

CHAPTER 21

STORAGE OF MEDICATIONS

Storage of Medications in the Nursing Home

1. **All drugs and non-Rx drugs must be locked**
 - a. Schedule II double locked (standard of practice all controls double locked)
 - b. Key with the charge nurse
 - c. No Aides (C.N.A.'s) in med room unless nurse present
 - d. Drug carts should not be stored in the hall

2. **External drugs separate from internal drugs**
 - a. Separate cabinet vs. separate shelf (both acceptable based on facility policy)
 - b. Poisons in a separate and distinct area
 - c. Cabinets clearly labeled
 - d. Med carts: external area and internal area

3. **Refrigerated drugs**
 - a. General use vs. medication refrigerator
 - b. Have a thermometer - 36 to 46 degrees F (USP Standard for drug storage)
 - c. Temperature Log
 - d. Handling problematic drugs
 - a. Flu vaccine
 - b. PPD

4. **Outdated drugs**
 - a. Procedures for checking: Rph + nurse
 - b. Cooperation with vendor pharmacist

5. **Discontinued drugs**
 - a. Procedure for handling control drugs
 - b. Procedure for handling non-control drugs
 - c. Drugs with resident at discharge
 - d. Drugs brought into the facility with no order

6. **Treatment cart storage**
 - a. Where kept
 - b. Clean
 - c. Proper labels
 - d. Expiration dates

7. **Inspection forms**

8. **Storage of medication in a patient's room**



Punch Card Cart



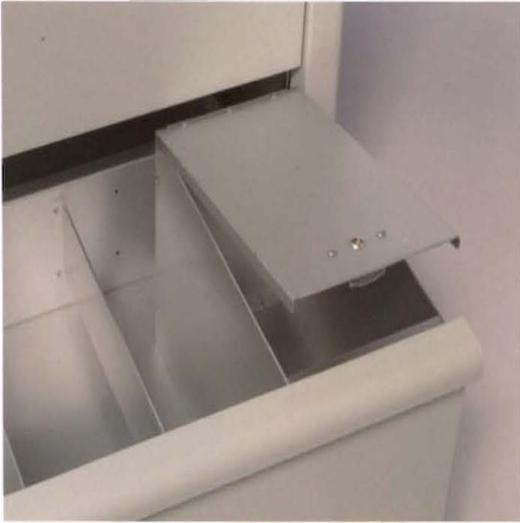
Punch or Bingo Cards



Unit Dose Box Cart



30 Day Box System



**Control Bin with 2nd
Lock**



**Multipak Systems
(AutoMed & PacMed)**



Treatment Cart

EXCERPTS FROM THE CDC VACCINE STORAGE AND HANDLING TOOLKIT

www.2a.cdc.gov/vaccines/ed/shtoolkit

Shelf Lives of Reconstituted Vaccines

Vaccine	Expiration After Reconstitution
Varicella vaccine	30 minutes (protect from light)
TriHIBit [®] vaccine (DTaP/Hib)	30 minutes
Menomune [®] (single-dose vials)	30 minutes
MMRV vaccine	30 minutes (protect from light)
Zoster vaccine	30 minutes (protect from light)
MMR vaccine	8 hours (protect from light)
ActHIB [®] vaccine (Hib)	24 hours
Menomune [®] (multidose vials)	35 days

Prefilling Syringes

Recommendation

The National Center for Immunization and Respiratory Diseases (NCIRD) strongly recommends that providers draw vaccine only at the time of administration.

The National Center for Immunization and Respiratory Diseases (NCIRD), Centers for Disease Control and Prevention strongly recommends that providers draw vaccine only at the time of administration to ensure

that the cold chain is maintained and that vaccine is not inappropriately exposed to light. **Do not** predraw doses before they are needed.

Problems Associated with Prefilling Syringes

NCIRD strongly discourages prefilling syringes and has identified the following problems associated with this practice:

- Once vaccine is inside the syringe, it is difficult to tell which vaccine is which; this may lead to **administration errors**.
- Prefilling syringes leads to **vaccine wastage** and increases the risk of vaccine **storage under inappropriate conditions**.
- Most syringes are designed for immediate administration and not for vaccine storage. **Bacterial contamination and growth** can occur in syringes you prefill with vaccines that do not contain bacteriostatic agents, such as the vaccines supplied in single-dose vials.
- No stability data are available for vaccines stored in plastic syringes. Vaccine components may interact with the plastic syringe components with time and thereby **reduce vaccine potency**.

Finally, prefilling syringes is a violation of medication administration guidelines, which state that an individual should only administer medications he or she has prepared and drawn up. This is a **quality control and patient safety problem** because if you do not draw up the vaccine yourself you cannot be sure of the composition and sterility of the dose you are administering.

INFORMATION FOUND IN THE 2001 P.D.R. UNDER TUBERSOL

Tubersol® is a stabilized solution of Tuberculin PPD. Data indicates that Tubersol® will remain stable for at least four weeks when pre-filled into syringes and stored between 2~and 8~C.4 However, in order to avoid possible contamination of the product this practice is not recommended. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solutions and container permit.

This language has been removed from the current package insert. Manufacturers for both Aplisol and Tubersol currently take the position that their product should not be pre-drawn or stored in pre-filled syringes since stability data does not exist for plastic syringes.

Don't Be Guilty of These Errors in Vaccine Storage and Handling

The following are frequently reported errors in vaccine storage and handling. Some of these errors are much more serious than others, but none of them should occur. Be sure your clinic or practice is not making errors such as these.

Error #1: Designating only one person in the office to be responsible for storage and handling of vaccines, instead of a minimum of two.

It's important to train at least one back-up person to learn proper storage and handling of vaccines. The back-up person should be familiar with all aspects of vaccine storage and handling, including knowing how to handle vaccines when they arrive, how to properly record refrigerator and freezer temperatures, and what to do in case of an equipment problem or power outage.

Error #2: Recording temperatures only once per day.

Temperatures fluctuate throughout the day. Temperatures in the refrigerator and freezer should be checked at the beginning and end of the day to determine if the unit is getting too cold or too warm. Ideally, you should have continuous thermometers that measure and record temperatures all day and all night. A less expensive alternative is to purchase maximum/minimum thermometers. Only certified thermometers should be used for vaccine storage. It's also a good idea to record the room temperature on your temperature log in case there is a problem with the refrigerator or freezer temperature. This information may be helpful to the vaccine company's telephone consultant in ascertaining whether your vaccine can still be used.

Error #3: Recording temperatures for only the refrigerator or freezer.

If your facility administers varicella, zoster (shingles), or live attenuated influenza vaccine, you should have certified thermometers in both the refrigerator and the freezer. Rather than buying cheap thermometers that may not accurately measure the temperature, buy quality thermometers that will last for years.

Error #4: Documenting out-of-range temperatures on vaccine temperature logs and not taking action.

Documenting temperatures is not enough. Acting on the information is even more important! So, what should you do? Notify your supervisor whenever you have an out-of-range temperature. Safeguard your vaccines by moving them to another location and then determine if they are still useable. Check the condition of the unit for problems. Are the seals tight? Is there excessive lint or dust on the coils? After you have made the adjustment, document the date, time, temperature, what the problem was, the action you took, and the results of this action. Recheck the temperature every two hours. Call maintenance or a repair person if the temperature is still out of range.

Error #5: Throwing away temperature logs at the end of every month.

It's important that you keep your temperature logs for at least three years. As the refrigerator ages, you can track recurring problems. If temperatures have been documented out of range, you can determine how long this has been happening and take appropriate action. It's also a great way to lobby for a new refrigerator.

Error #6: Storing vaccine in the refrigerator in a manner that may inappropriately affect its temperature.

The temperature in the vegetable bins, on the floor, next to the walls, in the door, and near the cold air outlet from the freezer may differ significantly from the temperature in the body of the refrigerator. Always store vaccines in their original packaging in the body of the refrigerator away from these locations. Place vaccine packages in such a way that air can circulate around the compartment. Never overpack a refrigerator compartment.

Error #7: Storing frozen vaccines in a dorm-style refrigerator.

Varicella, zoster (shingles), and live attenuated influenza vaccines must be stored in a freezer that has its own external door separate from the refrigerator. No matter how hard you try to adjust the temperature to +5°F in a dorm-style refrigerator's freezer, you won't be able to reach this low temperature in the freezer, and you'll probably freeze the rest of your vaccines in the refrigerator!

Error #8: Inadvertently leaving the refrigerator or freezer door open or having inadequate seals.

Remind staff to close the unit doors tightly each time they open them. Also, check the seals on the doors on a regular schedule, and if there is any indication the door seal may be cracked or not sealing properly, have it replaced. The cost of replacing a seal is much less than replacing a box of pneumococcal conjugate or varicella vaccine.

Error #9: Discarding multi-dose vials 30 days after they are opened.

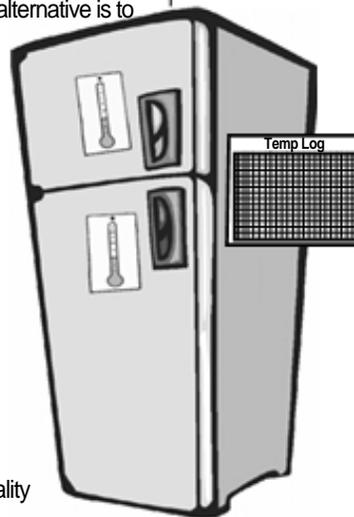
Don't discard your vaccines prematurely. Almost all multi-dose vials of vaccine contain a preservative and can be used until the expiration date on the vial unless there is visible contamination. However, you must discard multi-dose vials of reconstituted vaccine (e.g., meningococcal, yellow fever) if they are not used within a defined period after reconstitution. Refer to the vaccine package inserts for additional information.

Error #10: Not having emergency plans for a power outage or natural disaster.

Every clinic should have a written Disaster Recovery Plan that identifies a refrigerator with a back-up generator in which to store vaccine in the event of a power outage or natural disaster. Consider contacting a local hospital or similar facility to be your back-up location if you should need it.

Error #11: Storing food and drinks in the vaccine refrigerator.

Frequent opening of the refrigerator door to retrieve food items can adversely affect the internal temperature of the unit and damage vaccines.



REGULATIONS - Federal Survey Manual

483.60 (g) Storage of drugs and biologicals.

F376 (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.

Interpretive Guideline: 483.60(g)(1). Compartments in the context of these Regulations include but are not limited to drawers, cabinets, rooms, refrigerators, carts, and boxes. The provisions for **authorized personnel** to have access to keys must be determined by the pharmaceutical services committee required by 483.60(c).

F377 (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 1970 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.

Interpretive Guideline: 483.60(g)(2). Separately locked means that the key to the separately locked Schedule II drugs is not the same key that is used to gain access to the non-Schedule II drugs.

Survey Procedures and Probes: 483.60(g)(1) and (2). Observe during Environmental Quality Assessment: (Proper drug storage) -- Y = all drugs and biologicals are stored properly (locked and at proper temperature); N = drugs and biologicals not stored properly.

64B16-29.005 Storage.

All controlled substances, medicinal drugs or legend drugs shall be stored in a safe place. At a minimum, this shall require that the drugs be kept in a securely locked cabinet within a locked storage room. Schedule II order forms are to be stored under the same conditions. Records of purchases of all controlled substances, medicinal drugs or legend drugs shall be maintained in a separate file from the records of administration. The records of purchases and administration shall be maintained at the location.

Rulemaking Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History--New 10-17-79, Formerly 21S-14.05, Amended 4-24-88, Formerly 21S-14.005, 21S-29.005, 61F10-29.005, 59X-29.005, Amended 6-17-13.

SAMPLE POLICY & METHODS

Storing Drugs

POLICY:

Drugs and biologicals are to be stored in a secure and orderly manner under proper temperatures and are to be accessible only to licensed nursing and pharmacy personnel. All medications are to be stored in the containers in which they are received, internals separately from externals and both separately from poisons.

METHODS:

1. All drugs and biologicals are to be stored in a secure and orderly manner without crowding. Drugs are to be accessible **ONLY** to licensed nursing and pharmacy personnel.
2. Drugs are to be dispensed by the pharmacy in containers which meet official requirements for stability. All drugs are to be kept and stored in the containers in which they are received. No drug is to be transferred from one container to another.
3. All medications intended for oral administration are considered internal, and all medications not intended for instillation into an orifice or labeled **FOR EXTERNAL USE ONLY** are considered external medications. Externals include, for example, ointments for skin irritation, or medications for application to the skin or a wound involving a nursing treatment procedure, such as a dressing change. Internals include injectables, eye drops and eye ointments, and ear drops intended for instillation into the ear canal or may be stored separately.
4. Drugs for internal use are to be stored separately from drugs for external use. Both are to be stored separately from poisons. Drugs intended for internal use are to be kept and stored in the medication cart except those requiring refrigeration or in designated back-up storage areas marked **EXTERNALS** in the medication room.
5. Germicides, disinfectants, and other household substances are to be stored separately from drugs.
6. All controlled drugs in schedules II, III, and IV of the controlled substances act are to be stored in the medication cart in separate drawers designated for that purpose. Schedule II controlled substances are to be stored in a locked drawer.

SAMPLE POLICY & METHODS

7. Drugs are to be stored at proper temperatures. Drugs requiring storage at room temperatures are to be stored at a temperature of not less than 15 C (36F) or more than 8 C (46F). A medication requiring storage in a cool place may be stored in the refrigerator unless otherwise specified on the label. A thermometer is kept in the refrigerator containing medications to help assure proper temperatures.
8. Drugs stored in a multipurpose refrigerator are to be kept in a closed, separate container labeled DRUGS. Fruit juices, applesauce, and other foods used in passing medicines may be kept in the refrigerator on a separate shelf from drugs. Lunches and other foods not used in passing medication may NOT be kept in the medication refrigerator in the medicine room under any circumstances.
9. Drugs are not to be kept on hand after the expiration date which appears on the label. Outdated, contaminated, or deteriorated drugs, and those in containers which are cracked, soiled or without secure closures are to be immediately withdrawn from stock, re-ordered from the pharmacy if a current order exists for any patient, and disposed of in accordance with the procedures for drug destruction.

SAMPLE POLICY & METHODS

Returning Drugs for Credit

POLICIES:

1. Drugs are to returned to the pharmacy ONLY if credit can be issued.
2. Credit CANNOT be issued for controlled drugs, that is, drugs listed in Schedule II, III, IV or V of the controlled substances act. (See section -- Controlled Drugs--for a list of controlled substances).
3. Credit can usually be issued for a patient's discontinued or unused drug(s) If it has been supplied in a sealed, manufacturer's original container, or in unit dose packaging, provided that (1) it is unopened and (2) is bears a lot or control number.

METHODS:

1. Before returning a drug for credit ALL of the following information must be entered by the nurse on Medication disposition form:
 - a. The patient's name
 - b. The date returned
 - c. The prescription number, if any
 - d. The name of the drug
 - e. The strength of the drug
 - f. The quantity of drug returned

SAMPLE POLICY & METHODS

Disposition of Discontinued Drugs

POLICY:

Discontinued drugs or those which remain in the facility after discharge or death, which are not house-supplied or returned for credit, are to be destroyed by the facility and a verified and detailed record of their destruction is to be maintained in the patient's medical record.

METHODS:

1. Discontinued drugs or those which remain in the facility after discharge or death, which are not house-supplied or returned for credit are to be destroyed in the facility in the following manner:
 - a. Unless specifically contraindicated, tablets, capsules, liquids and the contents of vials and ampules are to be flushed down the toilet, exercising caution not to clog the drain.
 - b. Controlled drugs listed in Schedule II, III, IV or V of the Controlled Substances Act are to be destroyed as per 21S regulation.
2. The registered nurse witnessing the drug destruction is responsible for seeing that ALL of the following information is entered on a medication destruction record and filed in the patient's medical record:
 - a. The name of the patient
 - b. The name and the strength of the drug.
 - c. The prescription number, if any
 - d. The amount of drug destroyed.
 - e. The date of destruction
 - f. The signatures of the witnesses.
3. Those unused controlled substance medications not sent home with a discharged patient's family will be prepared for proper destruction as follows:
 - a. Medication will be placed in locked storage in the nursing administration office with proof-of-use sheet.

SAMPLE POLICY & METHODS

b. At intervals no less than quarterly, a dated list (DEA Form 41) of all controlled substances designated for destruction will be made by a Nurse and the consultant pharmacist. The information shall include:

- Patient name and room number.
- Prescription number.
- Name and quantity of medication.

The list shall be signed by the Nurse and consultant pharmacist.

c. The medication shall be destroyed by an authorized agent or mailed to the DEA in accordance with their procedures.

NURSING HOME**SAMPLE OF INSPECTION LIST FOR NURSING HOMES
CHECKLIST FOR INSPECTION GUIDE OF NURSING STATION**

FACILITY NAME:		
DATE:		
INDIVIDUAL PATIENT DRUGS	YES	NO
1. Is the cabinet or drug room locked?		
2. Are all drugs stored under proper security?		
3. Are medications stored under appropriate temps?		
4. Are drugs stored separate from non-drugs?		
5. Are externals & poisons separated from internal products?		
6. Is the external storage area clearly marked?		
7. Are resident's medication properly labeled with current directions?		
8. Are labels firmly affixed to containers?		
9. Are OTC drugs properly labeled?		
10. Have duplications for same patient been avoided?		
11. Is the same drug distribution system used for all medication?		
12. Have all discontinued meds been removed from nursing station and drug cart?		
13. Are counters in drug room clean & uncluttered?		
14. Is drug cart free of dust and spills?		
15. Are logs being sent with each drug delivery?		
16. Are logs being signed by nurse and retained?		
17. Are treatments stored in a locked cabinet or in a locked room?		
18. Do all tubes (ointments & creams) contain caps?		
19. Are injections properly labeled and stored?		
20. Are syringes being properly disposed of?		
FLOOR STOCK DRUGS AND SUPPLIES	YES	NO
1. Are arrangement and neatness satisfactory?		
2. Are only approved items available as floor stock?		
3. Is stock being rotated properly?		
4. Are excessive quantities avoided?		
5. Are all floor stock items properly labeled?		
6. Are all floor stock items in-date?		
7. Are internals separated from externals?		
REFRIGERATOR		
1. REFRIGERATOR READINGS	STATION	TEMP
	YES	NO
2. Are only drugs requiring refrigeration stored in the refrigerator?		
3. Are all drugs in refrigerator in-date?		
4. Are puncture dates recorded on injectables?		
5. Have all discontinued drugs been removed?		
6. Is only food used to administer medication stored in the refrigerator?		
7. Is food labeled, in a covered container and dated with date sent from kitchen?		
8. Are any controlled drugs under double lock?		

EMERGENCY DRUG KIT (EDK)	YES	NO
1. Is the EDK stored under proper security?		
2. Is there a current list of contents attached to the kit?		
3. Is the EDK sealed with a red lock?		
4. Are all drugs in the kit at least 3 months from expiration?		
5. Is the EDK LOG documented each time the kit is opened?		
CONTROLLED SUBSTANCE STORAGE AND HANDLING	YES	NO
1. Are all controlled substances (outside the EDK) stored under double lock and separate from other meds?		
2. Is only the charge nurse in possession of the keys?		
3. Is a shift count recorded for all C-II through C-V drugs in the facility?		
4. Are proof-of-use sheets current on all controlled substances?		
5. Do certificates of disposition check with physical inventory?		
6. Have all discontinued schedule drugs been sent to the Director of Nursing for destruction?		
7. Are records of disposition on file and current?		
ADMINISTRATION AND CONTROL OF MEDICATIONS	YES	NO
1. Do all items on the physician's order sheet appear on the MAR, PRN or TREATMENT sheet?		
2. Are all items on the order sheet available?		
3. Are needed drugs ordered from pharmacy prior to supplies running out in facility?		
4. re ordered medications shipped from the vendor pharmacy in a timely manor?		
5. Are only ordered items present?		
6. Do patient's medication inventories and renewal orders agree with medication label dates and dosage schedules?		
7. Are physician order sheets signed by physician?		
8. Are stop order policies being followed?		
9. Is the administration of routine medication documented?		
10. Is the administration of PRN medications documented with result on back of PRN sheet?		
11. Are held medications documented on the MAR?		
12. Are medication refusals documented on the MAR?		
13. Are sites of injections and patches being charted?		
14. Is alcohol consumption documented on the MAR?		
15. Are only approved bedside meds being used?		
16. Are drug incidents documented in nurses notes?		
17. Is the pharmacy notified of incident reports?		
18. Are missing drugs reported to the pharmacy?		
19. Are drugs sent with patients LOA noted in the nursing notes?		
GENERAL OBSERVATIONS	YES	NO
1. Is a metric-apothecary conversion chart, stop order policy, poison control and EDK list displayed?		
2. Are proper drug reference sources available?		
3. Is the pharmacy procedure manual available at each nursing station?		
4. Has remedial action been taken on previous deficits?		

 CONSULTANT PHARMACIST

STORAGE OF MEDICATIONS IN THE HOSPITAL

Includes patient specific medications and approved floor stock

- **SAFETY**
- **DRUG CONTROL – Must be “secure”**
 - Locked
 - Under constant surveillance by authorized personnel
 - Tamper evident seal for emergency medications
- 1. **STABILITY**
- 2. **PHARMACIST REVIEW**
- 3. **CHARGE** - mechanism to charge the patient

1. Storage

- a. **Drugs and biologicals are kept in secure areas, and locked when appropriate (§482.25(b)).**
- b. **Stored in pharmacy and other areas to support patient care (64B16-28.120)**
- c. **Medications are properly and safely stored throughout the organization according to manufacturer recommendations and pharmacists instructions (MM 03.01.01)**
- d. **Controlled substances must be locked within a secure area.**
- e. **Only authorized personnel have access locked drug storage areas**
 - i. **L&D and critical care is secure if access is limited**
 - ii. **OR suite is secure if actively providing care, otherwise non-mobile carts are locked and mobile carts are in a locked room**
 - iii. **Mobile carts are locked in a secure room**
 - iv. **Bedside medications – need to address security**
- f. **Under competent supervision**
- g. **Medication security**

Examples of non-compliance:

- medications left unattended on top of medication carts
- medication carts unlocked
- secretary, housekeeping staff have access to drugs
- extra break away locks available
- no policy addressing storage of drugs between receipt and administration
- carts stored in hallways > 15 minutes

2. Refrigerator

- a. Keep drugs separate (no food)

- b. Track temperatures on an ongoing basis (alarm, daily checks). Document action taken when out of range.
- c. Assure integrity of drug storage when the area is closed (such as over a weekend).
- d. 36-46 degrees F (2-8 degrees Celsius) per USP/NF standards (Dietary refrigerators are colder 34-40 F)

Examples of non-compliance:

Refrigerator deviated from recommended range and disposition of medications not defined in policy or no action documented.

Vaccine refrigeration temperature checks documented twice daily (CDC recommendation)

- 3. **Freezer** - Temperatures for drug storage are kept between –20 and –10 degrees C (-4 and –14 F).
- 4. Controlled **room temperature** for drug storage is kept between 68 and 77 degrees F.
- 5. **Warmer** temperatures according to hospital policy. Refer to manufacturer for expiration date guidelines. For example, IV solution, irrigation solutions and water or saline pour bottles are dated when placed in the warmer and stock is rotated so the oldest product is always in front. Warmers are kept \leq 104 F. When the expiration date is reached these products are removed from the warmer and identified as being warmed. They are used or discarded within 24 hours.
- 6. **Good practices**
 - a. Store externals separate from internals
 - b. Store flammables, hazardous drugs and chemicals separately
 - c. Cabinets under sinks only contain cleaning products – NO drugs
 - d. Cleanliness of mortar and pestles

7. **Should have policy on medication cart keys and keyless locks**

8. **Drug samples – not recommended in hospital, particularly controlled substances. Follow regulations for clinic use. Reference FS chapter 499**

9. **Outdated drugs – Quarantine Area**

Example of non-compliance:

Expired medications found in nuclear medicine department

Pharmacy does not have labeled quarantine area

Using date opened for expiration date

10. **Controlled drugs – Standard is to keep locked or controlled through automated dispensing technology (such as Omnicell, AcuDose, Pyxis). May double lock according to hospital policy. Address access privileges.**

Example of non-compliance:

Nurse has access to automated dispensing cabinet after employment is terminated

11. **Life safety procedures: NO cardboard boxes stored on floor and no storage within 18 inches of ceiling (from sprinkler head).**
12. **Medication storage areas are periodically inspected**
13. Concentrated electrolytes are present in patient care areas only when necessary and precautions are used to prevent errors
14. Policy addresses medication storage from time of receipt to time of administration
 - a. Safe storage
 - b. Safe handling
 - c. Security of medications
 - d. Disposition – returned to approved drug storage location or the pharmacy by end of shift
15. Home medications
 - a. Disposition (sent home or locked in pharmacy?)
 - b. Circumstances when they can be used
 - c. Pharmacist must visually inspect and approve
 - d. Notify physician if not authorized
 - e. Should not be liquid (including eye drops)

64B16-28.120 All Permits – Storage of Legend Drugs; Prepackaging.

(1) All medicinal drugs or drug preparations as defined by Section 465.003(8), F.S., shall be stored:

(a) Within the confines of the prescription department of a community pharmacy permittee as defined in Section 465.018, F.S.

(b) In a Class II Institutional pharmacy as defined by Section 465.019(2)(b), F.S., within the confines of the pharmacy provided, however, that those medicinal drugs established by the consultant pharmacist as supportive to treatment procedures such as medical drugs, surgical, obstetrical, diagnostic, etc., may be permitted to be stored in those areas where such treatment is conducted consistent with proper control procedures as provided by the policy and procedure manual of the pharmacy.

(2) All medicinal drugs or drug preparations as defined in Section 465.003(8), F.S., within Class I Institutional permittees as defined in Section 465.019(2)(a), F.S., and Special ALF Permit 64B16-28.870, F.A.C., shall:

(a) Be administered from individual prescription containers to the individual patient; and

(b) Be prohibited within the confines of Class I Institutional pharmacies unless obtained upon a proper prescription and properly labeled in accordance with Chapter 499, F.S., and the rules and regulations contained in Chapter 59A-4, F.A.C., incorporated by reference and effective August 1, 2006, pertaining to the licensure of nursing homes and related facilities.

(3) Prepackaging of medication, whether a part of a unit dose system or a part of a multiple dose drug distribution system in an extended care facility or hospital holding a valid Class II Institutional pharmacy permit, must be done in accordance with procedures set up by the consultant pharmacist of record in the policy and procedure manual; and in the case of a pharmacy holding a valid community pharmacy permit must be done in accordance with procedures set up by the prescription department manager.

(4) Medicinal drugs and proprietary preparations as identified above that are stored in treatment areas must be accessible only to licensed staff (pharmacists, nurses, physicians, advanced registered nurse practitioners, physician assistants, respiratory and physical therapist, radiology technicians and registered pharmacy technicians, etc.) in accordance with their license, practice act, or to other personnel specifically authorized by the institution.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 435.019(2), 465.003(7), 465.022 FS. History—New 9-18-84, Formerly 21S-1.44, 21S-1.044, Amended 7-31-91, Formerly 21S-28.120, 61F10-28.120, 59X-28.120, Amended 2-8-07, 8-16-10.

64B16-27.615 Possession and Disposition of Sample Medicinal Drugs.

(1) Pharmacies may not be in possession of sample medicinal drugs except:

(a) Pharmacies may possess the sample medicinal drugs that are listed within Rule 64B16-27.220, F.A.C., Medicinal Drugs That May be Ordered by Pharmacists.

(b) Institutional pharmacies may possess sample medicinal drugs upon the written request of the prescribing practitioner. Such possession must be in accordance with the provisions of Section 499.028(3)(e)2., F.S.

(c) Those community pharmacies that are pharmacies of health care entities, as defined by Sections 499.003(3) and (14), F.S., may possess sample medicinal drugs upon the written request of the prescribing practitioner. Such possession must be in accordance with the provisions of Section 499.028(3)(e)2., F.S.

(2) Sample packages of medicinal drugs that are found to be unsuitable for dispensing by reason of physical condition or failure to meet requirements of state or federal law shall be returned to the company of origin in accordance with the requirements of Chapter 499, F.S.

Specific Authority 465.005, 465.022, 499.028 FS. Law Implemented 465.018, 465.019, 465.022, 465.186, 499.028 FS. History—New 11-4-93, Formerly 61F10-27.615, 59X-27.615, Amended 11-18-07.

499.028 Drug samples or complimentary drugs; starter packs; permits to distribute.--

(1) As used in this section, the term:

(a) "Drug sample," or "complimentary drug," means a human prescription drug that is labeled "sample," "not to be sold," "complimentary," or other words to that effect, that is provided as a courtesy, that is not intended to be sold, and that is intended to promote the sale of the drug.

(b) "Starter packs," also known as "stock samples," "trade packages," "initial dose packs," or "starter stocks," means human prescription drugs that are generally distributed without charge by manufacturers or distributors to pharmacies to be placed in stock and sold at retail. Although starter packs are generally given without charge to the pharmacy, they are not intended to be a free sample to the consumer nor are they labeled as such. Starter packs are subject to regulation as prescription drugs under the Florida Drug and Cosmetic Act in the same manner as stock shipments of prescription drugs. Starter packs are not drug samples.

(2) A person may not sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. An officer or executive of a drug manufacturer or distributor is not subject to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade of a drug sample in violation of this subsection by other employees of the manufacturer or distributor.

(3) Except as provided in this section, a representative of a drug manufacturer or distributor may not distribute any drug sample.

(a) The manufacturer or distributor of a human prescription drug may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or to pharmacies of other health care entities. Such a distribution of drug samples may only be made:

1. In response to a written request for drug samples made on a form that meets the requirements of paragraph (b); and
 2. Under a system that requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and to return the receipt to the manufacturer or distributor.
- (b) A written request for a drug sample that is required by this section must contain:
1. The name, address, professional designation, and signature of the practitioner who makes the request;
 2. The name, strength, and dosage form of the drug sample requested and the quantity requested;
 3. The name of the manufacturer of the drug sample requested; and
 4. The date of the request.
- (c) Each drug manufacturer or distributor that makes distributions by mail or common carrier under this paragraph must maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and must maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this paragraph must be made available by the drug manufacturer or distributor to the department for its review and inspection.
- (d) The manufacturer or distributor of a drug subject to paragraph (1)(a) may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or distributor makes the distributions in accordance with paragraph (e) and carries out the activities described in subsections (4)-(9).
- (e) Drug samples may only be distributed:
1. To a practitioner authorized by law to prescribe such drugs if the practitioner makes a written request for the drug samples; or
 2. At the written request of such a practitioner, to pharmacies of hospitals or to pharmacies of other health care entities. The written request for drug samples must be made on a form that contains the practitioner's name, address, and professional designation, the name, strength, and dosage form of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or distributor of the drug sample, the date of the request, and the signature of the practitioner that makes the request.
- (4) A drug manufacturer or distributor must store drug samples under the conditions described on their labels that will maintain the stability, integrity, and effectiveness of the drug samples and will assure that the drug samples remain free of contamination, deterioration, and adulteration.
- (5) A drug manufacturer or distributor must conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or distributor. A drug manufacturer or distributor must maintain lists of the names and addresses of each of its representatives who distribute drug samples and of the sites where drug samples are stored. A drug manufacturer or distributor must maintain for at least 3 years records of all drug samples distributed, destroyed, or returned to the manufacturer or distributor, of all inventories maintained under this subsection, of all thefts or significant losses of drug samples, and of all requests made under ¹subparagraph 1. for drug samples. The drug manufacturer or distributor must make available to the department upon request any record or list maintained under this subsection. The department shall provide to the Department of Business and Professional Regulation the names of those practitioners who have received an excessive or inappropriate quantity of such drugs.
- (6) A drug manufacturer or distributor must notify the department of any significant loss of drug samples and any known theft of drug samples.
- (7) A drug manufacturer or distributor must report to the department any conviction of itself or of its assigns, agents, employees, or representatives for a violation of s. 503(c)(1) of the federal act or of this part because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.
- (8) Drug manufacturers or distributors must provide to the department the name and telephone number of the individual responsible for responding to a request for information regarding drug samples.
- (9) All out-of-date drug samples must be returned to the manufacturer or distributor of that drug sample.

(10) A manufacturer or distributor may not directly or through its agents, employees, or independent contractors, hold, distribute, or otherwise dispose of any complimentary drugs or drug samples in this state without first obtaining a complimentary drug distributor permit pursuant to this section.

(11)(a) Application for a permit by a manufacturer or distributor to hold, distribute, or otherwise dispose of drugs pursuant to this section must be made on a form prescribed by the department and must be accompanied by an application fee in an amount not exceeding \$250 per year, as is determined by the department.

(b) A permit issued under this section expires 2 years after the date of issuance, unless sooner suspended or revoked.

(c) A permit is renewable biennially upon the filing of an application for renewal and the payment of a renewal fee of not more than \$250 per year, as determined by the department, if the applicant meets the requirements established by this section and the rules adopted under this section.

(12) The department may suspend or revoke a permit issued under this section, after giving notice and an opportunity to be heard pursuant to chapter 120, when:

(a) Such permit was obtained by misrepresentation or fraud or through a mistake of the department.

(b) The holder of the permit has distributed or disposed of any prescription drug, directly or through its agents, employees, or independent contractors, to any person not authorized to possess such drug.

(c) The holder of the permit, or its agents, employees, or independent contractors, has distributed or possessed any prescription drug except in the usual course of its business.

(d) The holder of the permit, or its agents, employees, or independent contractors, has distributed any prescription drug that is misbranded or adulterated under this part.

(e) The holder of the permit, or its agents, employees, or independent contractors, has distributed any prescription drug without written request, when a written request is required by this section.

(f) The holder of the permit has in its employ, or uses as agent or independent contractor for the purpose of distributing or disposing of drugs, any person who has:

1. Violated the requirements of this section or any rule adopted under this section.

2. Been convicted in any of the courts of this state, the United States, or any other state of a felony or any other crime involving moral turpitude or involving those drugs named or described in chapter 893.

(13) The department may, pursuant to chapter 120, impose an administrative fine, not to exceed \$5,000 per violation per day, for the violation of this section or rules adopted under this section. Each day such violation continues constitutes a separate violation, and each such separate violation is subject to a separate fine. All amounts collected under this section shall be deposited into the Drug, Device, and Cosmetic Trust Fund. In determining the amount of fine to be levied for a violation, the following factors must be considered:

(a) The severity of the violation.

(b) Any actions taken by the permittee to correct the violation or to remedy complaints.

(c) Any previous violations.

(14) Chapter 893 applies to all drug samples that are controlled substances.

(15) A person may not possess a prescription drug sample unless:

(a) The drug sample was prescribed to her or him as evidenced by the label required in s. [465.0276\(5\)](#).

(b) She or he is the employee of a complimentary drug distributor that holds a permit issued under this part.

(c) She or he is a person to whom prescription drug samples may be distributed pursuant to this section.

(d) He or she is an officer or employee of a federal, state, or local government acting within the scope of his or her employment.

History.--s. 34, ch. 82-225; s. 114, ch. 83-218; s. 1, ch. 83-265; s. 8, ch. 84-115; s. 23, ch. 86-256; ss. 29, 52, ch. 92-69; s. 198, ch. 94-218; s. 23, ch. 97-98; s. 590, ch. 97-103; s. 39, ch. 99-397; s. 20, ch. 2008-207.

¹**Note.**--Subsection (5) does not contain subparagraphs.