CHAPTER 20

LABELING MEDICATIONS

AND EXPIRATION DATING
LABELING IN THE HOSPITAL

✓ Standard of Practice in Hospital –
  Unit Dose Medications
✓ Studies in 1960’s documented reduction in
  medication errors by 60%

Joint Commission requires:
- a standardized method of labeling to minimize errors
- label the container if prepared but not administered immediately

1. UNIT DOSE MEDICATION – (Prepackaging) reference 64F-12.006
   a) Name of drug (brand or generic or both),
   b) Strength
   c) Dosage Form
   d) Manufacturer
   e) Lot number
   f) Expiration date/beyond use date
   g) OR instead of (d) and (e) a control number which cross references to the manufacturer
      name and lot number

2. INTRAVENOUS ADMIXTURES (<USP 797> & Standard of Practice)
   a) Medications are labeled at minimum with:
      i) Medication name
      ii) Strength
      iii) Amount (if not apparent from container)
      iv) Expiration date when not used within 24 hours
      v) Expiration time when expiration occurs in less than 24 hours
   b) Compounded IV admixtures and TPN solutions include date prepared and diluent
   c) Medications prepared for multiple patients or when the person preparing the medication is not
      the person administering the medication the label must include:
      i) Patient name
      ii) Patient location
   d) Appropriate accessory and supplemental labeling (such as “refrigerate”)
   e) The initials of the person preparing each compound
   f) Placement of labels
      i) Affixed to containers so that they may be read while hanging
      ii) The name, type of solution and manufacturer’s lot number should be visible
      iii) Placed so that visible inspection of the infusion contents is possible

3. BULK or multi-dose items such as EENTT products (standard of practice)
   a) Patient name
   b) Room number
   c) Pharmacist’s initials
   d) Date dispensed
   e) Expiration date/beyond use date, if required
All syringes and medication containers are labeled on and off sterile field (National Patient Safety Goal 3D)

a) Minimum labeling:
   - name
   - strength
   - amount (if not apparent from container
   - expiration date if not used within 24 hours
   - expiration time when expiration occurs in less than 24 hours

b) Visually and verbally verified by 2 qualified individuals when person preparing is not the person administering the medication

c) only one medication is labeled at a time

d) original containers are saved and discarded at the conclusion of the procedure

e) any containers found unlabeled are immediately discarded

f) at shift or break change medications are reviewed and confirmed by the exiting and entering personnel

MAINTAIN IN P&P MANUAL
HOSPITAL

EXPIRATION DATING

PREPACKAGEx versus REPACKAGE

“Beyond Use” (Expiration Dates)

Reference:
1 USP Revised Standards for Product Dating, First Supplement to USP24th rev + NF 19th ed

- Differentiation between “expiration date” and “beyond use date”
  - Expiration date – scientifically determined
  - Beyond use date – for prescriptions or repackaged drug

- Prescription vial “beyond use date”
  - The manufacturer’s expiration date or
  - One year from the date dispensed, whatever is earlier
  - “Appropriate” to limit how long a patient can retain a prescription after dispensed

- Repackaging non-sterile oral and liquid dosage forms packaged in unit –dose containers
  - One year unless stability data or manufacturer labeling indicates otherwise
  - All other dosage forms = 1 year

ASSUMES the pharmacy follows USP/NF repackaging methods, uses appropriate containers, and the container is stored at controlled room temperature (68-77 F or 20-25 C).
  - Measure temperature weekly
  - If temp consistently < 25 C, no calculations need to be done (use 1 year beyond use date)
  - If not consistently < 25 C, use formula to calculate mean kinetic temperature (VERY COMPLEX)

- Containers – evaluate material used and moisture permeability
  - PVC NOT recommended – very moisture permeable
  - Check with manufacture of container

- Packaging systems with 2 or more dosage forms in the same container dispensed to a specified patient
  - 60 day “beyond use date”
  - once dispensed, can not returned to stock or reused

Non-sterile Multi dose containers
Manufacturer’s expiration date unless otherwise specified by manufacturer

IV Therapy
- multidose injectable containers – 28 days unless otherwise specified by manufacturer
- single dose injectable containers (bags, syringes, vials) opened or needle-punctured - 1 hour
- single dose injectable container opened or needle punctured in LAF hood - 6 hours
- ampules – immediate use only (NO reuse)
### Table 1: Stability of Medicinal Drugs under Different Storage Conditions

<table>
<thead>
<tr>
<th></th>
<th>Low Risk</th>
<th>Medium Risk</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Room Temp</td>
<td>48 hrs</td>
<td>30 hrs</td>
<td>24 hrs</td>
</tr>
<tr>
<td>Refrigeration</td>
<td>14 days</td>
<td>9 days</td>
<td>3 days</td>
</tr>
<tr>
<td>Frozen</td>
<td>45 days</td>
<td>45 days</td>
<td>45 days</td>
</tr>
</tbody>
</table>

**Warmer < or = 104 F** - Drugs or IV solutions stored in warmers – check with manufacturer on maximum temperature and beyond use dating

**IVs out of overwrap** – follow manufacturer’s beyond use dating

### Check for Outdated drugs

- Minimum every 4 months
  - Place in Quarantine Area to prevent mix-up
  - Use of “Reverse Distributor” – EPA pharmaceutical Waste Generator

- **Methods**
  - Annual inventory
  - Monthly inspections
  - At time of order

- **Additional Places to Check**
  - Crash carts
  - Emergency Dept
    - Operating Room
    - Nursing Units
    - Respiratory Therapy
    - Radiology

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**64B16-28.108 All Permits - Labels and Labeling of Medicinal Drugs.**

Each container of medicinal drugs dispensed shall have a label or shall be accompanied by labeling.

1. **Definitions.**
   - “Controlled substance” means any substance named or described in Schedules II-V of Section 893.03, F.S.
   - “Customized medication package” means a package that:
     1. Is prepared by a pharmacist for a specific patient.
     2. Is a series of containers.
     3. Contains two (2) or more solid oral dosage forms.
   - “Labeling” means a label or other written, printed, or graphic material upon an agent or product or any of its containers, wrappers, drug carts, or compartments thereof, as well as a medication administration record (MAR) if a medication administration record is an integral part of the unit dose system.
   - “Radiopharmaceutical” means any substance defined as a drug in section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any of those drugs intended to be made radioactive. This includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance, but does not include drugs which are carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.
   - “Serial number” means a prescription number or other unique number by which a particular prescription or drug package can be identified.

2. **The label affixed to each container dispensed to a patient shall include:**
(a) Name and address of the pharmacy.
(b) Date of dispensing.
(c) Serial number.
(d) Name of the patient or, if the patient is an animal, the name of the owner and the species of animal.
(e) Name of the prescriber.
(f) Name of the drug dispensed (except where the prescribing practitioner specifically requests that the name is to be withheld).
(g) Directions for use.
(h) Expiration date.
(i) If the medicinal drug is a controlled substance, a warning that it is a crime to transfer the drug to another person.

(3) The label on the immediate container of a repackaged product or a multiple unit prepackaged drug product shall include:
   (a) Brand or generic name.
   (b) Strength.
   (c) Dosage form.
   (d) Name of the manufacturer.
   (e) Expiration date.
   (f) Lot number:
      1. Manufacturer’s lot number, or
      2. Number assigned by the dispenser or repackager which references the manufacturer’s lot number.

(4) A medicinal drug dispensed in a unit dose system by a pharmacist shall be accompanied by labeling. The requirement will be satisfied if, to the extent not included on the label, the unit dose system indicates clearly the name of the resident or patient, the prescription number or other means utilized for readily retrieving the medication order, the directions for use, and the prescriber’s name.

(5) A unit dose system shall provide a method for the separation and identification of drugs for the individual resident or patient.

(6) A customized patient medication package may be utilized if:
   (a) The consent of the patient or the patient’s agent has been secured, and
   (b) The label includes:
      1. Name, address and telephone number of the pharmacy.
      2. Serial number for the customized medication package and a separate serial number for each medicinal drug dispensed.
      3. Date of preparation of the customized patient medication package.
      4. Patient’s name.
      5. Name of each prescriber.
      6. Directions for use and any cautionary statements required for each medicinal drug.
      7. Storage instructions.
      8. Name, strength, quantity and physical description of each drug product.
      9. A beyond use date that is not more than 60 days from the date of preparation of the customized patient medication package but shall not be later than any appropriate beyond use date for any medicinal drug included in the customized patient medication package.
   (c) The customized patient medication package can be separated into individual medicinal drug containers, then each container shall identify the medicinal drug product contained.

(7) The label affixed to the immediate outer container shield of a radiopharmaceutical shall include:
   (a) Name and address of the pharmacy.
   (b) Name of the prescriber.
   (c) Date of the original dispensing.
   (d) The standard radiation symbol.
   (e) The words “Caution Radioactive Material.”
   (f) Name of the procedure.
   (g) Prescription order number.
   (h) Radionuclide and chemical form.
(i) Amount of radioactivity and the calibration date and time.
(j) Expiration date and time.
(k) If a liquid, the volume.
(l) If a solid, the number of items or weight.
(m) If a gas, the number of ampules or vials.
(n) Molybdenum 99 content to the United States Pharmacopeia (UPS) limits.
(o) Name of the patient or the words “Physician’s Use Only.”
(8) The label affixed to the immediate inner container of a radiopharmaceutical to be distributed shall include:
   (a) The standard radiation symbol.
   (b) The words “Caution Radioactive Material.”
   (c) Radionuclide and chemical form.
   (d) Name of the procedure.
   (e) Prescription order number of the radiopharmaceutical.
   (f) Name of the pharmacy.
   (g) Beyond use date or, if the medicinal drug or product is dispensed in an unopened sealed package, the manufacturer’s expiration date.

NURSING HOME

LABELING
IN THE NURSING HOME

1. Traditional system in the Nursing Home
   a. Name and address of pharmacy
   b. Name of prescriber
   c. Name of the resident
   d. Date (original or refill date)
   e. RX number
   f. Directions
   g. Control drug requires transfer warning
   h. Name of the medication - Brand name, Generic name or both
      (MD may request to be withheld in the retail pharmacy).
   i. Quantity (not required in the retail pharmacy) (State)
   j. Expiration date
   k. Strength

2. Unit dose system in the Nursing Home (additional labeling requirements)
   a. Name (Brand name, Generic name or both)
   b. Manufacturer
   c. Lot number
   d. Strength of drug (Federal regulation)
   e. Dosage form
   f. Expiration Date

3. Small Containers
   a. Ophthalmic Ointments and Drops
   b. Insulin Vials
   c. Ampules

4. Floor Stock
   a. Open Dates on floor stock containers
   b. Non-Drug supplies
      Ex. Tape
      Bandages
5. Products with abbreviated discard dates
   a. General pharmacy policies
   b. Products with established discard dates on manufacturer’s packaging
      (see page 20.18 & 20.19)

6. Required Policies and Procedures:
   a. Reviewing MAR’s for directions
   b. Expiration dates
   c. Returning non-control U/D for credit
   d. Identifying manufacturers
   e. Re-labeling soiled or inaccurate labels
   f. Abbreviations on labels
   g. Labeling non-RX stock drugs
   h. Labeling products with outer-covers (i.e. IV bags)
   i. Labeling products too small for a traditional RX label
Expiration Dates in the Nursing Home

I. What drugs need expiration dates?
   1. All drugs in the nursing home must have a “beyond use” date.
   2. Unit dosed medication (unless direct from the manufacturer) should not exceed 1 year from package date
   3. Bulk containers (ex Multivitamins) – the manufacturer’s expiration date may be used unless the facility policy shortens this date
   4. Ophthalmics, Otics, Ointments – manufacturer’s expiration date unless facility policy shortens this date

II. Who should check dating?
   1. Nursing staff should be trained to routinely check expiration dates as part of their med pass responsibility
   2. The Consultant Pharmacist should be checking expiration dates during his/her monthly inspection

III. Policy regarding nursing checking expiration dates
   1. Nursing staff should be required to do a formal review of expiration dates at least monthly. The 3rd shift is an ideal time to do this inspection. Nursing policies should address this QA function
   2. Consultant Pharmacist should check expiration dates during the physical inspection each month
      Pharmacy policies should address the role of the Consultant Pharmacist

IV. Document Inspections
   1. Both nursing and the Consultant Pharmacist should document and sign their inspection reports
   2. The Consultant Pharmacist usually incorporates this inspection document in their monthly report to the Director of Nursing

VI. Repackaging - not prepared for direct dispensing to patient
   1. Repackaging refers to unit dosing product that will be distributed to another pharmacy for distribution.
   2. Repackaging medication does not fall under a Pharmacy permit. A company that wishes to repackage medications must be licensed by the FDA and the Florida Dept of Health as a Repackager
   3. FDA good manufacturing standards require that repackaged medications have a MAXIMUM expiration date of 6 months unless stability testing has been completed.

VII. Pre-packaging - dispensing to the patient
   1. Pre-packaging is what most Pharmacies do. The product can be pre-packaged and immediately dispensed to a patient or the pre-packaged medication can be prepared and stored in the pharmacy for future dispensing
   2. Pre-packaged medication should have a MAXIMUM expiration date of 1 year from the date packaged
State Survey Manual

59A-4.112 (5) Drugs and biologicals used in the facility shall be labeled in accordance with currently accepted professional principles, Chapter 499, F.S. and Chapter 61F10, F.A.C.

59A-4.112 (10) The facility shall maintain an Emergency Medication Kit, the contents of which shall be determined in consultation with the Medical Director, Director of Nursing and Pharmacist, and it shall be in accordance with facility policies and procedures. The kit shall be readily available and shall be kept sealed. All items in the kit shall be properly labeled. The facility shall maintain an accurate log of receipt and disposition of each item in the Emergency Medication Kit. An inventory of the contents of the Emergency Medication Kit shall be attached to the outside of the kit. If the seal is broken, the kit must be resealed the next business day after use.

Federal Survey Manual

F431 (Revised 9/20/2006)

§483.60(d) Labeling of Drugs and Biologicals

Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

§483.60(e) Storage of Drugs and Biologicals

(1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.

(2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.
(1) The manufacturer, repackager, or other distributor of any medicinal drug shall display the expiration date of each drug in a readable fashion on the container and on its packaging. The term "readable" means conspicuous and bold.

(2) Each pharmacist for a community pharmacy dispensing medicinal drugs and each practitioner dispensing medicinal drugs on an outpatient basis shall display on the outside of the container of each medicinal drug dispensed, or in other written form delivered to the purchaser:

(a) The expiration date when provided by the manufacturer, repackager, or other distribution of the drug; or

(b) An earlier beyond-use date for expiration, which may be up to 1 year after the date of dispensing.

The dispensing pharmacist or practitioner must provide information concerning the expiration date to the purchaser upon request and must provide appropriate instructions regarding the proper use and storage of the drug.

(3) This section does not impose liability on the dispensing pharmacist or practitioner for damages related to, or caused by, a medicinal drug that loses its effectiveness prior to the expiration date displayed by the dispensing pharmacist or practitioner.

(4) The provisions of this section are intended to notify the patient receiving a medicinal drug of the information required by this section, and the dispensing pharmacist or practitioner shall not be liable for the patient's failure to heed such notice or to follow the instructions for storage.
The following list represents revised recommendations based on manufacturer's literature or USP standards for expiration dating.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>EXPIRATION DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>External medications, bulk liquids and solid dosage forms</td>
<td>See manufacturer's container</td>
</tr>
<tr>
<td>Nitroglycerin sublingual products</td>
<td>Nitrostat &amp; NitroQuick - manufacturer's expiration date or 12 months after open date</td>
</tr>
<tr>
<td>Prepackaged unit dose medication</td>
<td>See package (maximum 1 year from package date)</td>
</tr>
</tbody>
</table>

**Do Not Refrigerate**

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>EXPIRATION DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suppositories</td>
<td>Store at room temperature unless specifically directed to refrigerate</td>
</tr>
<tr>
<td>Pepcid Suspension</td>
<td>30 days from mixed dated</td>
</tr>
</tbody>
</table>

**Store in Refrigerator**

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>EXPIRATION DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Insulin products</td>
<td>Good refrigerated for 28 days after open date</td>
</tr>
<tr>
<td>Ativan (Lorazepam) injectable</td>
<td>Good unrefrigerated for 14 days</td>
</tr>
<tr>
<td>Ativan (Lorazepam) Intensol Solution</td>
<td>Good unrefrigerated for 30 days, 90 days if refrigerated</td>
</tr>
<tr>
<td>Calcimar Injection</td>
<td>Good unrefrigerated for 48 hours</td>
</tr>
<tr>
<td>Epogen &amp; Procrit</td>
<td>Good unrefrigerated for 14 days - 21 days after initial entry if refrigerated</td>
</tr>
<tr>
<td>Insulin (Novolin)</td>
<td>Good unrefrigerated for 28 days after first use</td>
</tr>
<tr>
<td>Miacalcin Spray</td>
<td>Good unrefrigerated for 30 days - store upright</td>
</tr>
<tr>
<td>Pepcid Injection</td>
<td>Good unrefrigerated for 7 days</td>
</tr>
<tr>
<td>Phospholine Iodide Ophthalmic</td>
<td>Good Unrefrigerated for 30 days</td>
</tr>
<tr>
<td>Ventolin nebul 3ml</td>
<td>Good unrefrigerated for 14 days</td>
</tr>
<tr>
<td>Xalatan Ophthalmic - until opened</td>
<td>Good unrefrigerated for 6 weeks - protect from light</td>
</tr>
</tbody>
</table>

**Intravenous Products**

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>EXPIRATION DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Piggy Back IV solutions 100cc or below</td>
<td>15 days after removal from outer cover (if not spiked)</td>
</tr>
<tr>
<td>All Piggy Back IV solutions 1000cc</td>
<td>30 days after removal from outer cover (if not spiked)</td>
</tr>
<tr>
<td>All mixed medications for infusion</td>
<td>refer to expiration date provided by pharmacy</td>
</tr>
</tbody>
</table>

**Solutions for Irrigation**

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>EXPIRATION DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetic acid for irrigation</td>
<td>24 hours after opening</td>
</tr>
<tr>
<td>GCP Solution</td>
<td>30 days after mixing (refrigerate)</td>
</tr>
<tr>
<td>Sterile normal saline for irrigation</td>
<td>24 hours after opening</td>
</tr>
<tr>
<td>Sterile water for irrigation</td>
<td>24 hours after opening</td>
</tr>
</tbody>
</table>

**Ophthalmics, Otics and Inhaled Products**

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>EXPIRATION DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advair Discus</td>
<td>Discard 1 month after removal from the protective overwrap</td>
</tr>
<tr>
<td>Duo-Neb</td>
<td>Protect from light, store in foil overwrap. Discard after expiration date</td>
</tr>
<tr>
<td>Flovent</td>
<td>Discard 6 weeks after removal from moisture protective overwrap pouch</td>
</tr>
<tr>
<td>Foradil</td>
<td>4 months after open date or product expiration date (whichever is earlier)</td>
</tr>
<tr>
<td>Serevent</td>
<td>Discard 6 weeks after removal from moisture protective overwrap pouch</td>
</tr>
<tr>
<td>Ear Drops</td>
<td>Manufacturer's expiration date</td>
</tr>
<tr>
<td>Inhalers</td>
<td>Manufacturer's expiration date</td>
</tr>
<tr>
<td>Product Description</td>
<td>Storage and Expiration Details</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Miacalcin Nasal Spray</td>
<td>Once opened, store upright at room temp for up to 35 days</td>
</tr>
<tr>
<td>Mucomyst (acetylcysteine)</td>
<td>96 hours after opening if refrigerated</td>
</tr>
<tr>
<td>Ophthalmic Solutions &amp; Ointments</td>
<td>Manufacturer's expiration date</td>
</tr>
<tr>
<td>Nasal Sprays</td>
<td>Manufacturer's expiration date</td>
</tr>
<tr>
<td>Phospholine Iodide Ophthalmic</td>
<td>6 months after pharmacy reconstitution</td>
</tr>
<tr>
<td>Ventolin inhalation solution 0.5% 5mg/ml x 20ml</td>
<td>28 days after open date</td>
</tr>
<tr>
<td>Xopenex</td>
<td>Store unopened vials in foil pouch, use within 2 weeks after pouch is opened, use indivisual vials within 1 week after opening</td>
</tr>
</tbody>
</table>

**Miscellaneous Products**

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Storage and Expiration Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Multi Dose Injectables</td>
<td>28 days after open date</td>
</tr>
<tr>
<td>Ampules</td>
<td>single dose only</td>
</tr>
<tr>
<td>Aranesp</td>
<td>single dose only</td>
</tr>
<tr>
<td>B Complex with C &amp; B12 Injection</td>
<td>14 days after reconstitution (must be refrigerated)</td>
</tr>
<tr>
<td>Bacteriostatic Normal Saline</td>
<td>28 days after open date</td>
</tr>
<tr>
<td>Bacteriostatic water for injection</td>
<td>28 days after open date</td>
</tr>
<tr>
<td>Emergency Box</td>
<td>Must be replaced next work day after opening</td>
</tr>
<tr>
<td>Lasix (Furosemide) Oral Solution</td>
<td>60 days from open date</td>
</tr>
<tr>
<td>Morphine Sulfate Soln (Roxanol)</td>
<td>90 days from open date</td>
</tr>
<tr>
<td>Single dose vials and dosettes</td>
<td>24 hours</td>
</tr>
<tr>
<td>Sterile water for injection</td>
<td>One time use only</td>
</tr>
<tr>
<td>Tubersol (or Aplisol) tuberculin PPD</td>
<td>for original vial (28 days) after opening (refrigerated)</td>
</tr>
</tbody>
</table>
PHARMACY REGULATIONS

64B16-28.108 All Permits - Labels and Labeling of Medicinal Drugs.
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(e) “Serial number” means a prescription number or other unique number by which a particular prescription or drug package can be identified.

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(b) Date of dispensing.
(c) Serial number.
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(e) Name of the prescriber.
(f) Name of the drug dispensed (except where the prescribing practitioner specifically requests that the name is to be withheld).
(g) Directions for use.
(h) Expiration date.
(i) If the medicinal drug is a controlled substance, a warning that it is a crime to transfer the drug to another person.
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(c) Dosage form.
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   1. Name, address and telephone number of the pharmacy.
   2. Serial number for the customized medication package and a separate serial number for each medicinal drug dispensed.
   3. Date of preparation of the customized patient medication package.
   4. Patient’s name.
   5. Name of each prescriber.
   6. Directions for use and any cautionary statements required for each medicinal drug.
   7. Storage instructions.
   8. Name, strength, quantity and physical description of each drug product.
   9. A beyond use date that is not more than 60 days from the date of preparation of the customized patient medication package but shall not be later than any appropriate beyond use date for any medicinal drug included in the customized patient medication package.
(c) The customized patient medication package can be separated into individual medicinal drug containers, then each container shall identify the medicinal drug product contained.

(7) The label affixed to the immediate outer container shield of a radiopharmaceutical shall include:
(a) Name and address of the pharmacy.
(b) Name of the prescriber.
(c) Date of the original dispensing.
(d) The standard radiation symbol.
(e) The words “Caution Radioactive Material.”
(f) Name of the procedure.
(g) Prescription order number.
(h) Radionuclide and chemical form.
(i) Amount of radioactivity and the calibration date and time.
(j) Expiration date and time.
(k) If a liquid, the volume.
(l) If a solid, the number of items or weight.
(m) If a gas, the number of ampules or vials.
(n) Molybdenum 99 content to the United States Pharmacopeia (USP) limits.
(o) Name of the patient or the words “Physician’s Use Only.”

(8) The label affixed to the immediate inner container of a radiopharmaceutical to be distributed shall include:
(a) The standard radiation symbol.
(b) The words “Caution Radioactive Material.”
(c) Radionuclide and chemical form.
(d) Name of the procedure.
(e) Prescription order number of the radiopharmaceutical.
(f) Name of the pharmacy.

(9) The labeling on a carton or package containing a medicinal drug or product dispensed from an Extended Scope Renal Dialysis (ESRD) pharmacy shall include:
(a) “Use as Directed” statement.
(b) The name and address of the person to whom the products will be delivered.
(c) Name of the prescriber.
(d) Name and address of the ESRD pharmacy location from which the products were shipped.
(e) Prescription number.
(f) Any special instructions regarding delivery dates or locations.
(g) Beyond use date or, if the medicinal drug or product is dispensed in an unopened sealed package, the manufacturer’s expiration date.

POLICY:
All prescription drugs are to be labeled in accordance with federal and state laws governing prescription dispensing, and in accordance with standards of pharmacy practice. No person other than the pharmacist is to modify any prescription label. Non-prescription drugs are to be kept and stored in the manufacturer’s original container and identified with the patient’s name. The nurse receiving the drug is responsible for assuring that all drugs coming from the pharmacy are properly labeled.

METHODS:
1. The licensed nurse receiving medication is responsible for assuring that each item, regardless of which pharmacy supplies it, is properly labeled in accordance with the following procedures. Any drug improperly labeled is to be rejected and returned to the pharmacy which issued it.

2. Labels are to be permanently affixed to the outside of the prescription container. Under no circumstances should medicine be accepted by the nurse if the label is inserted into the vial.

3. All prescription medications, regardless of the source, are to be labeled as follows:
   a. The directions for use, as specifically as possible.
   b. The name of the patient, first name first.
   c. The name of the prescriber.
   d. The date the drug is dispensed.
   e. The name, address, and telephone number of the issuing pharmacy.
   f. The prescription number.
   g. The brand or generic name of the drug. When the generic name is used, the name or an acceptable abbreviation of the manufacturer is to follow. When a generic drug is dispensed in place of a brand name product, the generic name, the name or an abbreviation of the manufacturer, and a statement similar in effect to:
   h. Strength
   i. Quantity
   j. Expiration Date
4. Non-prescription drugs not dispensed by prescription are to be in the manufacturer’s original container and identified with the patient’s name.

5. Medication containers having soiled, damaged, incomplete, illegible, or makeshift labels are to be returned to the issuing pharmacy for re-labeling or destroyed in accordance with the procedures for drug destruction.

6. The drug label is not to be altered, modified, or marked in any way resulting in any change in the original meaning, nor are contents to be transferred from one container to another. If the pharmacy makes a typing error on the label, or the directions for use change, the medication should be returned to the pharmacy for re-labeling.

7. Crisco is occasionally ordered as an emulsion and is used for cosmetic purposes of reducing dry skin. Patient families may purchase the Crisco for the patient’s use and bring the manufactured sealed container to the facility. Crisco may be retained on the treatment cart and labeled by the nurse with the patient’s name, room number, and date Crisco was brought to the facility.
SAMPLE POLICY & METHODS

Checking for Expiration Dating

POLICY:

It is the policy of this facility that all medications provided to the residents will be of good
potency and in good date.

METHODS:

1. All medications received into the facility will be of good date and nursing personnel will check the dating when received. Medications received with expired dating will be removed from the facility using the appropriate procedures.

2. The 3 to 11 shift on Mondays will be responsible for checking all medications in the facility for dating. An appropriate log will be kept which identifies which areas of the facility is checked each week and the person responsible for checking. All areas of the facility where drugs are stored will be checked at least monthly.

3. The consultant pharmacist will check for dating on his regular visits. All outdated drugs found will be destroyed or returned to the vendor pharmacy and reported to the director of nursing. The director of nursing will counsel with the nurse responsible for last checking the area in which the drugs were found.