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 mediation 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
EXPIRATION DATING

PREPACKAGE versus REPACKAGE

“Beyond Use” (Expiration Dates)
Reference: 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

- 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)

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<thead>
<tr>
<th></th>
<th>Low risk</th>
<th>Medium Risk</th>
<th>High Risk</th>
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<tr>
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<td>48 hrs</td>
<td>30 hrs</td>
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<tr>
<td>Refrigeration</td>
<td>14 days</td>
<td>9 days</td>
<td>3 days</td>
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<tr>
<td>Frozen</td>
<td>45 days</td>
<td>45 days</td>
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20.4
Warmers $< \text{ or } = 104 \text{ F}$. 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

**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.
   - (a) “Controlled substance” means any substance named or described in Schedules II-V of Section 893.03, F.S.
   - (b) “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.
   - (c) “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.
   - (d) “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.
   - (e) “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.

(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.

Revised USP standards for product dating, packaging, and temperature monitoring

CLAUDIA C. OKEKE, LEONARD BAILEY, THOMAS MEDWICK, AND LEE T. GRADY

This article is intended to inform and update pharmacists and other interested parties about the current standards of the United States Pharmacopeia (USP) related to product dating, packaging, and temperature monitoring, especially with respect to the revisions concerning these practices that appear in the first supplement to The United States Pharmacopeia, 24th Rev., and The National Formulary, 19th Ed. (USP24/NF19). The stability of a drug or a drug dosage form may be influenced by the characteristics of the container or packaging in which it is enclosed and the temperature of the ambient space. This article presents each revision related to dating, packaging, and temperature monitoring and discusses the rationale. Also discussed are packaging and ambient storage conditions, with an emphasis on controlled room temperature (CRT) and mean kinetic temperature (MKT). For convenience, the “Expiration Date and Beyond-Use Date” section from the “General Notices” in the first supplement to USP24/NF19 is reprinted in Appendix A.

Revision of product dating specifications

The USP Subcommittee on Packaging, Storage, and Distribution (SCPSD) has revised product dating specifications as they relate to pharmacy practice. As seen in Appendix A, USP defines the expiration date as “the time during which the article may be expected to meet the requirements of the pharmacopeial monograph provided it is kept under the prescribed conditions.” The expiration date, which limits the time during which the article may be dispensed or used, is based on scientifically sound stability studies carried out by the manufacturer and is usually expressed in terms of the month and year, as stated on the manufacturer’s container. This means that the product can be used or dispensed...
until the last day of the stated month and year.

Pharmacists are required to affix beyond-use dates and not expiration dates to the prescription or repackaged vial. The definition of a beyond-use date may be found in the General Notices. Beyond-use dates are nearer than expiration dates to account for the fact that the manufacturer's original container has been opened in the repackaging process, thereby exposing the pharmaceutical article to ambient atmospheric conditions. This exposure, and the fact that containers into which dosage forms are repackaged may not have the integrity of the original package, necessitates a shortening of the expiration period from that originally set by the manufacturer.

The General Notices defines the beyond-use date for multiple-unit containers as "not later than (a) the expiration date on the manufacturer's container or (b) one year from the date the drug is dispensed, whichever is earlier." With respect to a multiple-unit container such as a typical prescription vial, a prescription label affixed by the pharmacist for a repackaged item should bear a beyond-use date that limits the patient's use of the medication. The appropriate terminology to be used on the prescription label is "Beyond-Use Date." The use of the term "expiration date" for a dispensed prescription is not correct.

The beyond-use date is essential because it also defines an appropriate period of time during which a prescription drug may be retained by a patient after it is dispensed. The beyond-use date takes into account various factors, such as the conditions under which the medication may be stored in the patient's home, the type of packaging, the nature of the drug being dispensed, and especially the frequent opening of the package. These factors are the rationale for requiring a limited beyond-use date. However, there are exceptions to these specific limits, including medications that are reconstituted before use that have special beyond-use dates from the manufacturer and other medications of special concern that have limited beyond-use dates from the manufacturer.

In response to comments received from interested parties regarding beyond-use dates for nonsterile medications that are repackaged into unit dose or single-unit containers, the requirement has been changed from the previous period of six months from the date of repackaging or 25% of the time remaining until the expiration date, whichever is less, to one year. The revised requirement states, "For nonsterile solid and liquid dosage forms that are packaged in single-unit and unit-dose containers, the beyond-use date shall be one year or less, unless stability data or the manufacturer's labeling indicates otherwise. For all other types of non-sterile dosage forms, the beyond-use date is one year or the time remaining of the expiration date."

The SCPSD believes that one year is acceptable as long as the pharmacy or repackaging facility follows the repackaging methods described in USP24/NF19 proposed general chapter 1146 (a new chapter to be discussed later in this article) and the container is stored at CRT. (The text in chapter 1146, which was published in Pharmacopoeia Forum [1988; 25(5):8738-45], states the old six-month period and not the current one-year date. This has been revised, and the revision was published in the May/June 2000 issue of Pharmacopeial Forum [pages 803 to 812].) USP defines CRT as "a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25° (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°; and that allows for excursions between 15° and 30° (59° to 86°F) that are experienced in pharmacies, hospitals, and warehouses." The concept of MKT is discussed later in this article.

General chapter 1146 ("Packaging Practice—Repackaging a Single Solid Oral Drug Product Into a Unit Dose Container"), which is still undergoing public review and comment, contains minimum standards for guiding those engaged in any type of repackaging practice. The chapter addresses the various types of packaging materials used in blister packaging and their degree of moisture protection (Appendix B). Although there is a section on polyvinyl chloride (PVC) films, it must be noted from the General Notices that PVC is not to be used for repackaging because of its poor moisture-barrier properties. The following are moisture permeability values, in grams per 100 square inches per 24 hours, for the indicated plastic systems: PVC (10 mil [1 mil = 1/1000 inch]), 0.280; polyvinylidene chloride (PVDC) (60 g)/ polyethylene [PE]/PVC (7.9 mil), 0.042; and Aclar (2.2 mm to 1.5 mil)/ PE/PVC (7.5 mil), 0.022 (Appendix B). These values demonstrate that the PVDC-containing system is 3 times better than plain PVC as a moisture barrier and that the Aclar-containing system is 12 times better. Thus, either of the two PVC laminate systems cited is an acceptable choice for repackaging. Another material that provides an economical alternative to medium moisture-barrier materials (such as some PVC laminate systems) is polypropylene. Polypropylene is not commonly used as a pharmaceutical blister film in the United States but is used widely in Europe as an alternative to PVC.

Pharmacists are encouraged to review chapter 1146 before choosing the type of blister material to use in repackaging. This chapter also discusses the process of blister packaging, the performance characteristics of the blister material, and the minimum requirements that must be met while repackaging. The SCPSD has as an objective the improvement of unit dose packaging.
Permeability to moisture

Another criterion for evaluating the permeability of plastics to moisture is found in USP24/NF19 chapter 671, "Factors Affecting Physical Integrity." In the section entitled "Single-Unit Containers and Unit-Dose Container Systems for Capsules and Tablets," a procedure is described whereby moisture permeability is measured in terms of the weight gain observed when a desiccant pellet is enclosed in a package (blister) and the pellet-containing package is allowed to stand in a chamber whose relative humidity is 75%. Since USP requires a class A container for unit dose packaging (i.e., a container that allows not more than 0.5 mg of moisture adsorption per day) and since PVC offers little or no barrier to moisture, PVC should not be used as a packaging material. It is the responsibility of the pharmacist to ascertain that the type of packaging material used for repackaging affords better protection against moisture than PVC.

Pharmacists should ask manufacturers of the materials for appropriate moisture-permeation-rate data for the materials used and should maintain proper documentation of the material's specifications. The SCPDS allows a one-year beyond use date as long as the pharmacist complies with the requirements.

Another type of packaging that should be considered is the custom-mixed patient medication package. This consists of a series of containers each of which contains two or more prescribed solid oral dosage forms prepared by a pharmacist for a specific patient. At the August 1999 USP Open Conference on Packaging, Storage, and Distribution, held in Washington, DC, concerns were raised about current practices of returning, redistributing, or reselling medications placed in an unused patient medication package. In addressing these concerns, the SCPDS recently proposed and adopted a revision to the requirements for patient medication packages in the USP24/NF19 chapter on containers. The beyond-use date on these patient medication packages should not be longer than 60 days or the shortest expiration date recommended for any of the articles on the original manufacturer's bulk container or the shortest recommended beyond-use date for any dosage form. The pharmacist should take note of this compendial requirement and give directions to any practice not meeting these requirements. The requirement states, "Once a medication has been placed in a patient med pak with another solid dosage form, it may not be returned to stock, redistributed, or sold if unused." CRT and MKT

Maintenance of CRT should be a familiar procedure in all pharmacies and repackaging facilities because all pharmacies are required to be kept at CRT. The General Notices defines CRT as "a temperature maintained thermostatically that encompasses the range and customary working environment of 20° to 25° (68° to 77° F), that results in a mean kinetic temperature calculated to be not more than 25°." Based on this definition, a pharmacy, hospital, or warehouse has to maintain the temperature of the area in such a way that the calculated MKT does not exceed 25 °C. This definition allows for occasional spikes or excursions in temperature that may result from sudden breakdowns in air conditioning and heating systems.

The chapter on pharmaceutical dosage forms in USP24/NF19 defines MKT as "a simple calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures. Thus, MKT may be considered as an isothermal storage temperature that simulates the non-isothermal effects of storage temperature." MKT addresses temperature fluctuations during the storage period of the product and will ordinarily be higher than the arithmetic mean temperature since it mirrors kinetic events, which are described by the exponential of the Arrhenius equation.

In the temperature-monitoring procedure, the pharmacist selects a convenient, regular weekly time to record the temperature of the pharmacy. Temperature-monitoring devices or high-low thermometers may be used for these measurements. Then the mean of the highest and lowest temperatures collected for the weeks are applied to the MKT equation. (If a pharmacy maintains the temperature below 25 °C throughout the year, MKT need not be calculated.) MKT is calculated with the following equation:

$$T_m = \frac{\Delta H}{n [(e^{-\frac{\Delta H}{RT_m}}) + e^{-\frac{\Delta H}{RT_1}}] + \frac{\Delta H}{RT_1}}$$

where $T_m$ = temperature in degrees Kelvin, $\Delta H$ = heat of activation (83.144 kJ/mol), $R$ = universal gas constant (0.0083144 kJ mol⁻¹ degree⁻¹), $T_1$ = average temperature in degrees Kelvin during the first time period, and $T_m$ = average temperature in degrees Kelvin during the last time period. Since weekly readings are required, the pharmacist performs a weekly reading of the pharmacy or the warehouse and records high and low temperature. The mean of the highest and lowest temperatures during the preceding week is entered into the equation. Two examples are presented to illustrate the manipulation of the data.

Example 1. This example is simplified, since it is unlikely that each of the 52 weekly means would be the same—in this case, 25 °C. The calculations in this example are intended to illustrate the use of the equation.

If the mean of the highest and lowest temperatures for each week over a period of 52 weeks was 25 °C (i.e., the same mean for each week), then...
until the last day of the stated month
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0.042; and Aclar (2.2 mil to 1.5 mil)/
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These values demonstrate that the
PVDC-containing system is 6 times
better than plain PVC as a moisture
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an objective the improvement of unit
dose packaging.
MKT can be calculated as follows for

\[ n = 52; \Delta H/R = -10,000; T_i = 25 \text{ °C} = 273.15 \text{ K}; \Delta T = 25 \text{ °C} = 273.15 + 25 \text{ °C} = 298.1 \text{ K}; R = 8.314 \text{ J/K mol} \cdot \text{mol}^2 \text{ K}^2 \text{ mol}^{-2}; \text{and } \Delta H = 83.144 \text{ kJ mol}^{-1} \]

\[ T_i = -10,000 \]
\[ \ln \left( \frac{1}{(52)^{e^{\Delta H/R}}/52} \right) \]
\[ T_i = -10,000 \]
\[ \ln \left( \frac{1}{(52)^{e^{\Delta H/R}}/52} \right) \]
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yielding \( T_i = 296.1 \text{ °K} = 273.15 \text{ °C} \)

Example 2. In this example a variety of average temperatures are used, as would be the case in actual practice. If the average of the highest and lowest temperatures ranged from 15 to 28 °C, then each average temperature value would be individually substituted into the equation. To save space, only 12 intervals, as shown in Table 1, are presented instead of 52.

\[ T_i = -10,000 \]

\[ \ln \left( \frac{1}{(52)^{e^{\Delta H/R}}/52} \right) \]

\[ T_i = -33.5458 \]

Calculating, with \( n = 12 \):

\[ T_i = -10,000 \]
\[ \ln \left( \frac{1}{(52)^{e^{\Delta H/R}}/52} \right) \]
\[ T_i = -10,000 \]
\[ \ln \left( \frac{1}{(52)^{e^{\Delta H/R}}/52} \right) \]
\[ T_i = -10,000 \]
\[ \ln \left( \frac{1}{(52)^{e^{\Delta H/R}}/52} \right) \]
\[ T_i = -10,000 \]
\[ \ln \left( \frac{1}{(52)^{e^{\Delta H/R}}/52} \right) \]

\[ T_i = -33.7713 \]

\[ T_i = 296.11 \text{ °K} = 23.01 \text{ °C} \]

Note that, because of the exponential nature of the kinetic processes, MKT is higher than the arithmetic mean, which in this case is 22.88 °C.

Temperature monitoring in pharmacies is very important. These sample calculations have been presented to help a pharmacist who records the weekly highest and lowest temperatures to perform the calculation correctly. These calculations can be performed manually with a pocket calculator or with a computer program or spreadsheet.

Conclusion

USP standards for product dating, packaging, and temperature monitoring have changed, and pharmacists must educate themselves about these revisions.

### Table 1

<table>
<thead>
<tr>
<th>Interval</th>
<th>Low</th>
<th>High</th>
<th>Average</th>
<th>Average Temp. (°C)</th>
<th>( \Delta H/R )</th>
<th>( e^{\Delta H/R} \times 10^{12} )</th>
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<tbody>
<tr>
<td>1</td>
<td>15</td>
<td>27</td>
<td>21</td>
<td>294.1</td>
<td>34.0000</td>
<td>1.7104</td>
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<td>2.0325</td>
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<td>3</td>
<td>17</td>
<td>25</td>
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<td>294.1</td>
<td>34.0000</td>
<td>1.7104</td>
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<td>22.5</td>
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<tr>
<td>5</td>
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<td>27</td>
<td>24.5</td>
<td>297.6</td>
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<td>6</td>
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<td>293.1</td>
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<td>296.1</td>
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</tr>
<tr>
<td>8</td>
<td>22</td>
<td>26</td>
<td>24</td>
<td>297.1</td>
<td>33.6367</td>
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<tr>
<td>9</td>
<td>23</td>
<td>27</td>
<td>25</td>
<td>298.1</td>
<td>33.5458</td>
<td>2.6993</td>
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<td>10</td>
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<td>28</td>
<td>24</td>
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<td>22</td>
<td>28</td>
<td>25</td>
<td>298.1</td>
<td>33.5458</td>
<td>2.6993</td>
</tr>
</tbody>
</table>

Appendix A—"Expiration Date and Beyond-Use Date" section from first supplement to USP24/NF19

The label of an official drug product, nutritional or dietary supplement product shall bear an expiration date. All articles shall display the expiration date so that it can be read by an ordinary individual under customary conditions of purchase and use. The expiration date shall be prominently displayed in high contrast to the background or sharply embossed, and easily understood (e.g., "EXP 6/03," "Exp June 89," "Expires 6/89," [writ—for additional information and guidance, refer to the Nonprescription Drug Manufacturers Association’s Voluntary Codes and Guidelines of the OTC Medicines Industry.])

The monographs for some preparations state how the expiration date that shall appear on the label is to be determined. In the absence of a specific requirement in the individual monograph for a drug product or nutritional supplement, the label shall

References


bear an expiration date assigned for the particular formulation and package of the article, with the following exception: the label need not show an expiration date in the case of a drug product or nutritional supplement packaged in a container that is intended for sale without prescription and the labeling of which states no dosage limitations, and which is stable for not less than 3 years when stored under the prescribed conditions.

Where an official article is required to bear an expiration date, such article shall be dispensed solely in or from a container labeled with an expiration date, and the date on which the article is dispensed shall be within the labeled expiry period. The expiration date identifies the time during which the article may be expected to meet the requirements of the Pharmacopeial monograph provided it is kept under the prescribed storage conditions. The expiration date limits the time during which the article may be dispensed or used. Where an expiration date is stated only in terms of the month and the year, it is a representation that the intended expiration date is the last day of the stated month. The beyond-use date placed on the label shall be not later than the expiration date on the manufacturer’s container. The beyond-use date is the date after which an article must not be used. Based on the information supplied by the manufacturer, the dispenser shall place on the label of the prescription container a suitable beyond-use date to limit the patient’s use of the article.

For articles requiring constitution prior to use, a suitable beyond-use date for the constituted product shall be identified in the labeling.

For all other dosage forms, in determining an appropriate period of time during which a prescription drug may be retained by a patient after its dispensing, the dispenser shall take into account, in addition to any other relevant factors, the nature of the drug; the container in which it was packaged by the manufacturer and the expiration date thereon; the characteristics of the patient’s container, if the article is repackaged for dispensing; the expected storage conditions to which the article may be exposed; and the expected length of time of the course of therapy. The dispenser shall, on taking into account the foregoing, place on the label of a multiple-unit container a suitable beyond-use date to limit the patient’s use of the article.

Unless otherwise specified in the individual monograph, or in the absence of stability data to the contrary, such beyond-use date shall be not later than (a) the expiration date on the manufacturer’s container or (b) one year from the date the drug is dispensed, whichever is earlier. For nonsterile solid and liquid dosage forms that are packaged in single-unit and unit-dose containers, the beyond-use date shall be one year or less, unless stability data or the manufacturer’s labeling indicates otherwise. For all other types of nonsterile dosage forms, the beyond-use date is one year or the time remaining of the expiration date.

The repackager must maintain the repackaging facility at a temperature, such that the mean kinetic temperature is not greater than 25°C. The repackaged dosage forms are similarly stored. The plastic material used in repackaging must afford better protection than polyvinyl chloride, which does not provide adequate protection against moisture permeation.

Appendix B—Packaging materials

Acetal: Acetal is a thermoplastic film made from poly(vinylidene fluoride) fluoropolymer (PVDF) and laminated to polyvinyl chloride (PVC) by using an adhesive layer (duplex) or with polyethylene between the PVC and PVDF films (triplex). Provides a barrier against medium to high moisture levels.

Polyethylene: Used in making containers that are interchangeably suitable for packaging dry oral dosage forms, not meant for reconstitution into solution. These containers are available as high-density and low-density polyethylene. (The test requirements for these containers are available in USP24/NF19 [general chapters 661 and 671].)

Polypropylene: A plastic that when formulated as a film is inherently good as a moisture barrier.

Polyvinyl chloride: Offers a nominal or zero barrier to moisture. This material is used when a product does not require an effective barrier to moisture.

Polyvinyl chloride/polyvinylidene chloride laminate: The polyvinyl chloride is coated with an emulsion of polyvinylidene chloride. Provides a barrier against medium to high moisture levels.
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).
   (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
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.
FLORIDA STATUTE

465.0255  Expiration date of medicinal drugs; display; related use and storage instructions.--

(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.
# Expiration Dates for Drugs and Biologicals

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><strong>General</strong></td>
<td></td>
</tr>
<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** | |
| Suppositories | Store at room temperature unless specifically directed to refrigerate |
| Pepcid Suspension | 30 days from mixed dated |

| **Store in Refrigerator** | |
| All Insulin products | Good refrigerated for 28 days after open date |
| Ativan (Lorazepam) injectable | Good unrefrigerated for 14 days |
| Ativan (Lorazepam) Intensol Solution | Good unrefrigerated for 30 days, 90 days if refrigerated |
| Calcimar Injection | Good unrefrigerated for 48 hours |
| Epogen & Procrit | Good unrefrigerated for 14 days - 21 days after initial entry if refrigerated |
| Insulin (Novolin) | Good unrefrigerated for 28 days after first use |
| Miacalcin Spray | Good unrefrigerated for 30 days - store upright |
| Pepcid Injection | Good unrefrigerated for 7 days |
| Phospholine Iodide Ophthalmic | Good Unrefrigerated for 30 days |
| Ventolin nebulles 3ml | Good unrefrigerated for 14 days |
| Xalatan Ophthalmic - until opened | Good unrefrigerated for 6 weeks - protect from light |

| **Intravenous Products** | |
| All Piggy Back IV solutions 100cc or below | 15 days after removal from outer cover (if not spiked) |
| All Piggy Back IV solutions 1000cc | 30 days after removal from outer cover (if not spiked) |
| All mixed medications for infusion | refer to expiration date provided by pharmacy |

| **Solutions for Irrigation** | |
| Acetic acid for irrigation | 24 hours after opening |
| GCP Solution | 30 days after mixing (refrigerate) |
| Sterile normal saline for irrigation | 24 hours after opening |
| Sterile water for irrigation | 24 hours after opening |

<p>| <strong>Ophthalmics, Otics and Inhaled Products</strong> | |
| Advair Discus | Discard 1 month after removal from the protective overwrap |
| Duo-Neb | Protect from light, store in foil overwrap. Discard after expiration date |
| Flovent | Discard 6 weeks after removal from moisture protective overwrap pouch |
| Foradil | 4 months after open date or product expiration date (whichever is earlier) |
| Serevent | Discard 6 weeks after removal from moisture protective overwrap pouch |
| Ear Drops | Manufacturer's expiration date |
| Inhalers | Manufacturer's expiration date |</p>
<table>
<thead>
<tr>
<th>Product Description</th>
<th>Shelf Life After Opening</th>
</tr>
</thead>
<tbody>
<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 withing 1 week after opening</td>
</tr>
</tbody>
</table>

### Miscellaneous Products

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Shelf Life After Opening</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.
Each container of medicinal drugs dispensed shall have a label or shall be accompanied by labeling.
(1) Definitions.
(a) “Controlled substance” means any substance named or described in Schedules II-V of Section 893.03, F.S.
(b) “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.
(c) “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.
(d) “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.
(e) “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 (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.
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 Q.A. 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
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.