REPACKAGING IN THE HOSPITAL PHARMACY

Kathy Crowther, CPhT

OBJECTIVES
- Define what repackaging is and why it is done
- Outline instances where repackaging of drugs is necessary
- Describe the importance of the unit-dose system in the hospital setting
- List labeling requirements for a repackaged product
- Identify the types of repackaging systems available to hospitals

PRE-TEST
- T or F Repackaging is done in the hospital setting primarily as a cost saving measure.
- T or F Repackaged products are given the same expiration date as the bulk bottle they are repackaged from.
- T or F Repackaged liquids may not contain overfill.
- T or F Labels for repackaging should include the lot number of the manufactured product used.
- T or F Extra measures should be taken to ensure that repackaged narcotics are tamper-proof.
- T or F Oral liquids repackaged into syringes should be labeled "For oral use only".

WHAT IS REPACKAGING?
Repackaging occurs when a drug product is removed from its original manufactured packaging to be placed in new packaging.

WHO DOES REPACKAGING?
- Mediset pharmacies
- Long-term care facilities
- Repackaging firms
- Hospitals

WHY IS REPACKAGING DONE?
- Hospitals – to have all medications available in unit-of-use (unit dose) form for nursing staff
- Mediset pharmacies and long-term care facilities – to have all daily doses already prepared to assure patient compliance
- Repackaging firms – to offer unit-of-use forms to hospitals so they don’t need to repack drugs
WHAT CAN BE REPACKAGED?
- Tablets and capsules
- Oral liquids (into cups or oral syringes)

MEDISET REPACKAGING
- Medications are placed in blister packs, usually a week’s worth at time
- Makes administration of daily doses easier for caregivers and elderly patients at home or in long-term care facilities

HOSPITAL REPACKAGING
- Done so drugs will be in unit-dose form before administration to patients
- Options include purchasing unit-dose products from the manufacturer, using a repackaging firm, or repackaging products in the pharmacy

THE UNIT DOSE SYSTEM – WHAT IS IT?
A unit dose package is one containing a discrete dose for a patient, for example, one tablet, or a measured quantity of an oral liquid.

BEFORE UNIT-DOSE …
- There was the stock bottle system
- Each nursing unit had stock bottles of all medications, solid and liquid, and nurses dispensed from these as needed
- In the same way, nursing homes and caregivers in a patient’s home dispensed from stock bottles
- Chance for serious errors was very high
- Opportunity for diversion was very high
THE UNIT DOSE SYSTEM – WHAT ARE ITS ADVANTAGES?

- Increased safety --- each individual dose is labeled for the nurse to check
- Reduced waste – only 24 hours worth of patient doses available to nursing staff
- Increased control of distribution – floor stock on the unit is eliminated along with all the problems associated with that system
- Ease of use

THE UNIT DOSE SYSTEM – WHAT ARE ITS DISADVANTAGES?

- Additional time/labor/training required to repackage drugs not available commercially in unit-dose form
- Additional time/labor required to prepare and deliver unit-dose items to nursing units or patients
- Cost of repackaging equipment, packaging, labels, etc.

THE UNIT DOSE SYSTEM – ITS IMPORTANCE

- Increased safety and control found in the unit-dose system greatly outweighs the disadvantages
- Preferred method of drug distribution according to ASHP (American Society of Hospital Pharmacists)
- Now used in all major hospitals as preferred method of drug distribution
- Means hospitals must do repackaging since not all drugs are available commercially in unit-dose form

MANUFACTURED UNIT-DOSE PRODUCTS

- Available for many oral drugs, both solid and liquids
- Can be expensive, but very convenient for hospital pharmacies
- Usually have longer dating than items repackaged in the hospital

REPACKAGING FIRMS
REPACKAGING FIRMS

- Drugs are purchased by the hospital and then sent to the repackager direct from the wholesaler or from the hospital.
- Advantages include reduced labor for the hospital and reduced investment in repackaging equipment and supplies.
- Disadvantages include loss of control and delays.
- While regulated by the FDA, third-party repackagers are not as closely regulated as manufacturers; there have been recalls and shutdowns.

WHEN IS REPACKAGING DONE IN THE HOSPITAL SETTING?

1. If no manufactured unit-dose or commercially repackaged product is available.
2. If commercially repackaged products are available, but are too expensive.
3. If a commercially available unit-dose product does not meet all labeling requirements for each individual package.
4. When the decision has been made not to use a third-party repackager or repackaging is needed immediately.
5. Repackaging system may be manual (least expensive) or automated (larger investment required).

ASHP GUIDELINES FOR REPACKAGING

1. Repackaging operations should be isolated from other pharmacy activities.
2. Only one drug product should be repackaged at a time.
3. All unused labels should be immediately destroyed to avoid labeling products incorrectly.
4. The bulk product should be examined prior to repackaging for signs of damage or contamination.
5. All repackaging equipment should be operated according to manufacturer’s instructions.
6. Packaging used should have documentation on light transmission, permeability and shelf life.

ASHP GUIDELINES FOR REPACKAGING, cont.

7. Labels should comply with all labeling requirements.
8. Repackaging operation should be overseen by a pharmacist and all finished products should be checked by a pharmacist.
9. Proper control records (repackaging log) should be kept and all batches should have an unique assigned lot number.
10. Pharmacist must determine an expiration date for the repackaged product not to exceed the expiration date of the original bulk product or the documented shelf-life of the packaging material.
11. Written procedures should be prepared and updated regularly.

AUTOMATED REPACKAGING SYSTEMS
AUTOMATED REPACKAGING SYSTEMS

- Typically cost in the tens of thousands of dollars
- Technician must fill the device and monitor repackaging process
- System prints label directly on the repackaged product
- Must be cleaned between uses to prevent cross-contamination
- Table-top machines tend to be bulky
- Back-up process needed for malfunctions and breakdowns
- Best for items needed in large quantities

MANUAL REPACKAGING SYSTEMS

- Drug is placed in the blister or cup by the technician, then sealed by hand
- Labels are generated on a printer using special computer software
- Generally a fairly rapid and simple process, especially for tablets and capsules
- Equipment costs only a few hundred dollars; however, packaging and labels tend to be expensive
- Ideal for small volumes of repackaging or items needed ASAP

PACKAGE REQUIREMENTS
PACKAGE REQUIREMENTS

Packaging used must protect the contents from:

1. Light
2. Moisture (humidity)
3. Temperature
4. Air
5. Handling (breakage and contamination)
6. Tampering

PACKAGE REQUIREMENTS

- Package should not deteriorate in any way during the shelf life of the product
- Package should not absorb any of the drug repackaged or affect it in any other way
- Package should be designed to withstand handling
- Package should be easy to open and allow for dispensing directly to the patient without using another container
- Package should be designed so that it is evident if the package has been opened. This is especially important for controlled substances.
- Package should have documented shelf life

LABEL REQUIREMENTS

According to ASHP, the minimum label requirements for repackaged items are:

- Generic name of drug
- Dosage form (e.g. tab, cap, oral solution, etc.)
- Strength
- Strength and dose of total contents
- Storage requirements (e.g. refrigerate)
- Expiration date (pharmacy assigned)
- Lot number (pharmacy assigned)

LABEL REQUIREMENTS, cont.

Other items that may be required by hospital policy:

- Brand name of drug (if brand product was used)
- NDC number of product repackaged
- Bar Code
- Repackager identity (e.g. ANMC IPRX)
- Class for controlled drugs (e.g. CII)
- Special drug classification, e.g. hazardous or look-alike/sound-alike
- Tablet-splitting information (e.g. ½ of a 10mg tab for a 5mg split tab)
LABEL REQUIREMENTS, cont.

Generic name of drug
- Should be spelled correctly
- Should be complete and specific
- Should indicate specific formulation of drug, e.g. extended release, delayed release

Dosage form
- Label should indicate specific dosage form of drug, e.g. tablet, capsule, solution, suspension

Strength
- For solids, product strength should be given with units, e.g. 15mg, 15mcg
- For liquids, product strength should be given as a concentration with units, e.g. mg/ml
- For liquids, product strength should be given as total dose/total volume, e.g. 50mg/10ml

Strength and dose of total contents
- If package contains multiple items to give one total dose, it should be clearly labeled, e.g. 650mg acetaminophen (= 325 mg tab X 2)

Storage requirements
- For items requiring refrigeration
- Room temperature is assumed if no storage information is given

Pharmacy-assigned expiration date
- Expiration date of repackaged product cannot exceed expiration date of bulk product used
- Expiration date of repackaged product cannot exceed recommended maximum shelf-life of packaging used
LABEL REQUIREMENTS, cont.

Pharmacy-assigned lot number

- Each repackaged product is given a unique lot number
- These are assigned in the repackaging log book

LABEL REQUIREMENTS, cont.

Brand name of drug (if brand product used)

- If brand product is used, the brand name should be included on the label
- Generic name of drug should still appear on label

LABEL REQUIREMENTS, cont.

NDC number

- NDC of bulk product used to repackage
- Inventory systems will typically keep track of the repackaged product as part of the bulk inventory
- Or inventory systems may account for them separately, in which case pharmacy will need to assign a “dummy” NDC number to the repackaged product

LABEL REQUIREMENTS, cont.

Barcode

- More and more hospitals are using bedside bar-coding to control distribution
- The barcode on the product is scanned by the nurse before administration
- Each repackaged item will need a barcode on the repackaged product that will be used to verify that the drug being given is on the patient’s medication profile
- Barcodes can be 1D or 2D

LABEL REQUIREMENTS, cont.

Repackager ID

- Information that identifies the repackaging institution

LABEL REQUIREMENTS, cont.

Controlled class

- Symbol indicating if a product is CII, CIII, CIV or CV
LABEL REQUIREMENTS, cont.
- Special drug classifications, e.g. hazardous, look-alike/sound-alike, or chemotherapy
- Hazardous drugs and chemotherapy drugs require special storage area separate from rest of pharmacy, special handling and labeling
- Look-alike/sound-alike drugs — typically one item of the pair is stored in a different area of the pharmacy to avoid mix-ups. Example: metformin and metronidazole

LABEL REQUIREMENTS, cont.
Tablet-splitting information
- If a tablet is split to make a dose, the repackaged label should indicate that package contains a split product
- Example: misoprostol 50mcg tab (1/2 of a 100mcg tab)

REPACKAGING LOG
- Should contain date of repackaging, initials of repackaging technician and initials of checking pharmacist
- Should contain generic name of drug repackaged, strength, total volume (for liquids), expiration date and lot number of bulk product used, pharmacy-assigned lot number and expiration date for the repackaged product and number of units repackaged
- Should include a label from the repackaged batch for documentation purposes
- Log is referenced for drug recalls

ORAL SOLIDS
- Packaging needs to have one side suitable for printing the label
- The other side of the blister or pouch needs to be transparent so the contents can be seen
- Closure needs to be secure, but easily openable
- Checking process should include making sure no packages are empty

ORAL LIQUIDS
- Package should deliver the labeled dose (overfill may be necessary, especially for thick suspensions)
- Package should be designed so patient can take the medication directly from the package (e.g. a cup)
- Checking process should include making sure no packages are empty or leaking
- Oral liquids repackaged into syringes should be labeled "For oral use only". The syringes used should not accept needles.
- Controlled substances repackaged into oral syringes should have tamper-proof caps.

POST-TEST
- T or F Repackaging is done in the hospital setting primarily as a cost saving measure.
- T or F Repackaged products are given the same expiration date as the bulk bottle they are repackaged from.
- T or F Labels for repackaging should include the lot number of the manufactured product used.
- T or F Extra measures should be taken to ensure that repackaged narcotics are tamper-proof.
- T or F Oral liquids repackaged into syringes should be labeled "For oral use only".
HANDS-ON !!!!!!