior to use.