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PHARMACY SERVICES AND AVAILABILITY

Policy

The purpose of this policy is to ensure the availability of pharmacy services for residents 24 hours per day, seven days per week.

General Guidelines

1. The hours of operation of the pharmacy will be consistent with the pharmacy regulations of the state in which the pharmacy and facilities are located.
2. The pharmacy is staffed by a registered Pharmacist, licensed in the state to practice pharmacy, during the hours of operation of the pharmacy.
3. The pharmacy schedules hours of operation to best serve the residents and customers in the area.
4. To ensure that appropriate clinical coverage is available after hours, a Pharmacist will be scheduled “on-call” after normal operating hours each day.
5. A “first-dose” or back-up pharmacy may be utilized contractually for after-hours or emergency pharmacy services if consistent with state pharmacy regulations.
6. The pharmacy shall provide each facility serviced with the hours of operation and telephone (“phone”) or pager numbers of the Pharmacist on call. This information is to be posted at each nursing station.

Procedure: On-Call or After Hours Services

1. The pharmacy may employ an answering service to pick up all phone calls when the pharmacy is closed.
2. The answering service will be informed of the personnel on call, and be given both pager numbers and home (or cell) phone numbers.
3. On-call personnel will carry a pager or cell phone while on call. The employee is responsible for checking to see that the pager is operational, such as testing it regularly, replacing batteries as needed and identifying repair needs.
4. All on-call personnel are responsible for obtaining pertinent clinical information about residents before initiating therapy. This information may include but is not limited to diagnoses, allergies, physician, medications and labs ordered, IV access type, and pump or delivery device.
5. The on-call Pharmacist is responsible for handling Pharmacist-related calls such as medication questions/information, compounding for medication changes or admissions, pump/device problems, and supply issues.
6. As allowed per state regulation, the Pharmacy Manager may establish a contractual relationship with a first-dose or back-up pharmacy to dispense medications after hours.
7. For continuity of care, all on-call personnel must establish a method of communicating information to and from staff members working during the normal/regular hours of operation.
EMPLOYEE ORIENTATION

Policy

The purpose of this policy is to provide guidelines for the adequate orientation and training of pharmacy personnel in order for them to correctly perform their duties related to the compounding of sterile preparations and the pharmacy’s infusion services.

General Guidelines

1. All infusion services pharmacy personnel are required to complete an orientation program within the first 90 days of employment.
2. Appropriate staff includes all Pharmacists, Technicians, Drivers, and any other personnel involved with pharmacy operations regarding infusion services. Qualified staff may be provided by traditional company personnel or through contractual arrangements.
3. Supervisory staff ensures that all personnel are oriented according to the responsibilities associated with the level of care, tasks and duties for which they are accountable.
4. Refer to the State Board of Pharmacy regulations and the Pharmacy Policy and Procedures regarding Human Resources.

Procedure

1. Upon hire, new personnel are to:
   a. Provide a copy of current Pharmacist or Technician license/certificate, as applicable;
   b. Provide copies of continuing education required for licensure, if applicable per state law;
   c. Comply with any health requirements based on job description; and
   d. Obtain a driving record investigation for personnel making deliveries.
2. All new personnel undergo an orientation that establishes job expectations, introduces pharmacy operating procedures and rules, assesses their ability to fulfill job expectations, and provides an understanding of the mission of the pharmacy and the role their job plays in the success of pharmacy operations. This orientation is conducted beginning the first day of employment and prior to the new staff member providing pharmaceutical care services. The following is a list of suggestions to be included in orientation:
   a. Pharmacy’s policies and procedures;
   b. Ethics and conflicts of interest;
   c. Safety program;
   d. Competency testing;
   e. Infection control and prevention, including universal precautions;
   f. Cleaning, disinfecting, and sterilization of equipment and supplies;
   g. Storage, handling, and access to medications, equipment and supplies;
   h. Handling and security of controlled substances;
   i. Guidelines for processing medication and supply orders appropriately; and
3. Specific training related to the compounding of sterile preparations should include the following concepts, policies and procedures:
   a. Handwashing / hand hygiene;
   b. Aseptic technique and validation;
   c. Cleaning and disinfection of the compounding areas;
   d. Personnel protection equipment and order for garbing;
   e. Principles of high efficiency particulate air (HEPA) filters, primary engineering controls (PECs), either devices or rooms/areas and risk levels for microbial contamination;
   f. Maintenance of sterile environments including surface and environmental sampling;
   g. Manipulation of sterile products with regard to identifying, weighing and measuring ingredients and the actual compounding process;
   h. Handling of needles, syringes and other devices used in the compounding process;
   i. Handling of hazardous materials (including cytotoxic agents);
   j. Beyond-use dating;
   k. Labeling, dispensing and delivery of compounded sterile preparations (CSPs);
   l. Disposal of medications and supplies;
   m. Recalls of medications and supplies;
   n. Medication monitoring including resident assessment and the care planning process;
   o. Equipment management and maintenance; and
   p. Forms applicable to infusion therapy compounding.

4. Instruction related to the compounding of sterile preparations shall include sources such as professional publications and multimedia resources as well as a competency assessment program.

5. Training shall be documented and a copy kept in the employee’s personnel file.
PHARMACY REFERENCES

Policy

The purpose of this policy is to provide guidelines to ensure Pharmacists have access to all appropriate reference materials needed to maintain high quality pharmaceutical practice.

General Guidelines

1. The following list includes reference materials recommended to be available where compounded sterile preparations (CSPs) are processed or available online in the pharmacy:
   a. Facts and Comparisons, or similar general medication information reference;
   b. Handbook of Injectable Drugs, or similar injectable medication reference;
   c. Medication interactions reference;
   d. Medical dictionary;
   e. Laboratory monitoring reference;
   f. Cytotoxic / chemotherapy reference;
   g. Infusion Services Policies and Procedures Manual;
   h. Board of Pharmacy regulations for each state where residents are serviced.

2. External databases and resources are also recommended. Suggestions for these sources include:
   a. Local medical library or university library to allow use of the facilities for research and literature searches related to health care;
   b. Drug Information Center phone number and hours of operation;
   c. Poison Control Center phone number and hours of operation;
   d. Community resources list to include local Medicare-certified home health agencies, meals-on-wheels programs, hospice programs, charity organizations and other related organizations; and
   e. State Abuse and Neglect Hotline number.

3. The Pharmacist-in-Charge (PIC) is responsible for complying with the regulations of the State Board of Pharmacy to be certain all references required by the licensing agency are in the pharmacy.
ORGANIZATIONAL ASPECTS OF IV THERAPY

GENERAL REQUIREMENTS FOR PHARMACY, COMPOUNDING ROOM CONFIGURATION AND SUPPLIES

Policy

The purpose of this policy is to provide guidelines and criteria for the pharmacy’s environment in order to ensure the quality of pharmacy-compounded sterile preparations (CSPs).

General Guidelines

1. The compounding area shall be isolated from the remainder of the pharmacy to minimize airborne contamination.
2. The United States Pharmacopeia (USP) standards shall be used as a reference for the International Organization of Standardization (ISO) classification of particulate matter in room air.
3. Risk levels are classified according to the probability of contaminating a compounded sterile preparation (CSP) with microbial, chemical and/or physical sources. Refer to Chapter <797> of the USP for the conditions of compounding and classification of risk levels.

Equipment and Supplies

Compounding Aseptic Containment Isolators (CACIs) and Compounding Aseptic Isolators (CAIs): This type of device utilizes an airtight glove/glove port design that allows the user to perform hands-on tasks inside the isolator without compromising the intended performance of the isolator. Air exchange into the isolator from the surrounding environment should not occur unless it has first passed through a HEPA filter.

1. General information for IV room includes:
   a. The compounding area shall contain only LAWFs, CACIs, CAIs and stainless steel or plastic equipment and materials as is necessary for compounding. Food and drinks are prohibited from the compounding areas.
   b. Sharps (needle) safety disposal containers should be replaced as necessary. Plastic containers with sealable covers are recommended.
   c. Waste containers should consist of a tubular metal frame or rubber/washable type container within which opaque trash bags can be suspended.
   d. HEPA filters should be kept free of debris such as cleaning solutions, aspirate from syringes and broken glass ampules.
   e. The compounding areas shall provide a well-lighted working environment.

Documentation

1. Temperature logs will be maintained indicating the date, initials and temperature readings of the following areas:
   a. Refrigerator;
   b. Freezer
2. Refer to the Temperature Log.
INFECTION CONTROL MEASURES

PHARMACY MAINTENANCE: CLEANING AND DISINFECTION OF THE COMPOUNDING ENVIRONMENT

Policy

The purpose of this policy is to provide guidelines for the routine maintenance of the pharmacy’s compounding areas.

General Guidelines

1. The compounding environment shall be maintained according to written policies and procedures as outlined as well as all state and federal laws. Personnel performing cleaning and maintenance shall be trained in the detailed procedures.
2. Compounding areas include clean room and ISO Class 5 devices.
3. Cleaning and disinfectant agents should be selected with regard to microbial activity, inactivation, residue compatibility and shelf life. Prepare disinfectant solution according to manufacturer’s instructions. Cleaning solutions should alternate to reduce the potential for developing resistant organisms. The type of disinfectant agent and the rotation schedule shall be documented on the Compounding Room Maintenance Log. Common types of disinfectants include:
   a. Isopropyl alcohol (sterile);
   b. Accelerated hydrogen peroxide;
   c. Quaternary ammonium;
   d. Phenolics;
   e. Chlorine; and
   f. Iodophors.
4. All cleaning materials shall be of non-shedding material and dedicated (and labeled) to use in the compounding areas only. They should not be removed from the compounding areas except for disposal. If cleaning tools are reused, thorough rinsing and sanitization is necessary after each use and storing in a clean environment between uses.
5. No cleaning activities shall be performed during the compounding of sterile preparations.
6. Garbing procedures shall be followed prior to cleaning activities.
7. Supply items removed from cartons shall be sprayed with sterile 70% isopropyl alcohol (IPA) and allowed to dry.
8. Sterile 70% IPA swabs shall be used for disinfecting entry ports on vials and parenteral solution containers. They should also be used for breaking ampule necks.

Equipment and Supplies

1. Appropriate cleaning or disinfectant agent;
2. Non-shedding cleaning materials such as microfiber towels, sponges and mops;
3. Sterile 70% isopropyl alcohol (IPA) solution and swabs.
Procedure

1. Cleaning and organizing of the compounding areas is to be performed at the beginning of each shift by the compounding Technician or Pharmacist. Before compounding is performed, all items are removed from the compounding areas and all surfaces are cleaned of loose material and spill residue.

2. Cleaning and maintenance of the compounding areas and pharmacy environment shall be maintained per the following schedule on regular business days. Cleaning and disinfecting should also occur upon spills, when surfaces are visibly soiled and for known or suspected contamination.

3. Daily:
   a. LAFWs, BSCs, CACIs, and CAIs should be cleaned and disinfected frequently, prior to compounding processes, before each batch preparation, before each work shift, periodically during continuous compounding, and at the end of the work day. Remove all items from the compounding surface prior to cleaning. Clean in the following order with an appropriate disinfectant: top, sides, and back of hood then the work surface (bottom). After disinfectant is allowed to dry, apply sterile 70% IPA to the surfaces and allow drying. Use caution not to get the HEPA filter wet. (Note: Sterile 70% isopropyl alcohol may cause cracking of plastic surfaces.)
   b. Sterile 70% isopropyl alcohol may be used liberally for cleaning surfaces and wiping down bottles, vials and other supplies and materials to assure they are free of dust and other contaminants.
   c. Empty all waste receptacles and replace waste bags at a time when compounding is not in process. Keep hazardous waste separate and dispose of appropriately. Place waste materials on unrestricted side of gowning room and remove prior to cleaning the restricted side. If a separate gowning room is not present, place waste outside compounding room.

4. Monthly: Recommend selecting a particular day of the month to be the designated monthly cleaning date.
   a. Storage shelving, wire racks, bins, trays and carts shall be emptied of all items and cleaned with an appropriate disinfectant. Allow storage units to dry. Wipe storage units with sterile 70% IPA and allow drying before restocking items.
   b. Eyewash solutions shall be checked for expiration date and changed if necessary.
   c. Waste container frames shall be cleaned.

5. Semi-Annually:
   a. LAFWs, BSCs, CACIs, and CAIs shall be tested and certified by a qualified individual at least every six (6) months and whenever the device or room is relocated, altered or has undergone major servicing. The notice of certification performance evaluation of shall be placed on the device itself.

Documentation

1. Cleaning and maintenance records shall be retained for a period of three (3) years and should indicate the following information:
   a. Initials of personnel completing the task;
   b. Date and time.

2. Refer to Compounding Room Maintenance Log.
COMPOUNDING AREA SURFACE TESTING

Policy

The purpose of this policy is to provide guidelines for surface sampling and testing of the compounding areas to maintain a controlled environment for the compounding of sterile preparations.

General Guidelines

1. Potential sources of contamination of compounding areas include improperly disinfected work surfaces, inadvertent touch contact by compounding personnel, damaged HEPA filters, improper room ventilation, and changes in personnel garbing procedures. Surface testing highlights conditions contributing to excessive microbial and particulate levels due to ineffective cleaning or personnel/equipment issues.

2. Random surface sampling shall be performed in all ISO classified areas on a periodic basis at the completion of compounding. Products for surface testing measure the number of microorganisms per area sampled and may utilize swabs for irregular surfaces and equipment, or contact plates for regular or flat surfaces.

3. Contact plates are filled with an agar growth media with neutralizing agents above the rim of the plate. A common type of contact plate used for surface testing is the RODAC (Replicate Organism Detection And Counting) plate. Plates need to be refrigerated until ready to use. Once sampling has occurred, plates are incubated to promote growth, the microorganisms are counted and results reported as the number of colony forming units (CFUs) per area sampled.

4. It is recommended that the same individual do the sampling, testing, cleaning and retesting for an entire quarter/period of time.

5. If microbial growth is elevated consistently, a review of garbing, cleaning and compounding practices shall be performed and documented with follow up personnel training.

Equipment and Supplies

1. Contact plates, such as RODAC plates, and/or swabs;
2. Refrigerator;
3. Sterile 70% isopropyl alcohol (IPA);

Procedure

1. Sample locations for testing include areas where there is little air movement or where airflows converge or are excessively turbulent. These conditions are most likely to occur:
   a. Interior walls and surfaces of ISO Class 5 devices (“hoods”) such as LAFWs, BSCs, CACIs, and CAIs;
   b. Adjacent to doors;
   c. In pass-through hatches;
   d. At low level return air grilles;
   e. Between HEPAs and clean rooms;
   f. In corners of rooms; and
   g. Areas within the clean room where there is personnel activity or where compounding processes occur.
2. Flat surfaces: Surface collection with use of contact plates is by gently pressing the rounded agar surface of the plate to the sample surface. Using a rolling motion, with a light uniform pressure, to ensure that the entire surface of the agar will contact the sample surface. Avoid pulling or sweeping the agar surface over the sample area, as this will destroy the agar surface, rendering the plate unusable. Immediately following the sampling, the area shall be thoroughly wiped with a nonshedding towel soaked in sterile 70% IPA.

3. Irregular surfaces: A sterile, cotton-tipped swab is moistened with sterile water and swabbed over such surfaces and into the corners of equipment. For other irregular surfaces, the swab should be rubbed over a surface area roughly the same size as the base of the contact plate three times in an opposite direction between each successive stroke. Following sampling, the swab head should be gently rotated over the surface of the agar three times, again rolling in opposite direction between each successive stroke.

4. After each sample is transferred to the contact plate, the lid should be replaced; taped shut and the bottom of the plate should be labeled with a description of the location the sample was obtained from. All labeling should be done with a waterproof marking pen. Plates should be stored upside down to prevent any condensation from dripping onto the agar.

5. Incubation and Counting:
   a. The plates are placed upside down in an incubator. The incubator should be set at 35 to 37°C. After a 24-hour period, the plates are observed for growth.
   b. After 48 hours, the plates are removed from the incubator and the colonies counted using an electronic colony counter pen, centimeter grate or sent to an outside microbiology lab for identification. Note that counting areas containing a profuse growth may lead to considerable error.
   c. Spreading colonies should be counted as one, but care should be taken to observe other distinct colonies intermingled in the growth around the plate periphery or along a hair line. These should also be counted as one colony, as should be colored colonies and halo-type spreaders.

6. Results may be rated according to the following system:
   a. 0-5 colonies: None or very slight colonies (considered excellent);
   b. 6-15 colonies: Slight (considered good);
   c. 16-30 colonies: Moderate (borderline acceptable);
   d. 31-50 colonies: Significant (poor); and
   e. >50 colonies: Heavy (unacceptable).

7. After the colony counting results are documented, the plates are placed in a biohazard bag and disposed of accordingly.

8. When testing is completed for ISO Class 5 devices or hoods, clean the hood and test areas with sterile 70% isopropyl alcohol.

9. Colony counts exceeding recommended action levels for microbial contamination shall be met with remedial action. The Pharmacy Manager shall determine a course of action to resolve any problems of this nature. Recommended action levels with regard to ISO classification with surface sampling include:
   a. ISO Class 5: >3 cfu per contact plate;
   b. ISO Class 7: >5 cfu per contact plate; and
   c. ISO Class 8 or worse: >100 cfu per contact plate.

Documentation

A Surface Testing Log is used to document results and shall be maintained in the pharmacy for a minimum of three (3) years.
ENVIRONMENTAL SAMPLING

Policy

The purpose of this policy is to provide guidelines for the sampling of primary engineering controls in order to demonstrate consistency within the compounding area with regard to viable and nonviable particle levels.

General Guidelines

1. Primary engineering controls (PECs) include a room or device such as laminar air flow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs) and compounding aseptic containment isolators (CACIs) that provide an ISO Class 5 environment.

2. Environmental sampling shall occur as part of the certification of new facilities and equipment, following servicing of equipment, as part of the re-certification of facilities and equipment, and in response to end-product problems or issues with compounded sterile preparations (CSPs).

3. Particle counts shall be performed at least every six (6) months to determine the number of particulates present in the air per cubic foot of space to ensure that when in use the room does not exceed the desired particle count. In addition, an independent certification company shall recertify the ante-area, buffer area, clean room and the hoods, and according to state laws.

4. Evaluation of the overall control of the compounding environment shall include the routine collection and review of sampling. The Pharmacy Manager shall consult competent microbiology personnel if an activity consistently shows elevated levels of microbial growth.

Procedure

Environmental Particle Testing:

5. The Pharmacy Manager shall establish a contract with an independent certification company for certification and re-certification of the primary engineering controls and compounding areas.

6. Environmental sampling shall occur at least every six (6) months.

7. Evaluation of airborne microorganisms in the controlled air environments is performed by trained individuals using suitable electric air samplers or by exposing sterile nutrient agar plates for a suitable time frame, depending on manufacturer’s recommendations. Air sampling is performed at locations judged by compounding personnel to be the most prone to contamination during compounding activities: this includes zones of air backwash turbulence within PEC devices, other areas where air backwash turbulence may enter the compounding area and areas used for staging, labeling, garbing and cleaning.

8. Growth medium such as soybean-casein digest medium may be used to support the growth of bacteria in low- to medium-risk microbial contamination levels. Microbial growth plates are covered and secured (such as with tape), inverted and then incubated. Incubation time periods correspond to the type of media utilized and according to the manufacturer’s instructions. Generally, for soybean-casein agars 48 to 72 hours at 30°C to 35°C (86°F to 95°F) is appropriate, whereas for malt extract agars used for fungal media 5 to 7 days at 26°C to 30°C (78°F to 86°F) is appropriate.

9. Certification that each PEC is functioning properly is documented by the independent certification company. Documentation of certification and re-certification of the PECs shall be reviewed and maintained by the Pharmacy Manager or Pharmacist-in-Charge.
10. The notice of certification for PEC devices and the performance evaluation shall be placed directly on equipment itself.

11. Pre-filters for PEC devices shall be visually inspected routinely and changed according to manufacturer’s instructions and as necessary.

**Pressure Differential Monitoring:**

12. A velocity meter or pressure gauge shall be installed to monitor the airflow between the buffer area and the ante-area and between the ante-area and the general pharmacy environment outside of the compounding area.

13. The velocity meter or pressure gauge reading shall be reviewed and documented at least once a day. Appropriate readings include:
   a. Pressure between the ISO Class 7 (buffer area) and the general pharmacy area shall not be less than 5 PA (0.092 inch water column);
   b. Differential airflow shall be maintained at a minimum velocity of 0.2 meters per second (40 feet per minute) between the buffer and ante-areas.

**Documentation**

1. The following forms may be used to document results from above testing:
   a. *Environmental Particle Testing Log*;
   b. *Pressure Differential Monitoring Log*.

2. Documentation should be kept in the pharmacy for a period of three (3) years.
INFECTION CONTROL MEASURES

HANDWASHING/HAND HYGIENE

Policy

The purpose of this policy is to provide guidelines for hand washing and hygiene techniques that will aid in prevention of the transmission of infection.

General Guidelines

1. Appropriate thirty (30) second handwashing with antimicrobial or non-antimicrobial soap and water shall be performed under the following conditions:
   a. Before and after compounding processing;
   b. When hands are visibly dirty or soiled with blood or other body fluids;
   c. After contact with blood, body fluids, secretions, mucous membranes, or non-intact skin;
   d. After removing gloves;
   e. After handling items potentially contaminated with blood, body fluids, or secretions;
   f. Before and after eating;
   g. After using a restroom; and/or
   h. When there is likely exposure to spores, such as Clostridium difficile or Bacillus anthracis. Note: Alcohol-based hand rubs are inactive against spores. For effective mechanical removal of spores, wash hands for 30 to 60 seconds with soap and water or 2% chlorhexidine gluconate.

2. The use of gloves does not replace handwashing.

3. Compounding personnel should remove all hand, wrist and body jewelry that can interfere with the fit of gloves before handwashing.

4. Natural nails shall be kept neat and trimmed.

5. Hand hygiene is always the final step after removing and disposing of personnel protective equipment.

Equipment and Supplies

The following equipment and supplies will be necessary when performing this procedure:

1. Running water;
2. Soap (anti-microbial or non-antimicrobial);
3. Electronic hand dryer or disposable nonshedding (lint-free) towels; and
4. Trash can.

Procedure

1. Washing hands (in the ante-area):
   a. Turn water on and regulate temperature.
   b. Leave water running throughout the procedure.
   c. Wet hands and forearms to elbow under running water.
   d. Remove debris from underneath fingernails using a nail cleaner under running water.
2. Note: Once inside the buffer or compounding area and prior to donning gloves, antiseptic hand cleansing shall be performed using a waterless alcohol-based surgical hand scrub per manufacturer’s instructions. Hands should be allowed to dry thoroughly before donning sterile gloves.
PERSONNEL PROTECTIVE EQUIPMENT AND ATTIRE

Policy

The purpose of this policy is to provide guidelines for the proper donning of personnel protective equipment and attire for employees compounding sterile preparations in order to prevent microbial contamination of compounded sterile preparations (CSPs).

General Guidelines

1. Sterile gloves.

Equipment and Supplies

1. Sterile gloves; and
2. Sterile 70% isopropyl alcohol.

Procedure

1. Before entering the buffer area, remove personal outer garments, and visible jewelry.
2. Move into the buffer area/clean room:
   a. Perform hand cleansing with a waterless antiseptic alcohol-based surgical hand scrub;
   b. Don sterile gloves;
   c. When gloves become contaminated as they contact nonsterile surfaces during compounding activities, disinfect by wiping or rubbing sterile 70% isopropyl alcohol. Let gloved hands dry thoroughly.
3. Gloves:
   a. Putting on gloves:
      • Open the package, do not touch the gloves;
      • With one hand, grasp a glove by the inside of the cuff;
      • Insert the opposite hand into the glove;
      • Leave the cuff turned down;
      • Pick up the remaining glove with the gloved hand;
      • Insert ungloved hand into the second glove; and
      • Pull up cuffs of the glove.
   b. Removing gloves:
      • Using one hand, pull the cuff down over the opposite hand turning the glove inside out;
      • Discard the glove into the designated waste receptacle;
      • With the ungloved hand, pull the cuff down over the opposite hand, turning the glove inside out; and
      • Discard the glove into the designated waste receptacle.
4. Discard all used PPE into the designated waste receptacle inside the ante-area.
NEEDLE HANDLING AND DISPOSAL

Policy

The purpose of this policy is to provide guidelines for the safe handling and disposal of needles in order to prevent employee injuries.

Equipment and Supplies

1. Needle box;
2. Recapping device (if needle box is not available); and

Procedure

1. After using a needle, if the needle disposal box is directly available, discard the needle without recapping.
2. If recapping is necessary and the needle box is not readily available, reply the cap using one of the following methods before transporting the needle:
   a. Use a needle-recapping device (e.g., stationary cap-holding device, Kelly clamp-type device, etc);
   or
   b. Place the cap on a horizontal surface and slide the needle into the cap. Do not recap the needle by hand.
3. Place used needles in the needle disposal box. Do not bend, break, or cut needles. When the disposal box is almost filled, seal the box and store it in a closed, puncture-resistant container marked “biohazard” until incinerated or picked up by a licensed vendor for proper disposal.
4. Do not discard used or unused needles into trash receptacles.
5. In the event of a needlestick injury, the employee shall:
   a. Immediately wash the wound vigorously with soap and running water; and
   b. If desired, apply alcohol or hydrogen peroxide to the wound.
   c. Notify the supervisor of a needlestick injury as soon as practical.
   d. Complete an incident report form with a supervisor.
ASEPTIC TECHNIQUE AND PERSONNEL COMPOUNDING VALIDATION

Policy

The purpose of this policy is to provide guidelines for the training and continued validation of personnel with respect to aseptic compounding sterile preparations and manipulations, compounding area attire, equipment cleaning and maintenance, and protection from hazardous material.

General Guidelines

1. Safety and accuracy:
   a. Residents receiving intravenous and injectable therapies tend to be the most critical. Since the IV route of medication administration bypasses all of the body’s natural defense mechanisms, every precaution must be taken to minimize risks of contamination.
   b. Completed compounded sterile preparations (CSPs) should be free of particles, bacteria, and all extraneous materials that may potentially contaminate.
   c. CSPs shall be accurately identified, measured, and mixed; and are appropriately purified, sterilized, packaged, sealed, labeled, stored, and dispensed.

2. Personnel training:
   a. All new personnel, including Pharmacists, Interns and Technicians, shall be instructed and observed in proper sterile compounding techniques. Instructions should include all aspects of sterile technique from handwashing through completion of final product.
   b. Appropriate training from expert personnel, audio-video instructional sources, and professional publications in theoretical principles and practical skills of aseptic manipulations shall occur prior to personnel processing CSPs.
   c. Compounding personnel shall perform didactic review, and pass written and media-fill testing of aseptic manipulative skills initially; at least annually thereafter for low- and medium-risk level compounding; and semi-annually for high-risk level compounding for practice sites performing high-risk compounding. Assessment shall include evaluation by direct observation.
   d. Personnel who fail written tests shall be immediately re-instructed and re-evaluated by expert compounding personnel to assure correction of all aseptic practice deficiencies.
   e. Pharmacists supervising compounding activities shall ensure, through appropriate reference sources that specific CSPs maintain their labeled strength within monograph limits for UPS guidelines or within 10% if not specified, until their beyond-use dates. Suggested references include recent editions of “Handbook on Injectable Drugs”, by Lawrence Trissel, “Extended Stability for Parenteral Drugs”, by Caryn Bing, and manufacturers’ medication package inserts.

3. Personnel cleansing and garbing:
   a. Personnel preparing to enter the buffer/clean area shall remove all jewelry from hands and arms.
   b. No chewing gum, candy, or food items may be brought into the ante-area, buffer area or clean room.
   c. Outer lab jackets and coats shall be removed.
   d. Perform hand hygiene per policy prior to the compounding process and upon leaving the buffer area/clean room. Keep hands within the cleaned area of the hood as much as possible. If compounding is interrupted, hands should be re-washed upon re-entering the aseptic preparation area, and as frequently as necessary.
e. Personnel entering the compounding area shall don attire in the appropriate order per policy. Sterile gloves are put on as the last uniform component. While in the compounding area, gloves that do not remain sterile and clean during compounding should be intermittently re-sanitized with sterile 70% IPA.

4. ISO Class 5 devices and environments and proper use within them:
   a. Minimize dust and clutter; keep the compounding environment clean. Only items essential to product preparation shall be placed in the hood. Paper, pens, and labels should not be present on workbench surfaces.
   b. Refer to cleaning schedules in the Pharmacy Maintenance Policy.
   c. Only one operator should work in the hood at any given time.
   d. Maintain a clear and direct path between the first air of the HEPA filter and exposed critical sites within the working area inside hood. Aseptic manipulations shall be performed well within the hood surface edges, and items arranged appropriately depending on the type of airflow utilized. Critical items should be placed as close to the air source as possible. For example:
      • Horizontal Air Flow Workbenches filter air flow from the back of the hood to the front of the hood. Therefore taller products should not be placed in front of smaller products. Passing hands behind and above access ports should be avoided. All work shall be performed at least six (6) inches from the front or back of the hood as the laminar flow air begins to mix with outside air at a distance less than six (6) inches and contamination is possible.
      • Vertical Air Flow Workbenches filter air flow from the top to the bottom, exiting at the back and front of work surfaces. Therefore taller products should not be placed directly next to smaller products. Passing hands over the top of products should be avoided.
   e. Hand movement between the filter and medications and supplies shall be minimized to reduce disruption of air flow. Avoid spraying or squirting solutions within the hood so as not to damage the HEPA filter.
   f. Coughing, sneezing and talking in the hood should be avoided.

5. Specialized compounding equipment and devices:
   a. All necessary medications and supplies shall be obtained and organized prior to compounding.
   b. Materials brought into the compounding area should be restricted to items that generate as small a particulate burden as possible.
   c. Each ingredient shall be inspected for defects, expiration date and damage before use. Expired or defective products shall not be used.
   d. Outer packages and wraps should be removed at the edge of the work area as the sterile contents are placed in the hood.
   e. The surface of ampules, vials and container closures should be disinfected by swabbing with sterile 70% IPA.
   f. Solutions from ampules shall be properly filtered to remove particles prior to use for the compounding of sterile preparations. Lyophilized powders should also be filtered. Five (5) micron filter needles or straws should be available as a conical filter with an attached needle or as a single filter needle product.
   g. There should be no touch-contamination of sterile needles and syringe parts. Contaminated products shall be replaced.
   h. Needles should be inserted cautiously into vials with rubber stoppers to avoid coring. Pierce with the bevel tip up then push laterally and down with heel.

6. Compliance with sterile compounding policies shall be documented and maintained on file in the pharmacy.
PHYSICIAN IV ORDERS

Policy

The purpose of this policy is to provide guidelines for IV medication orders to be consistent with principles of safe and effective order writing so that all prescribed medications are dispensed safely and accurately.

General Guidelines

1. Only authorized, licensed healthcare practitioners or individuals who are authorized to take verbal or telephone orders from practitioners, shall be allowed to write orders in the medical record. The pharmacy staff shall verify that individuals who prescribe medications are legally authorized to do so.
2. Only approved abbreviations and symbols shall be used when ordering and/or charting. Prescribing, nursing and pharmacy staff shall be given a list of approved abbreviations to be used when writing medication orders.
3. Each facility, in conjunction with the Consultant Pharmacist and the Medical Director, shall identify and approve appropriate order writing practices and related policies. They shall also approve any modifications to the list of approved abbreviations.
4. Physicians shall provide timely, accurate, and complete orders.
5. Verbal or Telephone Orders in the facility:
   a. Verbal or telephone orders shall be given in an emergency situation or when the Attending Physician is not immediately available to write or sign the order.
   b. Verbal or telephone orders shall always be based on actual conversations with the prescribing practitioner or on approved written protocols.
   c. Verbal or telephone orders shall be reduced to writing, by the person receiving the order, and recorded in the resident’s medical record. Documentation on the physician’s order sheet shall include “v.o.” (verbal order) or “t.o.” (telephone order).
   d. Documentation shall include the instructions from the Physician, date, time and the signature and title of the person transcribing the information.
   e. Unless otherwise prohibited by law, verbal or telephone orders for Schedule II medications shall be permitted in accordance with facility policy.

Procedure

1. A review of each order for IV medication shall be done by a Pharmacist according to applicable laws.
2. The Pharmacist shall verify medication orders with the Physician when there is a question regarding it. Any dose or order that appears inappropriate considering the resident’s age, allergy history, condition or diagnosis is verified with the nurse having verified it with the Attending Physician.
3. Orders for infusion or IV medications should include the following elements:
   a. Resident name;
   b. Date ordered;
   c. Name of medication;
   d. Name of base solution, as appropriate for IV medication orders;
   e. Strength of medication, where indicated;
f. Dosage;
g. Route of administration, including type of IV line;
h. Time, frequency or rate of IV administration;
i. Quantity or duration/length of therapy;
j. Diagnosis or indication for use;
k. Physician and/or Prescriber name; and
l. Signature of Nurse noting order.

4. Additional resident information that may be useful for the Pharmacist assessing IV therapy includes:
   a. Allergies;
   b. Age;
   c. Height and weight; and
   d. Pertinent laboratory results.

5. Stat orders should be communicated from the facility to the pharmacy immediately upon receipt from the Physician. Stat infusion medications and supplies shall be delivered to the facility within a timely manner whether during the pharmacy’s regular business hours or after hours/emergency times.

6. Orders for flushing protocols should also be written at the time of IV medication order writing if not already present in the resident's medical record.

7. Dispensing Pharmacists may use the Pharmacy Telephone Order Sheet to transcribe verbal or oral medication orders or changes directly from Physicians or Prescribers. The Pharmacist then shall communicate the new order to the facility Nurse for transcribing onto the resident’s medical record, if allowed by state law.
PURCHASING/INVENTORY CONTROL

Policy

The purpose of this policy is to provide guidelines for the selection of medications and supplies dispensed and to assure that all medications and supplies used in the process of compounded sterile preparations are of high quality and are cost effective.

General Guidelines

1. The pharmacy shall have an adequate inventory of medication in both its own inventory/stock and in the facility for the needs of residents.
2. A system is in place to assure that adequate supplies of appropriate medications are available both during established pharmacy hours of operations as well as during non-business/after hours or when back-order situations occur.
3. Merchandise received into the pharmacy shall be physically secured in order to prevent or minimize diversion.
4. A primary staff member shall be designated to perform duties of ordering and receiving medications. A back up staff member shall be cross-trained to perform these duties in the absence of the primary staff member.
5. Orders should be reviewed and approved by the Pharmacy Manager or Pharmacist-in-Charge prior to ordering.
6. When ordering controlled substances, the employee ordering shall be different than the employee receiving, whenever possible. Refer to the pharmacy operations policies and procedures regarding controlled substance registration, security, and ordering requirements.
7. A system is in place to ensure that items ordered match items received and match items billed. For example, the purchase order is compared to the packing slip and the invoice at the time the order is received.
8. Inventories shall be routinely performed for accurate medications/supply counts and costs assessments.

Procedure

1. All medications, supplies and ancillary products shall be purchased from contracted and licensed wholesalers, suppliers, or pharmacies.
2. Sample medications shall not be dispensed to residents.
3. Criteria used in the selection of medications include:
   a. Appropriateness for diseases and conditions treated;
   b. Effectiveness in terms of the following (if applicable):
      • Efficacy (alone and in comparison to other products);
      • Toxicity (alone and in comparison to other products);
      • Pharmacokinetic properties;
      • Bioequivalence;
• Pharmaceutical equivalence; and
• Therapeutic equivalence.

c. Risks related to:
• Known incidence of adverse drug reactions;
• Potential for error in prescribing or ordering, preparing, dispensing, and administering;
• Packaging;
• Labeling; and
• Acquisition costs and cost impact.

d. All medications purchased shall be approved products and comply with the Federal Drug Administration (FDA) requirements for bioequivalence.

4. Receipt of medications:
   a. The number of containers received from a vendor delivery shall be verified and signed for by an authorized pharmacy employee.
   b. Containers with controlled substances shall only be accepted by a Pharmacist or the designated controlled substance Technician and taken immediately to the controlled substance area and secured.
   c. A Pharmacist or Technician who did not place the order shall check off the received items against the invoice for accuracy. Any discrepancies shall be identified on the invoice for further action. All invoices shall be signed and dated by the authorized individual verifying the delivery. If a discrepancy is identified, the vendor and pharmacy billing personnel shall be notified immediately and proper steps taken to correct the misbilling.
   d. If there is a discrepancy with a controlled substance, the Pharmacy Manager shall be notified immediately as well as the vendor and billing personnel. If the Pharmacy Manager is not readily available, the Pharmacist-in-Charge shall be notified. Controlled substance discrepancies need to be reconciled immediately. If discrepancies cannot be reconciled, a notice to the DEA shall be completed.
   e. After an order is checked in, the purchase order or order sheet and the packing slip may be attached to the invoice and forwarded to the billing processor.
   f. For a controlled substance delivery, the original invoice should be stamped as either CII or CIII – CV, signed by an authorized individual and given to the billing processor.
   g. All packages received shall be inspected for obvious signs of breakage or damage prior to placement into inventory. Damaged products are separated and appropriate action taken for return to the vendor for credit.

5. Expiration dates shall be checked on all incoming stock and placed in storage so that items with the earliest expiration date are used first.

6. All products shall be stored under conditions appropriate to the manufacturers’ recommendations.

7. Medication storage areas shall be locked when authorized personnel are not present.

8. Recalled products shall be removed from stock and retrieved from residents if necessary, clearly identified, and stored away from the general inventory, then processed according to the recall instructions.

9. The Pharmacist or other designated personnel shall inspect all inventory on a routine basis for items which have exceeded the manufacturer’s expiration date. This shall occur not less than every six (6) months.

10. Inventory items identified as “out-of-date” shall be removed from stock, clearly identified, stored away from the general inventory and either returned for credit to the supplier or destroyed. Expired controlled substances shall be handled according to state and federal regulations.

11. Medications or supplies returned from residents may not be restocked for future use unless specifically approved by the State Board of Pharmacy regulations.
EMERGENCY PHARMACY SERVICE AND EMERGENCY KITS

Policy

The purpose of this policy is to provide guidelines in order that adequate emergency infusion medications are available to meet the needs of residents.

General Guidelines

1. This policy outlines use of emergency services and kits only. Refer to the Purchasing/Inventory Control Policy for details relating to the procurement of emergency medications.
2. Emergency pharmacy service is available on a 24-hour basis. Telephone numbers for emergency pharmacy services are posted at each facility nursing station.
3. Emergency needs for infusion medications are met by using the facility’s approved emergency medication supply, which may be limited quantities packaged as “kits” or stored in automated dispensing systems in accordance with state laws, or by special order from the pharmacy.
4. Attending Physicians and Prescribers should be informed as to the availability of emergency medications in the facility.
5. Medications and supplies deemed appropriate for emergency kits and storage shall be kept secure within the facility.
6. The medications contained in emergency kits and machines shall be checked periodically for integrity and expiration dating.
7. Emergency medications are only administered after a valid Physician’s order. The resident’s allergy history should also be checked prior to medication administration.
8. Use of emergency medications is documented.

Procedure

1. A list of medications and supplies approved for inclusion in the emergency kit or system shall be posted on the kit/system as well as available to facility and pharmacy staffs. This list should include:
   a. Medication or supply name;
   b. Quantity of item;
   c. Expiration date of item; and
   d. Pharmacy’s name and phone number.
2. A method of recording use of items from the emergency kit/system shall be in place. The Emergency Drug Kit Slip forms may be added to kits or available for Nurses to complete as items are removed from kits.
3. Emergency kits/systems shall be sealed or locked, whether by physical seal, key or code access.
4. Medications used from emergency kit/system or an entire kit shall be replaced per state laws.
5. If exchanging kits, the pharmacy shall delivery a sealed kit to the facility and pick up the opened and re-sealed kit within 72 hours of opening.
6. If replacing used doses of medication, the Nurse or pharmacy staff is instructed to replace the medication in the appropriate area of the kit/system within 72 hours of opening. A new seal is placed on the kit after the replacement medication has been added.

7. The kits/systems are inventoried by the pharmacy staff at least every thirty (30) days for completeness and expiration dating of the contents. The date of inventory is noted on the outside of the kit.

8. Emergency orders not available in emergency kits/systems, the Pharmacist:
   a. Determines that the order is a true emergency and that the order cannot be delayed until the next scheduled pharmacy delivery.
   b. If the medication is not available, the Pharmacist will arrange to provide the emergency medication as soon as possible.

Documentation

1. An *Emergency Drug Kit Slip* may be stocked by the pharmacy and/or the facility for facility Nurses to use indicating items used from the emergency kit for billing purposes.

2. An *Emergency Kit Tracking Log* may be utilized by the pharmacy to keep track of kit locations, expiration dates and seal numbers.
FACILITY HOUSE/FLOOR STOCK SUPPLIES

Policy

The purpose of this policy is to provide guidelines for pharmacy involvement in facility house/floor stock supplies for infusion therapy, as permitted by state law.

General Guidelines

1. The facility maintains a list and inventory of commonly used supplies considered as floor stock for infusion therapy as permitted by state law.
2. House supply inventory should be maintained based on residents’ needs, safety concerns and on known prescribing practices in the facility.

Procedure

1. The facility establishes a list of infusion therapy supplies to be utilized as floor stock. Pharmacists may participate with each facility in the development of an approved stock list of supplies.
2. The house supply list is provided to the pharmacy.
3. Generally, floor stock supplies are ordered from an outside source other than the provider pharmacy. Arrangements should be made between the facility and the provider pharmacy to provide these items for residents when the outside source is not available for timely deliveries.
4. The floor stock list is posted in medication rooms.
5. Floor stock items are labeled as “floor stock” or “house supply” and kept in the original manufacturer’s container.
6. The manufacturer’s or pharmacy’s label should include the following elements:
   a. Item name;
   b. Quantity;
   c. Directions for use;
   d. Lot number; and
   e. Expiration date (if applicable).
7. The facility staff is instructed on the removal of recalled items.
MEDICATION STORAGE AND HANDLING

Policy

The purpose of this policy is to provide guidelines for proper storage and handling of infusion medications and supplies, following manufacturer’s recommendations with regard to sanitation, temperature, light, moisture, ventilation, segregation, safety and security.

General Guidelines

1. Only licensed pharmacy personnel are allowed access to medications in the pharmacy.
2. The pharmacy dispenses medications in containers that meet legal requirements, including standards set forth by the United States Pharmacopeia (USP). Medications are kept in these containers.
3. Appropriate temperature ranges for medication storage areas include:
   a. Refrigerators: 2°C to 8°C (36°F to 46°F);
   b. Freezers: -20°C to -10°C (-4°F to 14°F);
   c. “Room” temperature: 15°C to 30°C (59°F to 86°F).
   d. Note: “Controlled” room temperature is considered to be 20°C to 25°C (68°F to 77°F).
4. Refer to the General Requirements for Pharmacy, Compounding Area Configuration and Supplies Policy regarding the Temperature Log.

Procedure

1. All prescription items shall be stored in the licensed (secured) areas of the pharmacy according to state pharmacy regulations.
2. All medication storage areas shall be cleaned and dusted periodically to prevent the accumulation of dust.
3. Medication storage areas shall be well-lit, free of clutter and extreme temperatures.
4. Adequate ventilation shall be maintained through proper heating and air conditioning systems.
5. Medication storage areas shall include a thermometer to allow routine temperature monitoring. Controlled temperature storage areas in the pharmacy should be monitored at least once daily on business days, with the results documented on a temperature log. If temperature falls outside of acceptable range, medications and solutions should be checked for damage, discarded if necessary, and reported to the Pharmacist for resolution.
6. All medications and supplies should be stored on pallets off the floor.
7. All solutions in glass containers are stored in an upright position.
8. Items for internal use are stored separate from products designated for external use.
9. Potentially harmful substances, cytotoxic agents and hazardous materials are clearly identified and stored in an area separate from other medications. This includes cleaning agents and disinfectants.
10. All items that have been removed from their shipping cartons are not to be stored in the warehouse.
11. Infusion solutions in plastic bags that have had their protective overwrap opened are to be dated with the date of removal of wrap and used within 30 days from the date for 100 mL solutions and greater, and within 15 days for 50 mL solutions. Solutions not used within these time limits shall be destroyed.
12. Compounded sterile preparations (CSPs) requiring refrigeration shall be refrigerated within one hour of preparation and maintained in a refrigerator until shipment to the facility.

13. All reconstituted medications stored in the refrigerator or freezer shall have the dates of reconstitution and expiration, Technician/Pharmacist’s initials, and storage requirements on the labeling.

14. All medications that must be refrigerated or frozen will be transported in appropriate packaging and protected from excessive temperatures and light during transport.

15. Refrigerators and freezers used to store medications shall be free of food and non-medication items.

16. Rotate inventory, using products with the earliest dating first.

17. Outdated, contaminated, or deteriorated medications and those in containers that are cracked, soiled, or without secure closures are immediately removed from stock, stored in a designated area away from other medications, and disposed of according to procedures for medication disposal or return to vendors.
STABILITY GUIDELINES AND BEYOND-USE DATING

Policy

The purpose of this policy is to provide guidelines to ensure that all compounded sterile preparations (CSPs) dispensed include appropriate and accurate information regarding stability and beyond-use dating.

General Guidelines

1. The FDA requires an expiration date on all medications and finished pharmaceuticals. The manufacturer assigns the expiration date, determined by appropriate stability testing. Expiration dates are related to any storage conditions stated on the labeling.

2. A beyond-use date (BUD) is defined as the date or time after which a CSP shall not be stored, transported or administered. The date is determined from the date or time the preparation is compounded and is assigned based on direct testing or extrapolation from reliable literature sources and other documentation. Careful interpretation of appropriate information sources for the same or similar formulations should be used along with the Pharmacist’s professional judgment in determining beyond-use dates of CSPs.

Procedure

1. Stability and Compatibility Data:
   a. Stability and compatibility data are reviewed by the Pharmacist before CSPs are prepared.
   b. Vitamins and non-stable additives will not be routinely added to the solution by the pharmacy unless the resident’s condition warrants such addition and is approved and ordered by the Physician. The Nurse will be instructed on making these additions when situations warrant this process.

2. Beyond-Use Dates (BUD):
   a. Beyond-use dates are determined based on currently available technical data obtained from pharmaceutical and infusion device manufacturers, current medical literature, and stability research. Pharmacists may refer to applicable publications to obtain relevant compatibility and degradation information regarding the medication or its congeners.
   b. All CSPs will be assigned a beyond-use date. The BUD assigned will reflect risk-level compounding conditions as well as specific storage conditions (e.g., controlled room temperature, refrigeration, freezing), container specifications and intended duration of therapy.
   c. CSPs requiring refrigeration are refrigerated within one hour after preparation.
   d. CSPs requiring an end-state frozen condition will include both a frozen and a thawed BUD on the label.
   e. The BUD cannot be later than the expiration date on the manufacturer’s container of all medications or solutions used in the compounding process.
   f. CSPs known to have been exposed to temperatures exceeding 40°C (104°F) for more than four (4) hours should be discarded.
   g. Single-dose injectable vials may be used up to six (6) hours in the ISO 5 environment (primary engineering control or IV hood), opened or punctured. For opened or punctured SDVs in worse
than ISO 5 conditions, use within one (1) hour is acceptable. Single dose ampules shall be discarded after opening and not stored for any time period.

h. Multiple-dose injectable vials (MDVs) contain preservatives and are designed for entry on multiple occasions. If MDVs are used, refrigerate the MDVs after opening unless otherwise specified by the manufacturer. The MDVs should be labeled with the date and time of opening along with the initials of the compounding personnel. Discard MDVs when empty, when suspected or visible contamination occurs, or when the manufacturer’s stated expiration date is reached, provided the manufacturer’s storage conditions have been adhered to. Expiration dating not specifically referenced in the package insert should not exceed 28 days once the vial has been opened.

i. Beyond-use dating for proprietary combination bag-and-vial systems, such as ADD-Vantage®, Add-a-Vial® and Minibag-Plus®, follow manufacturer’s instructions for handling and storage. These devices and instructions have been approved by the FDA.

3. In the absence of sterility testing, storage periods before administration for complete CSPs shall not exceed the following:

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Room Temperature</th>
<th>Refrigeration (2-8°C) (35-36°F)</th>
<th>Freezer (&lt;= -10°C) (&lt;= 14°F)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate Use</td>
<td>1 hour</td>
<td>1 hour</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Low</td>
<td>48 hours</td>
<td>14 days</td>
<td>45 days</td>
</tr>
<tr>
<td>Low with 12-hour BUD</td>
<td>12 hours or less</td>
<td>12 hours or less</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Medium</td>
<td>30 hours</td>
<td>9 days</td>
<td>45 days</td>
</tr>
<tr>
<td>High</td>
<td>24 hours</td>
<td>3 days</td>
<td>45 days</td>
</tr>
</tbody>
</table>

Per the United States Pharmacopeia (USP) Chapter <797> Pharmaceutical Compounding – Sterile Preparations

4. All CSPs shall include the beyond-use date on the label.
RESIDENT DISCHARGE OR TRANSFER

Policy

The purpose of this policy is to provide guidelines to facilitate the continuity of pharmaceutical and infusion care and services throughout the discharge or transfer process.

General Guidelines

1. Information about medications may be provided to residents at discharge according to procedures and in compliance with applicable laws and regulations for request of Protected Health Information (PHI).
2. Resident information may be provided upon request to the resident, their responsible party and to the pharmacy or other treatment provider to which the resident transfers following completion of appropriate HIPAA request for information. Pharmacy personnel work with the facility staff in coordination of care and information.

Procedure

1. Infusion medications and supplies previously dispensed may be sent with the resident upon discharge or transfer to another healthcare institution with authorization from the Physician and the payment source per their policies.
2. Information that may be appropriate to communicate to the facility Nurse upon resident transfer or discharge includes:
   a. Medication history and profile;
   b. Allergy history;
   c. Infusion medication order;
   d. Pharmacokinetic dosing information, if applicable; and
   e. Pharmacy contact information.
3. The Pharmacist shall instruct the facility nursing staff to educate the resident/responsible party on how the medication is to be used, possible adverse reactions, special precautions and proper storage of medications. If the directions for use are not the same as those on a prescription label, the Nurse should communicate this to the resident/responsible party.
4. Pharmacists are available for questions regarding medications upon discharge or transfer.
DISPOSAL OF MEDICATIONS

Policy

The purpose of this policy is to provide guidelines for safe and effective disposal of infusion medications in the pharmacy or return of unused medications to vendors.

General Guidelines

5. This policy outlines the disposal of non-controlled infusion medications only.
6. Except for the following situations, medications from nursing facilities shall not be returned to the pharmacy for credit or disposal:
   a. Refusal upon delivery due to order change;
   b. Refusal upon delivery due to resident’s death or expiration; and/or
   c. Pharmacy medication error in dispensing.
7. Medications returned from residents may not be restocked for future use.
8. Consult pertinent state laws for rules, regulations and requirements.

Procedure

1. Medications and supplies to be destroyed or returned to vendors shall be removed from stock and clearly identified. These items are stored away from the general inventory, and then processed according to the following procedures.
2. The Pharmacy Manager establishes an arrangement with a registered reverse distributor or individual vendors in order to process the return of unused or outdated medications.
3. All goods returned to a vendor shall be documented on a Returned Goods Form.
4. A Returned Goods Form should contain the following elements:
   a. Date of return to vendor;
   b. Name, address and phone number of vendor;
   c. Medication or item name/description;
   d. Quantity of medication; and
   e. Reason for return.
5. Attach a copy of the original purchase order to the Returned Goods Form when available.
6. Medications not returned to vendors may be destroyed and documented on a Medication Disposition Sheet.
MEDICATION PRODUCT RECALLS

Policy

The purpose of this policy is to provide guidelines for maintaining accountability records of all dispensed infusion medications and for tracking mechanisms necessary when items are recalled by the Federal Drug Administration (FDA) or manufacturers.

General Guidelines

1. The pharmacy accounts for all medication dispensed in the computer system and/or a hard copy system.
2. The pharmacy has processes in place to track information so that medications can be located and appropriate individuals notified. These processes include:
   a. Identifying each resident who is receiving or has received recalled medications by computer prescription tracking;
   b. Identifying the manufacturers of all medications in the pharmacy's stock and distributed to specific residents;
   c. Retrieving and disposing of medications recalled;
   d. Reporting of medication product defects to appropriate external sources;
   e. Educating facility staff about removing medications from the inventory which are recalled; and
   f. Notifying the Physician, long term care facility staff and others about medication that has been recalled, expired or discontinued.

Procedure

1. The Pharmacist or Technician shall record the lot number and expiration date of each item used in the compounding of sterile preparations on the *IV Medication Profile* or a compounding log. This shall serve as the documentation of lot numbers of items used in the event of a medication recall.
2. In the event of a recall, the Pharmacist shall ensure the following steps are taken in the pharmacy:
   a. Check the current stock for the products and lot numbers involved in the recall.
   b. If an item is found in the current stock that is directly affected by the recall:
      • Remove the product from the inventory and segregate it in an area identified for recalled items;
      • If advised by manufacturer, retrieve the product or medication from resident circulation; and
      • Return medications or supplies to manufacturer as directed in recall notice.
3. In the event that an item being recalled has been used in the compounding of sterile preparations for a current resident, the Pharmacist shall:
   a. Check the *IV Medication Profile* for all current residents receiving the recalled item for any lot numbers corresponding to the recall.
   b. Notify the facility of the recall, both in writing by faxing the recall notice from the FDA or manufacturer, and by phone call. Pick up the recalled medication from the facility.
   c. Notify the resident’s Physician of:
      • Date of occurrence;
• Potential harm to the resident;
• Level of recall; and
• Steps to be taken.

d. If only specific lot numbers of the medication have been recalled and not the medication itself (entirely), replace the medication with a good lot number for the resident, if available. In the event a replacement supply is not available, the Pharmacist shall contact the Physician and the facility Nurse to discuss alternative medication therapy.

e. If for some reason individual lot numbers were not tracked appropriately, then all residents who received the recalled medication shall have their medication replaced.

4. Appropriate documentation shall be noted on the resident’s IV Medication Profile or Communication/Progress Note and in a file designated for information on recalled items.
INFUSION MEDICATIONS NOT COVERED BY THIRD-PARTY PAYORS

Policy

The purpose of this policy is to provide guidelines to meet all the infusion therapy needs and continuity of care for the resident.

General Guidelines

1. In an event that the pharmacy does not offer infusion services necessary for a resident, it shall coordinate with other organizations to ensure that care is provided.
2. If a resident chooses to obtain infusion medications from a pharmacy other than the designated dispensing pharmacy, the facility shall coordinate the delivery of pharmaceutical care for the resident.

Procedure

1. When non-covered infusion medications are ordered, the Pharmacist notifies the facility Nurse and consults with the resident’s Physician to seek a change to a covered (formulary) item.
2. If the Physician elects not to change the order, and if appropriate, the Physician is asked to document medical necessity according to the process set forth by the third-party payor. The Pharmacist then attempts to obtain coverage following third-party payor procedures.
3. If coverage is not available and third-party rules permit, the pharmacy bills the resident or responsible party, or the facility, as allowed by state law.
COMPOUNDING STERILE PREPARATIONS GUIDELINES

Policy

The purpose of this policy is to provide guidelines for essential procedures and techniques for the safe preparation of compounded sterile products in order to prevent harm to residents and pharmacy personnel.

General Guidelines

1. All pharmacy prepared sterile preparations shall contain the prescribed and accurate ingredients and be free from microbial, pyrogenic, particulate and toxic contaminants. They shall be stable and compatible for the labeled beyond-use date and be properly labeled and stored.

2. Personnel assigned to the responsibility of compounding of sterile preparations shall successfully complete specialized training in aseptic technique and aseptic area practices prior to preparing compounded sterile preparations (CSPs). Specific personnel training includes an understanding of the following elements:
   a. International Organization of Standardization (ISO) classified air environments;
   b. Personnel protective equipment;
   c. Aseptic technique;
   d. Environmental quality specifications and monitoring; and
   e. Disinfection of gloves and surfaces.

3. The compounding of sterile preparations shall be performed in an ISO Class 5 environment whether in a laminar air flow workbench (LAFW) or a biological safety cabinet (BSC), compounding aseptic isolator (CAI), compounding aseptic containment isolator (CACI) or other device within the pharmacy. (These devices are often referred to as “hoods”.) Cytotoxic medications shall be prepared within the work space of BSC or CACI.

Equipment and Supplies

1. Certified hood: LAFW, BSC, CACI, or CAI;
2. Medications, diluents and solutions as ordered;
3. Syringes of appropriate size;
4. Needles of appropriate length and gauge;
5. Sterile 70% isopropyl alcohol (IPA); and
6. Other supply items as deemed appropriate for procedure, which may include but are not limited to:
   a. Filter needles;
   b. Transfer sets;
   c. Empty containers;
   d. Hand sealer;
   e. Tubing clips; and/or
   f. Foil seals (optional).
MEDICATION PREPARATION AND DISPENSING

Procedure

1. The buffer area/clean room door shall be kept closed at all times. No extraneous traffic shall enter the buffer area/clean room during the compounding process. No food, drink, or smoking shall be allowed in the compounding area. Coughing, sneezing and talking in the hood should be avoided.

2. All necessary medications and supplies must be obtained and organized prior to compounding. Materials brought into the compounding area should be restricted to items that generate as small a particulate burden as possible. Each ingredient shall be inspected for defects, expiration date and damage before use. Expired or defective products shall not be used.

3. Aseptic technique shall be used for the compounding of sterile preparations. Refer to Aseptic Technique and Personnel Compounding Validation Policy.

4. Perform a thorough cleaning of the hood before work begins in the compounding area and periodically thereafter. Refer to Pharmacy Maintenance Policy.

5. Compounding personnel shall ascertain that ingredients for CSPs are of the correct identity and appropriate quality using the following information:
   a. Vendor’s label;
   b. Certificates of analysis;
   c. Direct chemical analysis;
   d. Knowledge of compounding facility storage conditions;
   e. Record from the compounding facility accompanying the receipt of nonsterile components; and
   f. Expiration date. Note: Ingredients that lack a supplier’s expiration date cannot be used after one year, unless either appropriate inspection or testing indicates that the ingredient has retained its purity and quality for use in CSPs.

6. Syringe and needle use:
   a. Syringe and needle packages shall only be opened within the hood.
   b. Inspect the container and wrapping for damages. If the packaging is opened, discard the unit as sterility of the contents cannot be assured.
   c. Verify that the syringe is of the correct size and the needle is of the correct length and gauge for the compounding procedure.
   d. The protective overwrap should be opened by peeling the two sides of the wrap. Tearing the wrap should be avoided as this increases the number of particles on the work area and also increases the risk of contamination.
   e. Syringe specifics: Remove the syringe aseptically, taking care not to contaminate the barrel or needle connection. The syringe tip protector shall be left in place until ready for needle attachment, unless the syringe already has a needle attached. The stem portion of the plunger shall not be touched. Pulling or pushing the plunger shall be done with the lip of the plunger. Only one syringe shall be used per product.
   f. Needle specifics: Aseptically remove the needle cover without contaminating the needle hub. The needle shaft shall be metal and is lubricated with a sterile silicone coating. Needles should never be swabbed with alcohol. No part of the needle proper shall be touched and will be manipulated by their protective covers only. The protective covers shall be left in place until ready for use.
   g. Attaching a needle to a syringe: Hold the barrel of the syringe in one hand. Insert the tip of the syringe into the needle hub and twist the needle until tight. Do not touch the hub of the needle. Leave the needle guard in place until ready to use. To remove the guard, put it straight off, do not
twist. To remove the needle from the syringes, insert the needle into the needle guard and twist counterclockwise.

h. Removing air bubbles from syringes: Hold the syringes in vertical position with the needle pointing upward. Pull the plunger back a short distance to allow air to enter the syringe. Gently tap the barrel of the syringe with the fingers to free air bubbles on the side of the syringe and allow them to float to the top of the solution. Expel all the air in the syringe by slowly pushing the plunger in until the solution is at the top of the barrel. Adjust the desired volume of solution by aligning the rubber end of the plunger with the graduation marks on the barrel of the syringe.

7. Transfer needle use:
   a. Transfer needles are useful in transferring medications in the preparation of some admixtures, however they do have limitations. A transfer needle is simply a shaft with a point at each end. To facilitate manipulations, there is a centerpiece in the middle of the shaft. The transfer needle should always be manipulated by the plastic centerpiece.
   b. Open the package using aseptic technique.
   c. The uncovered end of the transfer needle is intended for insertion into the medication vial and the other end is intended for insertion into the solution container.
   d. At the time of the transfer, the medication should be in solution.
   e. The medication should be transferred from a vial to a container with a vacuum. The entire contents of the vial must be transferred since there is no way to measure the volume transferred.
   f. With sterile 70% IPA, swab the rubber closures of the medication vial and solution bottle.
   g. Insert the exposed end of the transfer needle into the medication vial.
   h. While grasping the centerpiece in one hand and the needle guard in the other hand, pull the needle guard off to expose the second needle point.
   i. Invert the medication vial and insert the second needle into the solution bottle. The medication is drawn into the solution bottle by the vacuum.

8. Manipulations of compounding containers such as flexible plastic bags, semi-rigid plastic containers, or cassettes:
   a. All materials shall be inspected for damage, such as signs of cloudiness, particulate matter, expiration dates and cracks.
   b. All injection surfaces shall be disinfected with sterile 70% IPA.
   c. If the medication is to be injected into a flexible plastic bag or semi-rigid plastic container, insert the needle attached to the syringe into the injection portal found on the bag or container. The injection portal has two diaphragms, which must be pierced for fluid to be transferred into the bag or container. Leaving fluid in between the diaphragms could result in an incompatibility or inaccurate dose.

9. Automated compounding device (ACD) use:
   a. ACDs should be calibrated prior to compounding per manufacturer’s guidelines in order to certify accuracy.
   b. The Pharmacist shall verify the quantity of ingredients visually or by weighing the final product.

10. Compounding specifics:
    a. Assemble equipment and supplies needed to compound the medications and place in the hood or on the compounding work surface.
    b. Minimize the risk of touch contamination. Disinfect gloves frequently with sterile 70% IPA.
c. Disinfect ampule necks and rubber stoppers of bottles and vials with sterile 70% IPA before they are used.
d. Prevent physical incompatibilities of certain additives by mixing in the proper order. For example, adding calcium and phosphate to parenteral nutrition (PN) and total parenteral nutrition (TPN) solutions. Refer to Parenteral Nutrition Policy.
e. Final filtering with a 0.22-micron filter of CSPs may be done as per the judgment of the Pharmacist. A 5-micron filter may be used for amphotericin and TPNs containing fats or lipids.
f. A foil seal may be placed on injection port of final CSP to indicate that an ingredient has been added.
g. After compounding a given order, the compounder shall leave vials, ampules and bottles along with syringes pulled back to the respective amounts added in order for a final Pharmacist check or verification. If vial contents are to be saved, the vial shall be dated and initialed; if reconstituted, the vial shall be labeled with the concentration.
h. The Pharmacist shall verify the identity and amounts of ingredients in the sterile preparation against the original prescriptions and the label on the IV Medication Profile.
i. A visual inspection against lighted white or black background shall be completed to check for leaks, cracks, particulate matter, contamination, precipitates and final fill volume of the completed CSP. The integrity of the container closure should also be inspected for any noticeable defects.
j. If there are doubts whether a component or product has been properly prepared or stored, the product should not be used.

Documentation

1. Computations and calculations for IV medications, solutions and parenteral nutrition admixtures shall be completed. These may be derived from a computer program specifically developed for that purpose. A computer-generated compounding worksheet may provide an accurate record of the materials and amounts required to derive the final prescription order. This worksheet lists all products involved in compounding the admixture along with areas to document respective lot numbers and expiration dates.

2. The Pharmacist is responsible for ensuring compounding instructions are documented correctly on the worksheet/profile.

3. Labels are generated from the compounding worksheet and are affixed to the finished compounded sterile preparation. A duplicate sample label should be affixed to the IV Medication Profile or compounding worksheet as a permanent record of labeling.

4. A Pharmacist shall perform a final (double-check) verification to assure the correct ingredients will be used per the IV Medication Profile and/or worksheet regardless of whether a Technician or a Pharmacist completed the compounding.

5. For compounded sterile preparations, document the following elements on the Dispensing Log on the reverse side of the IV Medication Profile:
   a. Date of compounding;
   b. Resident name;
   c. Prescription number;
   d. Refill date, if applicable;
   e. Medication or Ingredient names, strengths and amounts used;
   f. Quantity or number of doses prepared;
   g. Stability information;
h. Calculations, if applicable;
i. NDC numbers of ingredients and solutions;
j. Manufacturers’ lot numbers;
k. Manufacturers’ expiration dates;
l. Date of preparation;
m. Initials of personnel preparing CSP; and
n. Initials of Pharmacist checking final CSP.

6. A new prescription number shall be given to any order that is changed and the compounding profile will be updated appropriately.
WITHDRAWAL AND TRANSFER OF FLUID FROM A VIAL

Policy

The purpose of this policy is to provide guidelines for the proper medication withdrawal and transfer from a vial.

General Guidelines

1. Injectable medication vials are containers with a rubber stopper secured to its top by an aluminum band. A cap or aluminum cover usually protects the rubber stopper. Most protective caps do not ensure sterility of the rubber closure.
2. Vials with noted or suspected contaminants or abnormal properties should be discarded.
3. After initial opening, the beyond-use date of multiple-dose medication vials is 28 days unless otherwise specified by the manufacturer.

Equipment and Supplies

1. Medication vial;
2. Sterile 70% isopropyl alcohol (IPA) swab;
3. Syringe of appropriate size;
4. Needle of appropriate gauge; and
5. Sterile Luer Lok™ cap, if applicable.

Procedure

1. Assemble equipment and supplies needed to compound the medications and place in the hood or on the compounding work surface.
2. Inspect the vial’s protective cap and rubber stopper for physical integrity. Remove the vial’s protective cap.
3. Disinfect by wiping the rubber stopper with sterile 70% isopropyl alcohol swab, leaving no excess on top of the closure.
4. Attach a Luer Lok™ needle to a syringe of appropriate size. An 18-gauge needle is a common size.
5. Pull the syringe plunger back to approximately 2 to 3 mL less than the required volume of medication, not touching any part of the plunger except the flat portion at the end.
6. Remove the needle’s protective cover by pulling straight off. Do not twist.
7. Grasp the vial base with one hand.
8. With the other hand hold the syringe barrel and place the needle at a 45 degree angle to the rubber stopper.
9. Insert the needle with the bevel facing upward and with a slight pressure away from the bevel, applying lateral and downward pressure.
10. Once the needle has penetrated the rubber closure, bring the needle and syringe to a vertical position and complete the penetration.
11. Keeping the needle inserted into the vial, invert the vial and syringe so that the vial is now above the syringe.
12. Gradually inject the air in the syringe barrel into the vial in small increments at a time.
13. Avoid injecting all the air at once to prevent unnecessary foaming and ultimately excessive build-up of pressure inside the vial to a potential blowout.
14. Holding the index finger on the lip of the syringe, gently pull the plunger with the thumb and middle finger to withdraw fluid.
15. Remove air bubbles from the inside walls of the syringes by keeping the needle inserted in the vial and gently tapping the barrel of the syringe using “flicking” motion with your thumb and index the vial.
16. Determine the final medication volume and remove the needle from the rubber stopper of the vial. The vial is left with a slightly negative pressure to prevent “spitting” of solution from around the puncture site as the needle is withdrawn.
17. Remove the needle and syringe from the rubber stopper with a quick straight pull. This can be done with the vial inverted, but slightly tilted; making sure that the rubber stopper is not being bathed with the solution or rest the vial right side up on the work surface and withdraw.
18. The syringe is turned upward after withdrawal to prevent leakage out of the needle.
19. If the syringe volume needs to be adjusted after the needle has been withdrawn from the vial, pull back a short distance on the plunger before pushing the plunger forward to clear the needle and hub of fluid and minimize release of medication onto the work surface area.
20. Inject the contents of the syringe into an appropriately prepared container.
21. Remove the needle and place a sterile Luer Lok™ cap at the end of the syringe, if the medication is to be packaged in the syringe.
RECONSTITUTION OF A MEDICATION FROM A VIAL

Policy

The purpose of this policy is to provide guidelines for the reconstitution of a medication provided in a vial.

General Guidelines

4. Injectable medication vials are containers with a rubber stopper secured to its top by an aluminum band. A cap or aluminum cover usually protects the rubber stopper. Most protective caps do not ensure sterility of the rubber closure.
5. Vials with noted or suspected contaminants or abnormal properties should be discarded.
6. Reconstitution should always be done in accordance with manufacturers’ recommendations.
7. After initial opening, the beyond-use date of multiple-dose medication vials is 28 days unless otherwise specified by the manufacturer.
8. Refer to the Withdrawal and Transfer of Fluid from a Vial Policy for general guidelines on medication withdrawal from a vial.

Equipment and Supplies

1. Powdered medication in vial;
2. Diluent;
3. Sterile 70% isopropyl alcohol (IPA) swab;
4. Syringe of appropriate size;
5. Needle of appropriate gauge; and
6. Filter, if necessary.

Procedure

1. Assemble equipment and supplies needed to compound the medications and place in the hood or on the compounding work surface.
2. Inspect the vial’s protective cap and rubber stopper for physical integrity. Remove the vial’s protective cap.
3. Disinfect by wiping the rubber stopper(s) with sterile 70% isopropyl alcohol swab, leaving no excess on top of the closure(s).
4. Determine the correct volume of a suitable diluent to reconstitute the powdered medication by referring to the manufacturer’s guideline (or package insert).
5. Using a needle and syringe, remove the diluent from its container, eliminating all air bubbles inside the syringe.
6. Inject the diluent into the vial containing the powdered medication. As the diluent is added, an equal volume of air must be removed in order to prevent a positive pressure from developing inside the vial. To do this, let air in the vial flow back into the syringe before removing the needle from the vial.
7. Remove the needle and swirl or shake the vial, if permissible, until the entire medication is dissolved.
8. Reinsert the needle, inverting both the vial and syringe. If no air is in the syringe, pull back on the plunger to withdraw the proper volume of medication solution. If air is in the syringe barrel, gradually inject air in the vial a little at a time, pulling back on the plunger after each injection. Avoid injecting all the air at once in the solution in order to avoid foaming and excessive build up of pressure within the vial.

9. To remove air bubbles from the syringe, keep the needle inserted in the vial and tap the barrel of the syringe to allow air bubbles to surface. Push the plunger forward to expel air into the vial.

10. To prevent leakage, remove the needle and syringe from the stopper with a quick, straight pull, turning the syringe up.

11. If it becomes necessary to adjust the volume in the syringe after the needle has been withdrawn from the vial, pullback a short distance on the plunger before pushing the plunger forward. This clears the needle and hub of fluid and minimizes the release of medication into the work space.

12. Inject the contents of the syringe into the appropriate final container. If the solution is to remain in the syringe for administration, remove excess air and cap with a sterile syringe cap.

13. If lyophilized, the product should be filtered.
WITHDRAWAL AND TRANSFER OF FLUID FROM AN AMPULE

Policy

The purpose of this policy is to provide guidelines for the withdrawal and transfer of medication from an ampule.

General Guidelines

9. Ampules with noted or suspected contaminants or abnormal properties should be discarded.
10. Single dose ampules shall be discarded after opening and not stored for any time period.

Equipment and Supplies

1. Medication ampule;
2. Sterile 70% isopropyl alcohol (IPA) swab;
3. 5-micron filter straw or needle;
4. Syringe of appropriate size;
5. Needle of appropriate gauge; and
6. Sterile Luer Lok™ cap if applicable.

Procedure

1. Assemble equipment and supplies needed to compound the medications and place in the hood or on the compounding work surface.
2. Disinfect the neck of the ampule completely with a sterile 70% isopropyl alcohol swab.
3. Ensure no liquid remains in the neck of the top of the ampule. Hold the ampule upright and tap or flick the top of the ampule to remove any liquid trapped in the area in order to minimize the formation of aerosols upon opening.
4. Wrap a sterile 70% IPA swab around the neck of the ampule and grasp the ampule on each side with the thumb and index finger of each hand.
5. Attach a 5-micron filter straw or filter needle to an appropriate size syringe, leaving the protective covering on.
6. Press the plunger down towards the tip of the barrel to expel air and loosen plunger.
7. Remove the protective covering from the filter straw or filter needle.
8. With one hand, tilt the ampule slightly and insert the syringe through the opening of the ampule.
9. Withdraw the required volume by pulling the plunger away from the barrel of the syringe using the thumb and index finger of the hand in which the syringe is being held. Do not touch the plunger around the mid-portion when withdrawing the fluid. Do not block the laminar flow from the exposed sterile sites.
10. The tip of the needle should be below the fluid surface but not touching the bottom of the ampule. This will avoid aspirating any glass particles floating on the surface or laying on the bottom of the ampule.
11. After obtaining the desired volume from the ampule, remove the syringe from the ampule.
12. Tap the barrel of the syringe and remove any excess air bubbles.
13. Return the protective covering onto the filter straw or filter needle and remove from the hub of the syringe.
14. Place a sterile Luer Lok™ cap at the end of the syringe, or attach a new needle to the syringe and inject the contents of the syringe into an appropriately prepared container.
SMALL VOLUME SOLUTIONS INTO MINIBAGS

Policy

The purpose of this policy is to provide guidelines for the safe, accurate and aseptic filling of minibags with small volume parenteral solutions.

General Guidelines

1. The minibag route of administration allows medication to be given intravenously either into a primary IV line or through a secondary (“piggy back”) line.
2. Minibags may be utilized to deliver medications for such therapies as:
   a. Anti-infective therapy with antibiotics, antifungals and antivirals;
   b. Chemotherapy;
   c. Pain management; and
   d. Heparin therapy.
3. Procedures for preparation of minibags shall be conducted in the buffer area/clean room with appropriate supplies following hand hygiene and protective personnel attire procedures.
4. Preparation and storage of proprietary combination bag-and-vial systems should be done according to manufacturer’s instructions. Examples of such combination systems include ADD-Vantage®, Add-a-Vial® and Minibag-Plus®. These devices and instructions have been approved by the FDA.
5. Refer to associated policies: Withdrawal and Transfer of Fluid from a Vial, Reconstitution of a Medication in a Vial, Withdrawal and Transfer of Fluid from an Ampule, Labeling of Medications and Supplies, and Dispensing of Medications.

Equipment and Supplies

1. Reconstituted medication per order;
2. Minibag;
3. Sterile 70% isopropyl alcohol (IPA) swab;
4. Syringe of appropriate size;
5. Needle of appropriate gauge (vented, if necessary);
6. 5-micron filter needle, if necessary; and
7. Sterile Luer Lok™ cap, if applicable.

Procedure

1. Assemble equipment and supplies needed to compound the medications and place in the hood or on the compounding work surface.
2. All materials shall be inspected for damage, such as signs of cloudiness, particulate matter, expiration dates and cracks.
3. All injection surfaces shall be disinfected with sterile 70% isopropyl alcohol.
4. Injection ports of containers should be positioned toward the HEPA filter when compounding.
5. Select an appropriate size syringe and accurately withdraw the required dose from the appropriately prepared medication vial. Usual needle size is 19-gauge or 5-micron filter needle if the medication is lyophilized.

6. Insert the needle attached to the syringe into the injection portal found on the bag or container. The injection portal has two (2) diaphragms, which must be pierced for fluid to be transferred into the bag or container. Leaving fluid in between the diaphragms could result in an incompatibility or inaccurate dose.

7. Label, check/verify and store accordingly.
IV PUSH

Policy

The purpose of this policy is to provide guidelines for the safe, accurate and aseptic filling of medications in syringes to be utilized for the IV Push (IVP) route of administration.

General Guidelines

1. The IV push route of administration directly boluses medications into the venous system through a vascular access device at a rate not to exceed 1 mL/minute.
2. Many medications may be utilized for the IV push type of administration. Examples include:
   a. Antihistamines (such as diphenhydramine)
   b. Diuretics (such as furosemide and torsemide);
   c. Glucagon;
   d. Narcotics (such as hydromorphone and morphine); and
   e. Steroids (such as dexamethasone).
3. Follow the facility or pharmacy policy regarding medications deemed appropriate for the IV push route of administration and in accordance with state laws.

Equipment and Supplies

8. Medication vial or ampule;
9. Diluent, as appropriate;
10. Syringes of appropriate size;
11. Needles of appropriate gauge;
12. 5-micron filter needle or straw;
13. Needleless adapter;
14. Syringe tip connectors or caps; and
15. Sterile 70% isopropyl alcohol (IPA) swabs.

Procedure

8. Assemble equipment and supplies needed to compound the medications and place in the hood or on the compounding work surface.
9. Select appropriate size syringe and accurately withdraw medication from vial using a 5-micron filter needle. Replace needle with appropriate needleless adapter.
10. If diluent is required, check guidelines for specific diluent. If no specific diluent is required, use sterile water or 0.9% sodium chloride, following manufacturer’s guidelines.
11. Place a syringe tip connector or cap on the end of the syringe to cover the medication.
12. Label, check and store accordingly.
MEDICATION PREPARATION AND DISPENSING

ELECTRONIC INFUSION DEVICES/PUMPS

Policy

The purpose of this policy is to provide guidelines supplying pumps that best meet the needs of the resident with regard to pharmaceutical considerations and effectiveness of medication administration; and to provide guidelines for care and maintenance of pumps supplied by the pharmacy.

General Guidelines

1. Intravenous therapies shall be administered via the system that best meets the resident needs, and is provided by the Pharmacy.
2. A wide range of pumps are available from various manufacturers. The products offer various programmable features. Factors that play an important role in the decision to use various types of pumps as the delivery system of choice include, but are not limited to:
   a. Pole-mounted or Stationary Pumps:
      • Hydration, especially those with higher concentrations of potassium;
      • Cycled parenteral nutrition;
      • Antibiotics in fluids over 250 mL volume;
      • Steroid therapy;
      • Intravenous Immune Globulin therapy;
      • Amphotericin; and
      • Additives, solutions or medications that have narrow therapeutic index levels.
3. Procedures for preparation of intravenous solutions to be administered via pumps shall be conducted in the clean room with appropriate supplies following hand hygiene and protective personnel attire procedures.
4. Each pump has specific instructions for use procedures per manufacturer’s recommendations.

Procedure

1. The Pharmacist and the Nurse performing the resident assessment upon new orders for IV therapy determine the most appropriate infusion device.
2. Employees responsible for the pump dispensing, care, and maintenance shall be trained on the proper use, cleaning and calibration procedures. This includes clinical employees that may be called upon to answer questions related to the pump functions.
3. Nurses shall be provided with verbal and written instructions regarding pump operation and care upon initial pump dispensing.
4. Whenever possible, pumps shall be plugged into an electrical wall outlet at all times in the pharmacy’s clean pump/equipment area.
5. Pumps are dispensed per resident. Once intravenous therapy is complete, pumps are to be returned to the pharmacy for cleaning and inspection between resident uses.
6. Equipment shall be secured during transport to prevent damage.
7. Clean and dirty pumps shall be stored separately both during transport and in the pharmacy or warehouse. All pumps returned to the pharmacy from facilities shall be considered dirty and be initially placed in a designated area separate from clean equipment and supplies.

8. Administration sets/tubings, medication cassettes or other attachments should be removed and disposed of properly before returning to the pharmacy.

9. Employees performing equipment cleaning should wear disposable gloves.

10. Pumps shall be cleaned initially with a mild soap and water solution, followed by cleaning with a 1:10 bleach solution or other appropriate cleaner, mixed according to manufacturer’s instructions. Do not use abrasive cleaners. Allow to air dry.

11. After cleaning, pumps shall be inspected for the following:
   a. Visual structure (loose or broken parts, cracks, irregularities or other damage);
   b. Alarm functioning;
   c. Power cord and plug functioning;
   d. Battery functioning; and
   e. Volumetric accuracy or flow rate (calibration).

12. After cleaning and inspection, pumps shall be bagged and placed back into the general equipment inventory and documented in the Pump Tracking Log.

13. When a pump is determined to be faulty, the pharmacy is to be notified and the malfunctioning pump is to be returned to the pharmacy for inspection and repair. The malfunctioning pump shall be replaced immediately. Facilities geographically distant from the pharmacy may require a backup pump to be available in the facility in the event of pump failure. All faulty pumps shall be repaired and retested before being issued to another resident or facility.

14. All pumps will undergo servicing by a biomedical service company at least once annually, or at the manufacturer’s recommendation. Maintenance should be documented on the Pump Tracking Log. Preventative maintenance stickers shall be present on all pumps.

15. Facilities shall be informed of the pharmacy’s 24 hour emergency services for pump problems or replacement.

16. The Pharmacy Manager shall notify the pharmacy and nursing staffs of equipment hazards, defects and recalls as alerted.

**Documentation**

1. The *Pump Tracking Log* serves as a dynamic record documenting a specific pump by serial number, location (resident name and facility, or pharmacy), date of dispensing and return, cleaning, calibration and preventive maintenance checks.

2. Areas for pump placement shall be documented and labeled for easy identification of:
   a. “Clean” or resident-ready equipment;
   b. “Dirty” equipment;
   c. Equipment in need of repair or maintenance; and
   d. Obsolete equipment.

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Effective Date: 10/1/2015

Infusion Therapy Pharmacy Operations Policies and Procedures
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LABELING OF MEDICATIONS

Policy

The purpose of this policy is to provide guidelines for proper labeling of infusion medications and supplies and in accordance with state and federal laws.

General Guidelines

6. Prescription medications can only be labeled or have the labeled modified by the dispensing pharmacy, and only in accordance with state laws. Unattached labels shall not be sent by the pharmacy for Nurses to label.

7. Infusion medications and supplies dispensed by Physicians must conform to the label requirements as stated.

Procedure

1. All legend (prescription) items shall be labeled, including heparin and saline.

2. A Pharmacist shall verify the accuracy of every label according to the prescription.

3. Labels are permanently affixed to the outside of the infusion medication or supply item container. If a label does not fit directly onto the product, the label may be affixed to an outside container or carton, but at least the resident’s name shall be maintained directly on the actual product container.

4. Each label for prescription infusion medications includes the following information:
   a. Prescription number;
      • Note: Any changes in infusion formulas shall require a new prescription number.
   b. Resident’s name;
   c. Name, strength and/or volume of medications and solution;
      • Appropriate units should be used for electrolyte concentrations, depending on the medication. Examples include “mEq” for KCl, “units” for heparin, “mL” for multivitamin combinations and “mg” or “grams” for cefazolin.
      • Injectable liquid medications shall be labeled with strength as a concentration if so available. Directions should include the amount or volume to inject. For example, furosemide 40 mg/mL, inject 1 mL (40 mg).
      • Additives should be noted on the label as the total per container/bag unless otherwise ordered by the Physician (such as “amount per liter”).
      • Concentration should be expressed as amount “per liter” if so requested by the Physician, or the standard of practice.
   d. Name and quantity of each additive, if applicable;
   e. Directions for use, which may include:
      • Infusion rate and frequency (such as in mL/hr);
      • Ingredients that need to be added by the Nurse prior to administration; and/or
      • Duration of therapy, if known.
   f. Physician’s name;
   g. Physician’s DEA number, if required for controlled substances;
   h. Date of dispensing;
i. Initials of compounder;
   • If the compounder is not a Pharmacist, a supervising Pharmacist shall also initial the label.

j. Date after which the mixture shall not be used (beyond-use date);

k. Pharmacy name, address and telephone number;

l. Pharmacy’s DEA number, if required for controlled substances; and

m. Accessory labels to indicate storage requirements or special procedures (such as “keep refrigerated”).

5. Supplies used for infusion therapy should also be labeled with at least the following information
   a. Resident’s name;
   b. Name of item;
   c. Date of dispensing; and
   d. Initials of dispensing Technician and Pharmacist.

6. Non-prescription floor stock medications are labeled as “floor stock” or “house supply” and kept in the
   original manufacturer’s container. The manufacturer’s or pharmacy’s label should minimally include the
   following elements:
   a. Medication or supply item name;
   b. Medication strength;
   c. Quantity;
   d. Directions for use;
   e. Lot number; and
   f. Expiration date.

7. Any medication requiring special handling during disposal should be labeled accordingly (e.g., cytotoxic
   medications).

8. Improperly or inaccurately labeled medications rejected by a facility Nurse should be returned to the
   pharmacy for correction.
MEDICATION PREPARATION AND DISPENSING

DISPENSING OF MEDICATIONS

Policy

The purpose of this policy is to provide guidelines for the dispensing of infusion medications and supplies with consideration of resident safety, product stability, and in accordance with professional standards of pharmacy practice, and all applicable state and federal laws.

General Guidelines

1. All prescriptions shall be dispensed by or under the supervision of a licensed Pharmacist according to state and federal laws.
2. Sample medications shall not be stocked or dispensed.
3. Dispensing quantities shall be individually determined based on Physician orders, laboratory test results, medication stability, and resident needs and safety concerns.
4. Change of orders shall be implemented in a timely fashion to satisfy the needs of the resident and the Physician.
5. Nurses shall be advised of the need to be cognizant of expiration and beyond-use dating and use products accordingly.
6. Infusion products shall be packaged for delivery in order to prevent damage or tampering and to insure proper temperature storage.
7. Cytotoxic/chemotherapeutic agents and other potentially hazardous solutions will be sealed in plastic zip closure bags with appropriate labeling. Refer to the Policy on Cytotoxic/Chemotherapeutic Agents.

Procedure

1. Attention should be given to IV orders within the pharmacy in order to prioritize the workflow. In general, IV therapy should be started soon after orders have been received and administered within a timely manner.
2. All medication orders shall be entered into the computer system along with applicable resident information.
3. A medication billing assessment shall be performed in order to verify medication payment prior to dispensing. A transaction for each medication is created in the computer system prior to any medication leaving the pharmacy.
4. Medications and solutions available in emergency kits may be useful for first doses of IV therapy. Nurses and Pharmacists should be aware of emergency kit contents.
5. The pharmacy shall dispense only appropriate quantities of medications to minimize errors, waste or diversion, and according to the needs of the residents.
6. Verification of medications and supplies being labeled and dispensed shall include visual inspection, linear bar code scanning and comparison of National Drug Code (NDC) numbers.
7. The pharmacy staff shall notify the facility Nurse and/or Physician as necessary for any medications that are temporarily out of stock or unavailable.
MEDICATION INFORMATION

Policy

The purpose of this policy is to provide guidelines for dissemination of verbal or written information or fact sheets as reference material regarding intravenous medications and equipment being dispensed.

Procedure

1. The Pharmacist shall provide information to facility personnel for the safe use of intravenous medications and equipment dispensed. Verbal or written information is provided at the start of therapy and whenever there is a change in the medication or equipment.

2. Medication Guides shall be provided with each prescription that is dispensed for products that the FDA determines pose a serious and significant public health concern to residents in an outpatient setting, such as Assisted Living Facilities and Group Care Homes. A list of currently approved Medication Guides is available at: http://www.fda.gov/medWatch/safety/2009/safety09.htm.

3. Reference materials are available in the pharmacy for Pharmacists to consult should questions arise with unfamiliar medications or equipment. When an infusion medication is dispensed which has not previously had a medication information sheet documented, the Pharmacist dispensing the order shall locate medication information in an accepted reference.

4. User’s manuals or other references related to medication administration devices and equipment shall be provided to nursing personnel and any on-call pharmacy personnel.
DELIVERY OF MEDICATION

Policy

The purpose of this policy is to provide guidelines for a standardized procedure for the accurate, safe and timely delivery of medications and supplies.

General Guidelines

1. Personnel responsible for transporting CSPs shall be trained regarding delivery procedures unique to CSPs in order to ensure quality and packaging integrity. This should include, but is not limited to, cautionary labeling, proper storage, security, lighting, temperature, and any special packaging requirements. Training shall also include special handling procedures appropriate for cytotoxic and potentially hazardous substances as well as exposure to spills/splashes.
2. Medications, supplies and equipment shall be delivered in a safe and timely manner to each customer facility.
3. Medications shall be delivered within the appropriate/proper temperature range.
4. Any errors noted in receiving medications shall be brought to the attention of the Pharmacist in Charge.
5. All deliveries shall be documented on a delivery log. The delivery log is a computer-generated list of all medications and supplies.

Procedure

1. Drivers’ licenses of all drivers shall be checked on an annual or as-needed basis to verify the license is current and valid. Documentation will be maintained on a log for that purpose or within the employee’s personnel record.
2. Packaging of medications, supplies and equipment:
   a. Before leaving the pharmacy, medications shall be checked against the delivery log for accuracy and to ensure there is a dispensing transaction for each item.
   b. After removing from the refrigerator and being checked by a pharmacist, CSPs and IV solutions are placed in clean, reusable coolers/cartons with appropriate packing material to ensure medication stability and potency.
   c. Ice packs are added to coolers, if necessary, to maintain the temperature of the products during transit.
   d. If appropriate, individual supplies are bagged and placed into the delivery container.
   e. Protect products from excessive movement during delivery.
   f. A delivery log listing the medication, supplies and equipment names and quantities is enclosed with each shipment.
   g. All deliveries are boxed and sealed to maintain “clean” and “dirty” material in the delivery vehicle and to separate the facilities’ supplies.
   h. Reusable coolers/cartons are cleansed with an appropriate disinfectant after return from facility delivery.
3. General delivery process:
   a. Drivers are to deliver medications, supplies and equipment to the facility after the Pharmacist has checked the items according to prescriber’s orders.
   b. Upon arrival at the facility, the Driver shall be properly identified by an employee badge.
   c. The Driver shall place the items in a designated location at the facility.
   d. A facility Nurse shall sign the delivery log acknowledging the receipt of the delivery, reconciling the medications in the package with the delivery log.
   e. The Driver shall complete the delivery log indicating the date and time of arrival into the facility.
   f. Upon completion of a delivery, the Driver shall sign the delivery log and return it to the pharmacy.

4. Delivery of Schedule II Controlled Substances:
   a. Schedule II controlled substances shall not be sent to a facility via the U.S. postal services (mail).
   b. Schedule II controlled substances shall be delivered in accordance with all applicable state and federal laws.
   c. Schedule II controlled substances shall be delivered via pharmacy Driver or employee; or by a contracted courier.

5. Delivery of hazardous medications:
   a. All staff shall don appropriate personnel protective equipment during the handling of hazardous wastes including packaging biohazard or cytotoxic agents, sharps containers, pumps and poles.
   b. All hazardous medications shall be labeled as such and sealed in a labeled container prior to transport.
   c. All reusable equipment, such as pumps and poles, shall be picked up from the facility upon completion of cytotoxic therapies. Dirty pumps and poles shall be placed in plastic bags prior to removal from the facility, and labeled as dirty.
   d. All hazardous waste, including dirty pumps and poles, shall be placed in the designated dirty area of the transport vehicle.
   e. Upon transport back to the pharmacy, all hazardous waste, including dirty pumps and poles, shall be brought into the building through a designated entrance and placed in the designated dirty area of the warehouse.

6. Use of courier services to transport medications, supplies and equipment:
   a. It is preferable that, whenever possible, a pharmacy Driver or employee makes the initial delivery to the facility.
   b. To maximize efficiency, pharmacy staff shall attempt to route deliveries.
   c. During busy times when internal drivers or employees cannot meet the schedule, a courier service, that has been pre-arranged to make the deliveries, is used.
   d. Courier deliveries shall be logged in the same manner as deliveries performed by pharmacy staff indicating the name of the delivery service.
   e. The use of mail carriers such as United Parcel Services (UPS), Federal Express, and the U.S. Post Office (mail) is resorted to in remote locations or over excessive distance for all medications except Schedule II prescriptions.
   f. A facility Nurse shall sign the delivery log upon receipt of the delivery.
   g. If a Nurse is not available to sign for the delivery, the medications and supplies shall be returned to the pharmacy.
   h. If the contracted courier service or other mail carrier is unable to complete a delivery to a facility, the courier staff should contact the pharmacy for further instructions concerning alternate delivery plans or return to the pharmacy.
RECORDKEEPING OF PRESCRIPTION FILES AND CONTROLLED SUBSTANCES

Policy

The purpose of this policy is to provide guidelines to ensure accountability and maintenance of all dispensed prescription records are in compliance with regulatory standards, and state and federal laws.

Procedure

5. Retention of Prescriptions:
   a. Prescriptions for all medications and medical supplies dispensed to residents shall be maintained on the premises of the pharmacy. For most long term care prescriptions, prescriptions shall be in the form of faxed physician order sheets or facility telephone order sheets.
   b. These records shall be maintained for a minimum of number of years as dictated by state pharmacy laws.

6. Telephone Prescriptions:
   a. Telephoned (or verbal) prescriptions from facility Nurses to Pharmacists shall be received and promptly transcribed to a Pharmacy Telephone Order Sheet by a Pharmacist prior to processing, such as compounding, filing, and dispensing.
   b. Documentation of a telephone or verbal order shall contain the:
      • Resident’s name;
      • Medication/solution;
      • Dosage;
      • Route of administration;
      • Frequency;
      • Duration;
      • Related medical supplies, if applicable;
      • Laboratory orders, if applicable;
      • Physician’s name;
      • Name of agent or Nurse giving orders, if applicable;
      • Date of call; and
      • Initials of the Pharmacist receiving orders.
   c. The Pharmacist shall then assign a separate prescription number to each legend item.
   d. The transcribed written order should then be entered into the pharmacy computer for processing.

7. Changes in Prescriptions:
   a. Alterations in the medication regimen shall be noted by a Pharmacist on the original copy of the faxed orders or documented on a Pharmacy Telephone Order Sheet. The notation shall include the revised regimen, date of change, name of the person conveying the change (prescriber or agent), and initials of the Pharmacist receiving the information.

8. Documentation of Dispensing:
   a. Documentation of all dispensing pursuant to a prescription shall be recorded on the IV Medication Profile and the delivery log and shall be initialed by the Dispensing Pharmacist.
   b. A copy of the prescription label is to be maintained in the resident’s IV Medication Profile for compounded sterile preparations when the prescription is initially dispensed.
   c. Refills must be documented by the Pharmacist’s initials, date dispensed and quantity dispensed.
9. Controlled Substances:
   a. Prescriptions for controlled substances shall be dispensed and maintained according to federal requirements and the state laws in which the pharmacy is licensed.
   b. A Controlled Substance Perpetual Inventory Log shall be maintained by the pharmacy.
   c. Controlled substances may be dispensed with an Individual Resident's Controlled Substance Record for documentation at the facility for use and disposition purposes.

10. Renewal of Prescriptions:
   a. Any interruption in therapy due to hospitalization or otherwise requires the generation of a new prescription order before therapy is reinstated.
   b. To comply with state pharmacy law, prescriptions must be renewed annually, or every six (6) months for controlled substances.
ADVERSE DRUG REACTION REPORTING

Policy

The purpose of this policy is to provide guidelines for communicating, documenting and reporting suspected adverse reactions from intravenous medications.

General Guidelines

1. An adverse drug reaction (ADR) is any response to a medication/drug that is noxious or unintended and that occurs at any dose used for prophylaxis, diagnosis or treatment, excluding failure to accomplish the intended purpose.
2. An adverse event or reaction may be one that results in the discontinuation of therapy, hospitalization, treatment with another therapy/agent and/or significant injury.
3. The pharmacy and the facility both maintain their own files on ADR's. ADR reports shall be communicated between the pharmacy and facility as they occur. Pharmacists shall communicate any known or suspected ADRs to the facility's quarterly quality assurance or medication management committee meetings.

Procedure

1. The Pharmacist shall review the resident’s allergy history prior to the first dose of a compounded IV medication dose to identify any potential cross-sensitivities.
2. When a suspected ADR is encountered, the following protocol should be followed:
   a. The Pharmacist and facility Nurse shall review the reaction or untoward event.
   b. A plan of action shall be formulated and implemented.
   c. The Physician shall be contacted with recommendations for the plan of action documented.
   d. A Suspected ADR Report shall be completed. The following information should be included:
      • Resident’s name and age;
      • Description of reaction, date and outcome;
      • Suspected medication, route, dose and date of administration;
      • Medication profile;
      • Treatment, therapy or plan of action; and
      • Other relevant history.
3. A MedWatch FDA Form #3500 (found at [www.fda.gov/medwatch/getforms.htm](http://www.fda.gov/medwatch/getforms.htm)) may also be completed and sent to:
   Department of Health and Human Services
   Food and Drug Administration
   Division of Epidemiology and Surveillance
   5600 Fisher Lane
   Rockville, MD 20857
4. When ADRs are reported to the MedWatch program, the Pharmacy Manager shall also be notified. A copy shall be kept on file in the pharmacy.
5. All suspected ADR reports shall be reviewed at least quarterly by the pharmacy’s Performance Improvement Committee and management to ensure that appropriate action is being consistently implemented. The following items shall be addressed:
   a. Review reports of suspected ADRs for trends or causative processes.
   b. Institute improvements in the process to prevent or reduce adverse drug reactions in the future.
   c. Assess effectiveness of improvements.
   d. Continually review processes (from internal and external sources) to reduce and/or detect potential adverse drug reactions.
THERAPEUTIC MEDICATION MONITORING GUIDELINES

Policy

The purpose of this policy is to provide guidelines for clinical monitoring in order to assist Pharmacists in providing effective infusion medication therapy while minimizing the potential for adverse drug reactions or toxicities.

General Guidelines

Definitions Pertinent To Clinical Monitoring Guidelines:

1. APPARENT VOLUME OF DISTRIBUTION: The size or volume of a theoretical compartment found in the serum; accounts for the total amount of medication in the body present throughout the body in the same concentration.
2. BIOAVAILABILITY: The amount of unchanged medication reaching the systemic circulation after extravascular administration compared with the amount administered.
3. CLEARANCE, METABOLIC: A measure of how well the body can biotransform a medication into either an active or inactive compound in order to enhance removal from the body.
4. CLEARANCE, RENAL: A measure of the kidney’s ability to remove a substance from plasma or serum; expressed as a volume/unit of time. This may involve one or more of the following processes: glomerular filtration, tubular secretion and tubular reabsorption.
5. CLEARANCE, TOTAL SYSTEMIC: A measure of the ability of the body to remove a substance from a specific body fluid by all processes.
6. DISPOSITION: The processes that occur after absorption of the medication. These include, but are not limited to, distribution, metabolism and elimination.
7. DISTRIBUTION: The movement of medication within the intravascular space and from the intravascular space to extravascular fluids and tissues. This movement may be reversible.
8. ELIMINATION: Irreversible loss of medication which primarily occurs by two processes, metabolism and excretion.
9. ELIMINATION RATE CONSTANT (k): The fraction or percentage of the total amount of medication removed per unit of time. The elimination rate constant is a function of clearance and volume of distribution.
10. FIRST PASS EFFECT: The hepatic or gastrointestinal wall metabolism of a medication that occurs upon oral absorption, but before the medication reaches the systemic circulation.
11. FREE MEDICATION CONCENTRATION: The concentration of a medication in a biologic fluid (plasma, serum) that is not bound to protein. The unbound medication is presumed to be the fraction which is pharmacologically active.
12. HALF-LIFE (t1/2): The time required for the serum concentration to fall by one half.
13. LEAN BODY WEIGHT (Ideal Body Weight or IBW): The actual body weight minus the excess of adipose tissue.
14. LOADING DOSE: Dose of a medication that can be given to rapidly achieve a desired serum concentration.
15. NON-LINEAR KINETICS (zero order kinetics): Shown by medications for which the absorption, excretion or metabolism is capacity limited and therefore may become saturated at high serum concentrations. These medications use Michaelis-Menton kinetics for estimating level predictions.

16. PEAK SERUM CONCENTRATION (Cpmax): The maximum serum concentration attained following administration of a dose of a medication.

17. PHARMACOKINETICS: The study of the time course of medication and metabolite concentration in different biological fluids and tissues of the body and the mathematical relationships which can be used to interpret those values in a particular patient.

18. TROUGH SERUM CONCENTRATIONS (Cpmin): The concentration of medication in the serum immediately before the next dose approximating the lowest serum concentration between doses.

19. USUAL THERAPEUTIC RANGE: The range of concentrations in which a therapeutic effect is most likely to occur in a majority of patients.

Therapeutic Monitoring Principles:

1. Sampling:
   a. Accurate and precise timing, both in administration of the medication and in obtaining blood samples, are of utmost importance in medication monitoring.
   b. For meaningful interpretation, timing and duration of dosing and samples is imperative.
   c. For long-term therapies, the samples should be collected after a “steady state” has been reached (approximately 4-5 half-lives).
   d. The sample is drawn at the time of maximum serum medication concentration (peak) and/or immediately before the administration of another dose (trough) depending on the clinical indication.
   e. To obtain a peak serum concentration the clinician must allow for the medication to be distributed before drawing a sample.
   f. For most medications the initial distribution phase is between 1-2 hours.

2. Relationship between dose, serum level and clinical response:
   a. The intensity of the pharmacological action of many medications correlates better with serum concentrations than with dose.
   b. For most medications, the dose administered corresponds to some extent with the intensity of the pharmacological effect, but a significant variability in the dose-response relationship is observed among many patients due to several factors.
   c. Serum medication concentrations may depend on:
      • Compliance or medication adherence;
      • Correct medication for indication;
      • Absorption;
      • Distribution;
      • Biotransformation; and
      • Excretion
   d. In addition, the medication concentration is influenced by regional blood flow, binding to serum proteins, fluid status of the patient, and transport mechanisms.
   e. Tissue responsiveness, the presence of other medications, disease state and the patients age are additional factors that alter the intensity of the pharmacological effect of the medication.

3. Medications that should be monitored should be assessed based on the following guidelines:
   a. Dangerous toxicities with poorly defined clinical endpoints;
b. Steep dose response curves;
c. Narrow therapeutic ranges;
d. Indicated or used for long-term therapy;
e. Used in the treatment of life-threatening diseases;
f. Considerable inter-individual pharmacokinetic variability;
g. Non-linear pharmacokinetics;
h. Wide distribution in the body; and/or
i. Reliable analytical methods for serum measurements.

4. Interpretation of serum medication concentrations and dose adjustments:
   a. Medication concentration determinations must always be interpreted in the context of all clinical data.
   b. Therapeutic ranges have been established to aid in the interpretation of serum medication concentrations. These therapeutic ranges vary not only in medical literature, but also from one laboratory to another and must be used only as a general rule when monitoring.
   c. Many factors alter the effect of a medication concentration at the site of action:
      • Occasionally patients will exhibit an adequate therapeutic effect while demonstrating a medication concentration in either the subtherapeutic or toxic range.
      • Patients may develop a tolerance to certain medications during long-term therapies, in these cases, the upper limit of the therapeutic range may be raised.
      • In addition, therapeutic ranges of serum medication concentrations require adjustment when other medications with synergistic or antagonistic actions are administered concurrently.
      • The existence of pharmacologically active metabolites and changes in protein binding must be considered when interpreting serum concentrations.
   d. The following may produce unexpected serum medication concentrations:
      • Non-compliance;
      • Inappropriate dosage;
      • Malabsorption;
      • Poor bioavailability of the medication;
      • Medication interactions;
      • Changes in liver/kidney function;
      • Altered protein binding;
      • Fever;
      • Genetically determined fast or slow metabolism of certain medications; and/or
      • Drawing blood samples from central lines with improper or inadequate flushing of the line.

5. Clinical indication for measuring medication concentrations:
   a. When a medication overdose is suspected or in cases in which the expected therapeutic effect has not been observed.
   b. Establishing the optimum medication dose in cases which no means of response, by simple reliable parameters, is available.
   c. The knowledge of a medication concentration is important when symptoms resulting from toxicity and under-treatment are similar, especially when symptoms of the disease to be treated are already present.
   d. The knowledge of the serum medication concentration is useful in establishing a dose level.
   e. Determining serum medication concentration is necessary when a change in bioavailability is suspected or when persistent adverse reactions occur.
f. Determination of concentrations may be particularly important during clinical trials of new or experimental medications.

Procedure

1. All residents receiving medications should be routinely monitored by a collaborative process with the resident which involves the Pharmacist, Nurse, Physician and other disciplines.
2. Each resident shall have updated Physician's orders with a complete list of all medications.
3. The Consultant Pharmacist shall monitor the resident's Physician's orders at the facility at least monthly and more often if appropriate. The Dispensing Pharmacist shall also monitor orders upon admission and receipt. Monitoring may consist of reviewing:
   a. Potential interactions (drug-drug, drug-food, drug-nutrient);
   b. Adverse drug reactions;
   c. Medication allergies or sensitivities;
   d. Resident's response to medication;
   e. Potential medication complications;
   f. Potential medication interference’s or incompatibilities;
   g. Managing adverse effects from administering any recalled medication;
   h. Reviewing laboratory tests, which determine adverse drug reactions or therapeutic and toxic levels;
   i. Keeping the medication profile updated; and/or
   j. Making pharmacokinetics evaluations of the dosage regimen when appropriate.
4. The Pharmacist shall verify that medications are administered:
   a. In proper amounts (dosage);
   b. In proper frequency; and
   c. By the optimal route in the prescribed formulation.
5. Periodic medication pass observations are monitored by the Consultant Pharmacist or designee.
6. The Consultant and Dispensing Pharmacists communicate and share information about medication monitoring on a regular basis. This process may be formal or informal.
ANTIBIOTICS

Policy

The purpose of this policy is to provide guidelines for the clinical monitoring of intravenous antibiotic therapies.

General Guidelines

1. Medical selection criteria for residents receiving IV antibiotic therapy in the long-term care setting may include:
   a. Clinical stability;
   b. Available sites for peripheral IV catheter placement or have a central venous catheter/access device; and
   c. Appropriate laboratory monitoring available.

2. Pharmacokinetic symbols and definitions:
   a. $k$ = elimination constant, which is the slope of the concentration versus time graph;
   b. $t_{1/2}$ = half-life of the medication in hours;
   c. $V_d$ = volume of distribution in liters;
   d. $C_{p_{max}}$ = peak concentration;
   e. $C_{p_{min}}$ = trough concentration;
   f. $t_{in}$ = time the infusion takes in hours (normally 0.5 to 1 hour);
   g. $t_{max}$ = time after infusion that peak level is to be drawn (normally 30 minutes);
   h. $\tau$ = dosing intervals in hours;
   i. $t_{min}$ = time between $C_{p_{max}}$ and $C_{p_{min}}$. This value is normally the dosing interval minus 1.5 hours (if the infusion is administered over 30 minutes) or minus 2 hours (if the infusion is administered over 60 minutes).

3. Administration of the first dose of antibiotics in the facility should always be given under direct medical supervision with ready availability of resuscitative medications, equipment and trained personnel. If the first dose of an antibiotic therapy is to be given in the facility, the following criteria should be adhered to:
   a. A complete medication history should be obtained, to uncover any history of allergic reactions to antibiotic medications.
   b. A Nurse is present for the administration of the first dose and for 30 minutes post-completion of that dose.
   c. An emergency anaphylactic order and medications are available in the facility, such as in an emergency kit or automated dispensing system.

4. If a resident has a positive, well-documented history of an allergy (not side effects) to any antibiotic, it is recommended that the first antibiotic dose is not administered in the facility but rather in the hospital, clinic or Physician’s office.

5. Intravenous antibiotics may be administered via a variety of modes, such as:
   a. Small volume minibags administered intermittently;
   b. Syringe pump and prefilled syringes administered intermittently;
   c. Programmable infusion pumps allowing intermittent dose infusions at preset intervals and a keep-vein-open (KVO) rate between intervals; and
   d. Prefilled disposable antibiotic infusion device.
6. Potential side effects and complications of IV antibiotics to monitor for include, but are not limited to:
   a. Mechanical:
      • Catheter-related such as:
        ➢ Accidental dislodgment;
        ➢ Air embolism;
        ➢ Infiltration;
        ➢ Occlusion or clotting; and/or
        ➢ Phlebitis.
      • Pump malfunctioning
   b. Systematic:
      • Cutaneous such as itching and rash;
      • Dizziness;
      • Febrile episodes;
      • Nephrotoxicity; and/or
      • Ototoxicity.
   c. Gastrointestinal:
      • Diarrhea;
      • Nausea; and/or
      • Vomiting.
   d. Anemia(s):
      • Eosinophilia;
      • Leukopenia; and/or
      • Thrombocytopenia.

7. Laboratory tests commonly recommended for particular IV antibiotics:

<table>
<thead>
<tr>
<th>Antibiotic</th>
<th>Laboratory Test</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aminoglycosides</td>
<td>BUN</td>
<td>Twice Weekly</td>
</tr>
<tr>
<td></td>
<td>CBC with Differential</td>
<td>Weekly</td>
</tr>
<tr>
<td></td>
<td>Peak and Trough Levels</td>
<td>Weekly</td>
</tr>
<tr>
<td></td>
<td>Serum Creatinine</td>
<td>Twice Weekly as ordered</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cephalosporins</td>
<td>CBC with Differential</td>
<td>Weekly</td>
</tr>
<tr>
<td></td>
<td>Platelet Count</td>
<td>Weekly</td>
</tr>
<tr>
<td></td>
<td>Prothrombin Time (for Cefoperazone, Cefotetan)</td>
<td>Weekly</td>
</tr>
<tr>
<td>Penicillins</td>
<td>CBC with Differential</td>
<td>Weekly</td>
</tr>
<tr>
<td></td>
<td>Platelet Count</td>
<td>Weekly</td>
</tr>
<tr>
<td></td>
<td>Serum Electrolytes</td>
<td>Weekly or as ordered</td>
</tr>
<tr>
<td></td>
<td>Urinalysis (for Methicillin)</td>
<td>Weekly</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>BUN</td>
<td>Weekly</td>
</tr>
<tr>
<td></td>
<td>CBC with Differential</td>
<td>Weekly</td>
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</tr>
<tr>
<td></td>
<td>Serum Creatinine</td>
<td>Weekly</td>
</tr>
</tbody>
</table>
Procedure

1. Pharmacist implications for antibiotic monitoring include:
   a. Obtain chart order with appropriate length of therapy (or stop date);
   b. Determine appropriateness of antibiotic against the defined treatment goals;
   c. Determine or aid in determining appropriate laboratory monitoring tests, frequency and plan of
      communication of results with the Nurse and/or Physician.
   d. Determine appropriate antibiotic stability data beyond-use dates, and any specific compounding
      techniques necessary;
   e. Determine or aid in determining appropriate changes in the dosage regimen from lab test
      evaluations; and
   f. Nurse and/or Physician communication documentation within the *IV Medication Profile*.

2. When receiving an antibiotic order, the following resident and order information should be obtained:
   a. Medication and dose
   b. Route or IV line type;
   c. Frequency;
   d. Intended length of therapy;
   e. Site of infection;
   f. Culture and sensitivity results;
   g. Renal status, such as serum creatinine, BUN, and fluid status;
   h. Previous medication levels, if applicable;
   i. Plan for monitoring with laboratory results such as peak and trough orders, if applicable;
   j. Age;
   k. Height and weight;
   l. Nutritional status, such as albumin level;
   m. Presence of other diseases such as diabetes, renal failure/kidney disease, and congestive heart
      failure;
   n. Concurrent medications and administration of other medications that may have synergistic side
      effects such as nephrotoxins.

3. Aminoglycoside (gentamicin, tobramycin and amikacin) and vancomycin specific monitoring:
   a. Therapeutic medication monitoring is essential in maximizing the antibacterial effect of these
      agents as well as avoiding toxicities. Consequently, a plan of care for residents being treated with
      aminoglycosides generally includes medication monitoring.
   b. In order to be accurate with dosage regimen recommendations based on serum medication level
      determinations, it is critical that data such as dose, time of administration, length of infusion and
      timing of samples be recorded.
   c. Dosing is best accomplished by individualization of pharmacokinetics with regard to the resident’s
      age, height, weight and current creatinine or renal function. Nomograms can provide the clinician
      with an initial dosage regimen, but further dosage adjustments should be based on measured peaks
      and troughs. Computer-based kinetics programs are widely available for this purpose.
• Aminoglycosides:
  o Intermittent Dosing: The dose of aminoglycoside required for a particular resident is highly variable and depends on many factors. The following guidelines for intermittent dosing are estimates only:

<table>
<thead>
<tr>
<th>Medication</th>
<th>Initial Dose: Divided into 2 or 3 Doses Per Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amikacin</td>
<td>15mg/kg/day</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>5 to 7.5mg/kg/day</td>
</tr>
<tr>
<td>Tobramycin</td>
<td>5 to 7.5mg/kg/day</td>
</tr>
</tbody>
</table>

  o 24-Hour Dosing: Once daily or 24-hour dosing offers decreased administration time and immediately effective serum concentrations that increase the antibacterial efficacy of the medication. Peaks are usually not monitored when using the 24-hour dosing guidelines. Generally troughs should be less than (<) 0.5 mcg/mL or non-detectable. Half-life with normal renal function in adults is approximately 2 hours. However, half-life is extremely variable and is influenced by a number of factors such as renal status, age, gender, and concomitant diseases. General dosing guidelines for residents with normal renal function are:

<table>
<thead>
<tr>
<th>Medication</th>
<th>Initial Daily or 24-hour Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amikacin</td>
<td>15mg/kg/day</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>6 to 7mg/kg/day</td>
</tr>
<tr>
<td>Tobramycin</td>
<td>6 to 7mg/kg/day</td>
</tr>
</tbody>
</table>

• Vancomycin
  o Vancomycin is widely distributed throughout the body and is eliminated by a two-model compartment, and is 55 % protein bound. The terminal half-life (t1/2) is approximately six (6) hours in adults with normal renal function.

d. Infusion times:
  • Aminoglycoside doses: 30 to 60 minutes;
  • Vancomycin doses: 60 to 120 minutes

e. Serum levels and blood draws for laboratory evaluations:
  • Aminoglycosides:
    o Peak and trough concentrations generally correspond to efficacy.
    o High trough levels are generally associated with increased nephrotoxicity. Aminoglycosides penetrate into tissues unequally so as a general rule, higher levels are used for infections in areas of low penetration (such as the bronchioles and lungs), middle range levels for soft tissue infections, and levels in the lower range for kidney infections (such as urinary tract infections).
    o Trough levels are to be drawn immediately prior to a given dose.
    o Peak levels are usually obtained 30 minutes after the completion of the infusion to account for adequate medication distribution.
MEDICATION MONITORING

- Usual ranges for serum peak/trough in adults with normal renal function:

<table>
<thead>
<tr>
<th>Medication</th>
<th>Time Peak is to be Drawn</th>
<th>Desired Peak Range</th>
<th>Desired Trough Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amikacin</td>
<td>30 minutes post-infusion</td>
<td>20-35 mcg/mL</td>
<td>1-10 mcg/mL</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>30 minutes post-infusion</td>
<td>5-10 mcg/mL</td>
<td>1-2 mcg/mL</td>
</tr>
<tr>
<td>Tobramycin</td>
<td>30 minutes post-infusion</td>
<td>5-10 mcg/mL</td>
<td>1-2 mcg/mL</td>
</tr>
</tbody>
</table>

- Vancomycin:
  - Whereas vancomycin is often monitored using pharmacokinetics, a direct correlation between vancomycin serum levels and therapeutic effect has not been proven as in the case of aminoglycosides.
  - Monitoring may best be accomplished by evaluating trough levels only as generally trough levels are thought to be a good indication of possible toxicity. Peak levels are not associated with efficacy as with the aminoglycosides, however some clinicians continue to monitor both peak and trough levels in an effort to attempt the avoidance of ototoxicity and nephrotoxicity. Serum peak and trough levels are dependent on the indication being treated with vancomycin, however in general the desired trough range is 5 to 19 mcg/mL and the desired peak range is 20 to 40 mcg/mL.
  - Trough levels should be drawn immediately prior to a given dose.
  - The timing of serum level determinations for peak concentrations is controversial as some clinicians prefer to draw the peak two (2) hours after the infusion has been completed while others prefer one (1) hour post-infusion. In either situation, the most important data to have available is the time the infusion was started and the time the peak level was drawn.
  - Periodic serum levels should be ordered after approximately 4 to 5 half-lives initially and weekly thereafter or as per Physician’s orders.

f. Side effect profiles
  - Aminoglycosides: Reversible renal toxicity is a side effect of the aminoglycosides. Vestibular, auditory and neuromuscular toxicities are also possible.
  - Vancomycin: Leukopenia and the “Red-Man’s Syndrome” are common side effects of vancomycin. Red-man’s Syndrome results from histamine release and is characterized by a red, flushed face and neck and is usually associated with rapid rates of infusion or administration. Other toxicities include ototoxicity and nephrotoxicity.
# ASEPTIC TECHNIQUE ASSESSMENT FORM

Employee Name: __________________________________________________________

Location: ________________________________ Date: __________________

Evaluator to mark the space with an “X” for each activity completely acceptably or “N/A” for activities not applicable; mark an “x” for activities not completed successfully or “N/O” for activities not observed.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Met or N/A</th>
<th>Not Met or N/O</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Turns on hood at least 30 minutes prior to compounding. Refrains from eating, drinking, smoking, gum chewing during compounding.</td>
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<tr>
<td>2. Removes visible jewelry prior to entering compounding area.</td>
<td></td>
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<tr>
<td>3. Performs hand hygiene properly per policy. Re-washes if necessary.</td>
<td></td>
<td></td>
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<tr>
<td>4. Cleans compounding area/hood and related compounding equipment with appropriate disinfectant prior to compounding and documents on appropriate form.</td>
<td></td>
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<tr>
<td>5. Protects integrity of HEPA filter. Works at least six inches within the hood, keeping non-essential materials out of the hood and area.</td>
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<tr>
<td>6. Examines supplies prior to use for possible defects (e.g., cracks, particulate matter, cloudiness, cores, etc.).</td>
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<tr>
<td>7. Arranges items in proper mixing order, maintaining a clear path between the filter and the product to create an aseptic field.</td>
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<tr>
<td>8. Uses proper technique in assembling syringe and needle within the hood, assuring plunger shaft, syringe tip or needle is not contaminated.</td>
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<tr>
<td>9. Uses sterile 70% isopropyl alcohol to disinfect ampule necks, vial tops, and medication properly prior to entry, allowing sufficient time to dry.</td>
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<td>10. Uses filter needles when appropriate (e.g., ampules, etc.).</td>
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<tr>
<td>11. Cleans, sets up and calibrates automated compounding device if used.</td>
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<td>12. Prepares multiple admixtures in sequential order to avoid confusion.</td>
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<tr>
<td>13. Disinfects gloves with sterile 70% isopropyl alcohol during prolonged compounding manipulations.</td>
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<tr>
<td>14. Inspects final product under direct light source for particulate matter (e.g., precipitates, cores, etc.).</td>
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<tr>
<td>15. Disposes of needles, syringes, and other waste properly.</td>
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<td>16. Labels product completed as well as incompletely used multi-dose vials with expiration date and follows proper storage procedures.</td>
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</tbody>
</table>

Comments: ________________________________________________________________

Evaluator’s Signature: ___________________________ Date: ____________________

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# Appendix A: Sample Forms and Documentation

## Compounding Room Maintenance Log

Month / Year: ______________________________________________________________________

<table>
<thead>
<tr>
<th>Date</th>
<th>Disinfectant Agent Prep</th>
<th>Clean Hood (Daily)</th>
<th>Clean Floors (Weekly)</th>
<th>Trash Disposal (Weekly)</th>
<th>Clean Ante-area Shelves (Weekly)</th>
<th>Done By (Initials)</th>
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</table>

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AuBurn LTC

Effective Date: 10/1/2015

Infusion Therapy Pharmacy Operations Policies and Procedures

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APPENDIX A: SAMPLE FORMS AND DOCUMENTATION

SUSPECTED ADVERSE DRUG REACTION (ADR) FORM

Suspected Adverse Drug Reaction definition:
An adverse drug reaction is any response to a drug, which is noxious and unintended and occurs at doses used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological functions. (World Health Organization)

Often ADRs are thought of as a secondary effect of a drug that is usually undesirable and different from the therapeutic and helpful effects of the drug or suspected allergic reaction in a resident with no documented history of allergy to that medication.

Categories of ADRs include side effects, hypersensitivity, idiosyncratic responses, toxic reactions and adverse drug interactions.

Reporting procedure:
• Complete this form when an adverse drug reaction is suspected.
• Forward a completed form to the physician.
• Fax a completed form to the facility.
• Update resident’s record as appropriate.

Type of Reaction: (circle appropriate letter A-G)
Mild
A- Reaction occurred but required no change in treatment with suspected drug
B- Suspected drug was held, discontinued or changed but no antidote or additional treatment was needed

Moderate
C- Suspected drug was held, discontinued or changed AND minimal pharmacologic intervention (such as antipruritics) was needed
D- Suspected drug was held, discontinued, or changed AND/OR an antidote or significant pharmacologic intervention (steroids, epinephrine) was required to reverse the reaction

Severe
E- Reaction required hospitalization and significant pharmacologic intervention with no permanent organ toxicity or impairment
F- Reaction was potentially life threatening and caused permanent harm or disability

Death
G- Reaction caused death

Resident: _____________________________ Date of Event: _______________________

Facility Name & Room#: ______________________________________________________

Suspected Drug: _____________________________

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Effective Date: 10/1/2015
Resident: __________________________________________________________

**Clinical signs and symptoms of reaction:** (check appropriately)

- □ headache
- □ agitation
- □ confusion
- □ uneasiness
- □ EPS
- □ hallucinations
- □ respiratory depression

- □ rash
- □ hives
- □ flushing
- □ pruritis
- □ SOB
- □ bronchospasm
- □ other: _______________________

- □ hypotension
- □ hypertension
- □ tachycardia
- □ bradycardia
- □ angina
- □ syncope
- □ other: _______________________

- □ nausea
- □ vomiting
- □ diarrhea
- □ cramps
- □ dizziness
- □ seizures

**Physician notified:**

Orders Received: __________________________________________________

**Outcome:** (mark appropriately)

- □ Drug discontinued
- □ Drug dose modified
- □ Treatment needed to reverse reaction
- □ Long term care stay prolonged
- □ Cognitive impairment or deterioration
- □ Hospitalization required
- □ Disability resulted
- □ Life threatening
- □ Death
- □ Allergy added to profile
- □ Other: _______________________

Resident’s Current Status: ____________________________________________

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Effective Date: 10/1/2015
Person completing form: ____________________________________________
Date: ___________________________________________________________________