SUBJECT: MEDICATION PATIENT INFORMATION AND RECONCILIATION	REFERENCE #8001
DEPARTMENT: HOME HEALTH	PAGE: 1 OF: 5
	EFFECTIVE:
APPROVED BY:	REVISED:

DEFINITION:

A medication is any product designated by the Food and Drug Administration (FDA) as a drug, as well as any prescription medications, sample medications, herbal remedies, vitamins, nutriceuticals, over-the-counter drugs, vaccines, diagnostic and contrast agents used on or administered to persons to diagnose, treat or prevent disease or other abnormal conditions, radioactive medications, respiratory therapy treatments, parenteral nutrition, blood derivatives and intravenous solutions (plain, with electrolytes and/or drugs). This definition of medication does not include enteral nutrition solutions (which are considered food products), oxygen and other medical gases.

POLICY:

- _____ HHA shall implement a patient medication information/ reconciliation process to obtain and document a complete list of a patient's current medications upon admission, including, when possible, the name, dosage, route, frequency and purpose for every scheduled and as-needed medication a patient reports.

- Patient medication information/reconciliation shall be conducted by a registered nurse/ qualified healthcare staff and is a multidisciplinary process involving the patient/family.

- Physicians and other healthcare professionals managing the patient's medications (i.e., pharmacists) shall review the HHA Medication Reconciliation/Verification Form in order to make decisions about drug therapy and to document any discrepancies and their resolution.

- The attending physician shall make any additions, deletions or corrections to the patient's medication orders using the physician's order sheet.

- The HHA Medication Reconciliation/Verification Form shall be placed in a highly visible location within the patient's medical record to assure easy accessibility by providers writing orders and other healthcare providers involved in managing the patient's medications.

- The complete list of the patient's medications shall be provided to the patient or the patient's family upon discharge.

- _____ HHA shall make available and readily accessible medication management information when needed (except in emergency situations when time does not permit) to any staff, including contracted staff, physicians and Licensed Independent Practitioners, involved in the management of the HHA patients' medications. This information shall include, but is not limited to:

  - The patient's age and sex
  - The patient's height and weight if appropriate to the patient and/or to the medication to be ordered, prepared, dispensed, administered and/or monitored
  - The patient's diagnoses, comorbidities and currently occurring conditions
  - The patient's current medications, including prescription, over-the-counter medications and herbal remedies
  - The patient's allergies and any past sensitivities
  - Any relevant laboratory values
  - Pregnancy and lactation status, if appropriate
  - Any other information required by the HHA for safe medication management

- Medication information obtained by a therapist (PT/ST) is verified with the physician and/or dispensing pharmacy by the Case Manager/Nursing Supervisor.

PROCEDURE:

- During the initial assessment visit, the Registered Nurse shall generate a list of the patient's current medications, including prescription and over-the-counter (OTC) medications and herbal remedies. The information is documented in the initial assessment as outlined by the requirements of the OASIS Data Set and in the HHA's Medication Reconciliation/Verification Form, and includes at least the following information:

  - Name of the medication/herbal remedy
  - Date the medication was initially prescribed for the patient
  - Date the OTC and/or herbal remedy was initiated

- When a medication order expires
- How many refills on a current order of medications
- Whether the current dosage is new or changed
- Classification of the medication or herbal remedy
- Dosage, route and frequency of administration of the medication and/or herbal remedy

- The Registered Nurse shall obtain a comprehensive medication history which should include the following information:
  - Past sensitivities, including symptoms
  - Past drug interactions, including those involving herbal remedies
  - Past drug/food interactions
  - Patient's ability to comply with past medication regimens

- The Registered Nurse shall perform an assessment of the patient's current medications/ herbal remedies to determine whether actual or potential interactions exist between the current medications and herbal remedies, based on the current body of knowledge. This information is documented in the visit notes of the appropriate discipline.

- If the list of the patient's currently prescribed medications and OTC drugs includes any look-alike, sound-alike drugs, the Case Manager/Clinical Supervisor should verify the drug, including dosage, frequency, route of administration and indications for use with the prescribing physician. Verification shall be documented in the patient's medical record.

- The Medication Profile is completed in its entirety, including dosage, frequency and administration routes, according to HHA policy.

- The patient's/family member's involvement in development of the list and agreement as to the accuracy of the list is evidenced by:
  - The patient's/family's signature on the Medication Profile *or*
  - A notation in the record that the patient's/family's provided the information/physical medication containers, reviewed the list and agreed that the list was accurate and complete.

- Any questions or concerns about the patient's current medications and herbal remedies are directed to the ordering physician.

- The list of current medications shall be incorporated into the Plan of Care.

- A copy of the completed medication list shall remain in the patient's home chart.

- Copies of the Plan of Care shall be distributed/conveyed to all healthcare team members involved in the management of the HHA patients' medications, care, treatment and/or services, as appropriate.

- The patient/family shall be instructed about the patient's medications verbally and in written format understandable to the patient/family. The patient's/family's response to instructions shall be documented in the medical record.

- The patient's medications shall be reviewed and assessed during each skilled visit. Any changes to the medications or changes in the patient's response to the medications shall be conveyed to the ordering physician and all physician's involved in the patient's Plan of Care, as appropriate.

- When the patient is discharged from the HHA, the patient/family shall receive written instructions regarding his/her medications, i.e., name of medication, dose, route, frequency, the reason for the medication.

- The patient/family shall also be instructed to keep a list of medication he/she is taking, to bring this list to all physician appointments and to give the list to his/her physician.

- The Medication Profile shall be reviewed and updated as necessary according to HHA policy.

- The completeness and accuracy of the medication record shall be audited monthly as part of the HHA's Quality Assessment and Performance Improvement (QAPI) program, and quarterly summary reports shall be submitted to the Governing Body.

- Any permanent harm or death that occurs that is related to medications is a sentinel event and shall be reported to the Joint Commission as per the HHA's Sentinel Event policy.

- Root cause analysis shall be conducted on any identified variances, and a plan of correction shall be developed, implemented and evaluated.

REFERENCES:

- Institute for Healthcare Improvement (IHI). (2011). How-to Guide: Prevent Adverse Drug Events by Implementing Medication Reconciliation. Retrieved from http://www.ihi.org/topics/adesmedicationreconciliation/Pages/default.aspx

- Institute for Safe Medication Practices (ISMP). (2011). Key Definitions. Retrieved from http://www.ismp.org/selfassessments/hospital/2011/definitions.pdf

HHA MEDICATION RECONCILIATION/VERIFICATION FORM
SAMPLE

Patient:________________________________ MR#: ____________________

Address:________________________________ Patient Phone: ____________________

Pharmacy:________________________________ Pharmacy Phone: ____________________

Physician:________________________________ Physician Phone: ____________________

Allergies:________________________________ Patient Height:__________ Patient Weight: __________

Prescribed Medications/Over-the-Counter, Natural and/or Herbal Medications

Date	Medication	Dose	Route	Frequency	New	Changed	Discontinued	Reason for Medication	Effectiveness	Actual/ Potential Drug Interactions	Laboratory Monitoring	Side Effects
					❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No				❑ Yes ❑ No	
					❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No				❑ Yes ❑ No	
					❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No				❑ Yes ❑ No	
					❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No				❑ Yes ❑ No	
					❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No				❑ Yes ❑ No	
					❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No				❑ Yes ❑ No	
					❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No				❑ Yes ❑ No	
					❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No				❑ Yes ❑ No	
					❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No				❑ Yes ❑ No	

Signatures:	**Initials:**	**Signatures:**	**Initials:**

MEDICATION PROFILE "A"
SAMPLE

Patient:_____ Patient Phone: _____

Address:_____

Pharmacy:_____ Pharmacy Phone: _____

Physician:_____ Physician Phone: _____

Allergies: _____

Date	Drug/Dose	Frequency	ROA	Class

MEDICATION PROFILE "B"
SAMPLE

Patient Name:_____ MR#: _____

Pharmacy:_____ Phone: _____

Prescribed Medications

New/ Changed	Date	Discontinue Date	Medication/Dose	Route	Frequency	Side Effects

Over-the-Counter, Natural and/or Herbal Medications

Date	Initials	Medication	Date	Initials	Medication

Signatures: **Initials:**

_____ _____

_____ _____

SUBJECT: CONTROLLED SUBSTANCES	REFERENCE #8004
DEPARTMENT: HOME HEALTH	PAGE: 1 OF: 1
	EFFECTIVE:
APPROVED BY:	REVISED:

The Comprehensive Drug Abuse Prevention and Control Act commonly known as the Controlled Substance Act, concerns the use and sale of controlled substances such as narcotic depressants, stimulants, and hallucinogens. This Act requires that the nurse understands his/her responsibility in the administration, handling and record keeping of controlled substances. Violation of this act is a Federal offense and reportable to the proper authorities.

RNs, LPNs/LVNs and pharmacists are the only staff authorized to handle controlled substances.

All controlled substances are to be monitored as closely as possible and compared to medication orders to verify patient is taking controlled substances appropriately.

A controlled substance may be given only with a physician's order. If a medication is not given because the patient refused it, a partial dose is given, or the medication is contaminated documentation is required.

Any amount of controlled drug that is missing and cannot be accounted for requires an incident report, detailing particular information regarding the loss of the drug. The incident report must be signed by the supervising nurse. Any missed dose must be reported to the physician.

A nurse may accept a verbal order for narcotics from a physician. It must be confirmed by the written order within 48 to 72 hours. To continue administration of narcotics, orders must be renewed on monthly basis.

A written order from the physician is required before an RN can teach the administration of narcotics to family members. Patients will not be taught to self-administer narcotics.

Family members of patients receiving narcotics shall maintain a record of the doses and times of administration.

The patient vital signs shall be checked before administering narcotics.

All narcotics are the personal property of the patients. Upon discharge from the agency, the patient and/or the patients' family will dispose of the remaining medication. Then, the medication sheet will be signed by the patient and/or family.

SUBJECT: MEDICATION TRANSFER COMMUNICATION	REFERENCE #8005
DEPARTMENT: HOME HEALTH	PAGE: 1 OF: 1
	EFFECTIVE:
APPROVED BY:	REVISED:

POLICY:

A complete, current and accurate list of the patient's medications, including prescribed and over-the-counter medications and herbal remedies, shall be communicated in writing to the next provider of service, when the organization refers or transfers a patient to another setting, service, practitioner or level of care within or outside the organization.

PROCEDURE:

- When patient care is assigned, either permanently or temporarily, i.e., weekends, to another HHA staff member (either HHA employee or contracted staff), the replacement staff is provided with a copy of an updated and current patient medication list by the prior clinician (SN, PT, OT, ST). This list may be submitted to the Case Manager or Clinical Supervisor to convey the information to the replacement staff.

- When a patient is referred/transferred to another setting or level of care outside the HHA, a transfer/discharge form, which includes a list of the patient's medications, is completed by any and all licensed clinicians involved in the patient's care and/or services and submitted to the Case Manager or Clinical Supervisor.

- The completed transfer/discharge form information is provided to the setting or level of care outside the HHA by the Case Manager or Clinical Supervisor.

- As part of the organization's Quality Assessment and Performance Improvement (QAPI) program, a sample of records of patients referred or transferred to another setting, service, practitioner or level of care within or outside the organization shall be routinely audited and reported to the QAPI Committee to ensure that a written list of the patient's medications was communicated appropriately to the next provider of service.

- Root cause analysis shall be conducted on any identified variances, and a plan of correction shall be developed, implemented and evaluated.

SUBJECT: HIGH ALERT MEDICATION MANAGEMENT	REFERENCE #8006
DEPARTMENT: HOME HEALTH	PAGE: 1 OF: 4
	EFFECTIVE:
APPROVED BY:	REVISED:

POLICY:

- _____ HHA shall maintain a list of high alert medications that require specific safeguards to reduce the risk of errors related to ordering and prescribing, transcribing, preparation, storage, distribution and administration.

- High alert medications are drugs that have an increased risk of causing significant harm to a patient when used in error. Because the consequences of an error associated with use of these medications can result in significant patient injury, special precautions shall be employed with their overall management throughout the institution.

PROCEDURE:

- The following are categories of medications and specific medications that require special precautions in handling during all phases of medication management processes, which may include, but are not limited to, reducing staff access to these medications; using auxiliary labels; using automated alerts in computer databases in the Pharmacy and on all patient care computer screens; standardizing the ordering, preparation and administration of these products; and employing automated or independent double checks when necessary:

    - High Alert Drug Categories:

        - IV Adrenergic agonists (i.e., epinephrine)
        - IV Adrenergic antagonists (i.e., propranolol)
        - Inhaled and IV Anesthetic agents (i.e., propofol)
        - Cardioplegic solutions (hypothermic and hyperkalemic solutions administered to the myocardium during cardiac surgery)
        - Chemotherapeutic agents
        - Hypertonic Dextrose (20% or greater)
        - Dialysis solutions

- Epidural or Intrathecal medications
- Glycoprotein IIb/IIIa inhibitors (i.e., eptifibatide)
- Oral hypoglycemics
- IV Inotropic medications (i.e., digoxin)
- Liposomal forms of drugs (i.e., liposomal amphotericin B)
- IV moderate sedation agents (i.e., midazolam)
- Oral Moderate sedation agents for children (i.e., chloral hydrate)
- IV/Oral Narcotics/Opiates
- Neuromuscular blocking agents (i.e., succinylcholine)
- IV Radiocontrast agents
- IV Thrombolytic/Fibrinolytics
- Total parenteral nutrition solutions
- Medications with black box warnings

- Specific High Alert Drugs:
  - Insulin, subcutaneous and intravenous
  - Intravenous amiodarone
  - Opiates and narcotics
  - Injectable potassium chloride (or phosphate) concentrate
  - Injectable colchicines

- Intravenous (unfractionated) heparin
- Injectable, low molecular weight heparin
- Sodium chloride solutions above 0.9%
- Intravenous lidocaine
- Injectable magnesium sulfate
- Oral methotrexate, for non-oncologic use
- Nesiritide
- Injectable nitroprusside sodium
- Warfarin
- Psychotropics

☐ The Pharmacy shall outline any additional specific precautions to be undertaken with the management of these medications.

☐ The Pharmacy and Therapeutics Committee shall review this list of high alert medications every six (6) months and as needed to evaluate the specific precautions implemented by the Pharmacy to reduce errors associated with these medications, and to determine necessary additions or deletions from the list.

NOTES:

- List of High Alert Medications, see http://www.ismp.org/Tools/highalertmedications.pdf
- NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016, see https://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf
- ISMP Medication Safety Self- Assessment for High-Alert Medications, http://www.ismp.org/selfassessments/SAHAM/

REFERENCE:

Institute for Safe Medication Practices, http://www.ismp.org

SUBJECT: CONTRACTED PHARMACY AND ON-CALL PHARMACIST	REFERENCE #8007
	PAGE: 1 OF: 1
DEPARTMENT: HOME HEALTH	EFFECTIVE:
APPROVED BY:	REVISED:

POLICY:

- _____ HHA has contracted with_____Pharmacy to provide medications for the HHA's patients.

- A Pharmacist will be available at all times to provide drug information and provide pharmacy services as needed, 24 hours per day, seven (7) days per week.

- An on-call Pharmacist shall be available and have access to the Pharmacy after normal Pharmacy business hours for urgent or emergency conditions.

PROCEDURE:

- The HHA RN will contact the patient's attending physician for medication orders.

- The attending physician must submit a verbal or written order to the Pharmacy for the medication.

- The Pharmacy will notify the HHA when the medication is available for pick-up.

- The Pharmacy will dispense a quantity of medication as ordered and consistent with the patient's life expectancy plus appropriate dosage and frequency of the medication.

- Controlled substances and other medications are available through the Pharmacy.

- If the assistance of a Pharmacist is required after normal Pharmacy business hours, the following procedure will be used to reach the on-call Pharmacist.

    - The pager number of the on-call Pharmacist will be kept in the HHA Manager's office.

    - If the Pharmacist is unable to resolve the problem by phone, the Pharmacist will return to the Pharmacy to assure that the patient's medication needs are met.

    - The Pharmacist will respond to the HHA within_____minutes of receiving a page.

    - The Pharmacist will arrive at the Pharmacy (if it has been established Pharmacist presence is necessary) within_____minutes of contact.

SUBJECT: LOOK-ALIKE, SOUND-ALIKE MEDICATION MANAGEMENT	REFERENCE #8008
DEPARTMENT: HOME HEALTH	PAGE: 1 OF: 2
	EFFECTIVE:
APPROVED BY:	REVISED:

POLICY:

- _____ HHA shall maintain a list of look-alike, sound-alike medications that are stored, dispensed or administered in the organization, and implement measures to prevent errors involving the interchange of these medications.

- The Institute for Safe Medication Practices (ISMP) has identified medications that have the potential for erroneous interchange due to their look-alike, sound-alike nature. While not every medication on the list may require special management, all individuals that manage or utilize medications in any manner should become familiar with the medications identified by ISMP and should be aware of the potential for error due to the look-alike, sound-alike nature.

    - The medication names listed on the ISMP website may not sound alike as they are read or spoken aloud; however, when handwritten or communicated verbally, these names have a high potential for causing a sound-alike erroneous interchange.

PROCEDURE:

- The Pharmacy, in conjunction with nursing services and the medical staff, will develop and maintain a list of look-alike, sound-alike medications that are used throughout the organization.

    - The list will be approved by the medical staff as a physician awareness issue due to the nature of potential medication interchange.

    - Because of the fluid nature of the healthcare industry, the list will be reviewed annually by Pharmacy Consultant for revision and continued approval.

- The Food and Drug Administration and ISMP recommend using tall man letters as one strategy to help prevent medication errors caused by look-alike medication names by drawing attention to dissimilarities in their names. The list of FDA-approved established medication name sets with recommended tall man letters is available at http://www.fda.gov/Drugs/DrugSafety/MedicationErrors/ucm164587.htm). Examples of medications written using tall man letters include:

    - medroxy**PROGESTER**one; methyl**PREDNIS**olone; methyl**TESTOSTER**one

    - **DAUNO**rubicin - **DOXO**rubicin

NOTE:

The Joint Commission website no longer maintains a look-alike, sound-alike medication list; please refer to the ISMP website referenced below for a current list of look-alike, sound-alike medications.

REFERENCE:

See the Institute for Safe Medication Practices website for the most current list of look-alike, sound-alike medications: http://www.ismp.org/tools/confuseddrugnames.pdf

SUBJECT: SELECTION OF MEDICATIONS	REFERENCE #8009
	PAGE: 1
DEPARTMENT: HOME HEALTH	OF: 1
	EFFECTIVE:
APPROVED BY:	REVISED:

POLICY:

- The HHA Medical Director and Pharmacy Consultant shall be responsible for the development of a basic medication list or formulary of accepted medications to be used for patients which shall be continually reevaluated and revised to ensure the distribution of the most effective, newest, safest and most economical therapeutic agents available.

- The HHA's Governing Body in collaboration with the Medical Director, Patient Care Services Director, and Pharmacy Consultant, as appropriate, shall be responsible for defining which classifications of medications and which medication administration routes HHA staff shall be allowed to administer.

- The list of approved medications and routes shall be reviewed on an annual basis and more frequently as needed.

- The selection of medications shall be based on indications for use, effectiveness and risks.

- Medication concentrations shall be limited.

- The basic medication list/formulary shall include the strength and dosage of each medication.

- This list of medications shall be available to all clinical staff at all times.

- The Pharmacy shall:

    - Communicate medication shortages and outages to prescribers and HHA staff

        - In the event of a medication shortage or outage, medication substitution protocols shall be followed. These substitution protocols have been developed by the Medical Director and Pharmacy Consultant.

    - Work with the Medical Director to procure medications that are not on the HHA's drug list

- All clinical staff shall be educated regarding the medication substitution protocols.

SUBJECT: SAFE STORAGE OF MEDICATIONS IN THE PATIENT'S HOME	REFERENCE #8010
	PAGE: 1 OF: 1
DEPARTMENT: HOME HEALTH	EFFECTIVE:
APPROVED BY:	REVISED:

PURPOSE:

To provide guidelines for the safe storage of medications.

POLICY:

The HHA RN is responsible for instructing the patient/family regarding the safe storage of medications. “Safety” is defined both in terms of patient’s safety and protection of the drug against damage from heat, sun, etc.

PROCEDURE:

- The HHA RN plans with the patient/family for the safe therapeutic storage of drugs during the assessment process and on an ongoing basis.

- Consideration will be given to the following:

  - Medications should be stored separately from other poisonous drugs and chemicals.
  - Medication should only be removed from storage during instruction and administration times.
  - Medications should be kept out of the reach of children, pets, and confused or disoriented patients.
  - Drugs requiring refrigeration are to be stored inside the refrigerator.
  - Urine testing and other diagnostic materials are to be stored away from all medications, heat, light and moisture.

SUBJECT: EMERGENCY MEDICATIONS	REFERENCE #8011
	PAGE: 1
DEPARTMENT: HOME HEALTH	OF: 2
	EFFECTIVE:
APPROVED BY:	REVISED:

PURPOSE:

- To ensure that emergency medications and/or supplies are consistently available, controlled and appropriately secured.

- To uphold the patient's right to receive information in an appropriate and understandable format and to be involved in the decision-making process regarding his/her care, treatment and/or services, as appropriate.

POLICY:

- _____ HHA qualified staff shall have an anaphylaxis kit available in the patient's home as appropriate, i.e., during infusion of intravenous medications or investigational drugs.

- If it is determined that the patient's home environment is not a safe and secure storage site for the anaphylaxis kit, the nurse will keep the kit in his/her possession.

- Emergency medications shall not be used by any HHA staff in the event a patient suffers a cardiopulmonary arrest.

- Physician orders are required for an anaphylaxis kit to be present in a patient's home while receiving care, treatment and/or services from the HHA.

- An anaphylaxis kit must be readily available per a physician's order during the entire infusion. A kit will typically contain, but is not limited to:

  - Adult:

    1 - administration set
    2 - 21 g butterfly
    1 - 90 mm airway
    2 - tongue blade (for airway insertion)
    1 - diphenhydramine (Benadryl) 50 mg per mL IV, IM or PO
    1 - 0.3 mg EpiPen-Injector
    2 - epinephrine 1:1,000 (IM)
    6 - prep pads
    3 - pairs gloves
    1 - D_5W 500 mL

- Pediatric:

1 - microdrip set	1 - 0.15 mg EpiPen Junior Injector
2 - 23 g butterfly	1 - epinephrine 1:2,000 (IM)
1 - 60 mm airway	6 - prep pads
2 - tongue blade (for airway insertion)	3 - pairs gloves
1 - diphenhydramine (Benadryl) 12.5-25 mg PO, 1.25 mg/kg IV or IM	1 - D_5W 500 mL

- The Pharmacy responsible for dispensing the intravenous medication or investigational drug shall provide the anaphylaxis kit in a separate container that is appropriately labeled with the contents. The kit will contain emergency medications in unit-dose, age-specific and ready-to-administer forms, whenever possible.

PROCEDURE:

- The Clinical Supervisor/Case Manager is responsible for ensuring that orders for the anaphylaxis kit along with specific criteria for administering emergency medications are in place prior to administration of the intravenous or investigational medications.

- Prior to administering each dose of the intravenous or investigational drugs, the skilled nurse must verify that the contents of the anaphylaxis kit are complete and have not expired.

- The HHA RN shall instruct the patient/family to store the anaphylaxis kit in a safe and secure location in the patient's place of residence, if appropriate, and shall document the instructions. If there is not a safe and secure location in the patient's home or if the home is not a safe and secure location for the kit, the nurse shall retain the kit in his/her possession.

REFERENCE:

Vallerand, April. (2017). *Davis's Drug Guide for Nurses, 15th Edition*. Philadelphia, Pennsylvania: F.A. Davis Company.

SUBJECT: PRESCRIBING/ORDERING - GENERAL PRACTICES	REFERENCE #8012
	PAGE: 1 OF: 8
DEPARTMENT: HOME HEALTH	EFFECTIVE:
APPROVED BY:	REVISED:

POLICY:

- _____ HHA shall develop, implement and maintain policies and procedures to support the ordering of care, treatment and services for all patients.

- The HHA staff shall provide care, treatment and services using the most current patient orders.

PROCEDURE:

- All orders for medication and treatment must be documented in the patient's medical record, signed by the patient's licensed independent practitioner or non-physician practitioner as allowed by State law and agency policy, and be legible.
  - The prescribing practitioner shall be contacted for clarification of any orders staff members feel are not legible.
  - Any orders requiring clarification due to legibility shall be referred to Medical Records for Quality Assessment and Performance Improvement (QAPI) activities.

- Abbreviation:
  - Medication orders shall contain only abbreviations and symbols which have been approved by the medical staff. A list of these abbreviations shall be included with the formulary.
    - Medication orders shall not contain abbreviations and symbols included on the medical staff approved "unacceptable medication abbreviation/ symbols/dose designation list".

Definitions: When used with medication orders:

- "Hold" means to discontinue a medication for a period of time. An order to "hold" a medication is permissible and generally reflects the prescriber's intent to have the patient cease receiving the medication for a period of time with the understanding that the medication has a high likelihood of being reinstated pursuant to the original order. However, any medication ordered as a "hold" may be formally discontinued by the prescriber.
    - A medication ordered as "hold" shall not be dispensed by the Pharmacy and shall not be administered by nursing or other staff approved to administer medications. The patient shall not receive the medication as long as that medication's hold order remains in effect.
    - Medications may be ordered as "hold" status when the prescriber feels it is in the best interest of the patient to discontinue that medication for a period of time (if the prescriber wishes to permanently stop the patient from receiving this medication, the order shall be written as "discontinue").
        - An example of an acceptable reason to order a medication as "hold" would be if serum levels of the medication were at an undesirably elevated or toxic range, the medication would be held until the patient's serum levels returned to the desired range for that medication. In this instance the medication would then be reinstated.
        - To reinstate dispensing and administration of a medication that has been ordered on a hold status, the physician shall write "resume" and the name, dose, strength, frequency and route of the medication.
    - Only orders for individual medications which have been placed on hold may be written as resume medication. Blanket orders to resume or reinstate previous orders for medications are not permissible.
- "Stat" means within 15 minutes
- "Now" means within one (1) hour

- Standing orders means a group of orders that commonly apply to all or almost all patients of a like category and reflect generally accepted medical therapies. Standing orders are written documents containing medical directives for the provision of patient care in selected stipulated clinical situations. Standing orders must be approved by the medical *and* nursing staff for use in this HHA. Standing orders may be revised in accordance with the necessity to individualize the orders to the needs of the specific patient to which the orders have been applied. As standing orders related to this policy and procedure, standing orders may contain orders for the dispensing, administration and monitoring of patient effects of medication.

☐ Metric:

- Medication orders shall be written in metric notation only and shall avoid the use of a leading decimal, or a trailing zero.

☐ PRN:

- Orders for "as needed" or "PRN" medications shall specify the indication(s) for use and be specific for dose and dosage frequency.

☐ Renewal:

- The use of the terms "renew", "repeat" and "continue" in reference to previous orders shall not be acceptable.

- Standard Administration Times:

  - Unless otherwise specified, doses shall be administered at the following times.

Sig	Administration Times
Daily	0900
Daily (warfarin)	1800
BID	0900, 1700
TID	0900, 1300, 1700
QID	0900, 1300, 1700, 2100
Q4H	0400, 0800, 1200, 1600, 2000, 2400
Q6H	0600, 1200, 1800, 2400
Q8H	0600, 1400, 2200
Q12H	0900, 2100
Nightly	2100

- Therapeutic Substitution:

  - In limited, low risk, high volume cases, certain over-the-counter groups of drugs or products may be substituted for different drugs or products. Examples of such items are enteral formulae, liquid antacids and multivitamins. The Pharmacy shall authorize such substitution and shall make the medical and nursing staff aware in the formulary and other publications.

- Medication-Related Devices:
  - A medication-related device is a special device used to deliver medication to the patient (such as a nebulizer). The medication-related device must be present to allow the patient to receive the medication in the manner intended.
    - To further clarify, a medication-related device such as a nebulizer is required to provide the medication in the *manner* the LIP desires, as opposed to ordering of medications where this does not apply, for example specific ordering of an IV pump for routine IV infusion is not necessary as the medication could be adequately provided by IV pole and manually calculated gravity drip.
    - All medication-related devices must be specifically ordered by the licensed independent practitioner, i.e.,_____mg of Alupent via hand held nebulizer.
- Respiratory services must be ordered by a doctor of medicine or osteopathy, or by a non-physician practitioner (physician assistant or nurse practitioner) so long as writing respiratory care orders is within the scope of his/her license and the order is co-signed by the doctor of medicine or osteopathy.

- There must be evidence of a diagnosis, condition or indication for use on the medical record for each medication ordered by the patient's licensed independent practitioner.

- To be considered complete, all medication orders shall include:
  - Name of the drug
  - Dosage form
  - Dosage strength
  - Dosage
  - Quantity or duration (as appropriate)

- Route and frequency of administration
- Reason the drug is ordered/indications for usage (as appropriate)
- Time and date the order is written
- Specific instructions for use
- Name of prescriber
- Age and weight of patient for every neonatal/pediatric patient; adults as applicable
- Any new allergies and old allergies
- The patient's name must be documented on the order sheet or written on a prescription (from Rx pad)

- If the patient's age and weight and any known allergies or lack thereof is not documented in the medical record at the time the order is written, the prescriber shall obtain these facts and document them with the written order.

 Verbal Orders:

- Verbal (direct or telephone) orders shall be written immediately, read back to the prescriber, and signed with the name of the prescriber and the name of the transcriber. Verbal orders for drugs may be taken by a Pharmacist or licensed nurse, as well as RT and PT within the scope of their practice, and as approved by the institution. Verbal orders must be co-signed by the physician ordering the medication, or other physician or non-physician practitioner who is responsible for the care of the patient as allowed by State law, scope of practice laws, HHA policy, and medical staff bylaws, rules and regulations, within the time frame mandated by State law.

- The physician must date and time his/her signature.
    - All verbal and/or telephone orders for medications shall include the following criteria:
        - Date and time the order is prescribed verbally or via telephone
        - The name of the individual prescribing the drug and his/her licensure (i.e., MD, DPM)
        - The generic *and* brand name of the drug
        - Drug dosage (strength or concentration)
        - Quantity and/or duration
        - Route drug is to be administered
        - Frequency of administration
        - Age and weight of the patient if this is not known, or in clinical circumstances where this is appropriate
        - Known allergies (if this has not been determined at the time of the verbal/telephone order)
        - The reason the drug is ordered for the patient
        - Specific indications for use, as appropriate
        - Name and level of licensure of the individual receiving and documenting the order
- Verbal or telephone orders shall not be accepted for chemotherapies.

ADDITIONAL TOOLS:

- World Health Organization (WHO). (April 2015). Essential medicines and health products. WHO Model Lists of Essential Medicines. *WHO Model Lists of Essential Medicines for Children*, 5th Edition. Retrieved from http://www.who.int/medicines/publications/essentialmedicines/en/

- World Health Organization (WHO). (April 2015). *WHO Model Lists of Essential Medicines for Children*. Retrieved from http://www.who.int/selection_medicines/committees/expert/20/EMLc_2015_FINAL_amended_JUN2015.pdf

- Institute for Safety Medication Practice (ISMP). (n.d.). Medication Safety Tools and Resources. Retrieved from http://www.ismp.org/tools/

REFERENCE:

Institute for Safe Medication Practice (ISMP). (2011). ISMP Acute Care Guidelines for Timely Administration of Scheduled Medications. Retrieved from http://www.ismp.org/tools/guidelines/acutecare/tasm.pdf

SUBJECT: TELEPHONE/VERBAL ORDERS	REFERENCE #8013
DEPARTMENT: HOME HEALTH	PAGE: 1 OF: 5
	EFFECTIVE:
APPROVED BY:	REVISED:

CHECK STATE-SPECIFIC RULES AND REGULATIONS

PURPOSE:

To provide care, treatment and/or services according to a state licensed physician or licensed practitioner's orders or prescriptions in compliance with applicable laws and regulations.

POLICY:

- _____ HHA provides care, treatment and/or services to patients in accordance with current physician orders.

- HHA staff accept telephone/verbal/facsimile and/or written orders from physicians and other licensed independent practitioners (LIPs) whose credentials have been verified according to HHA policy.

- The HHA ensures the accuracy of telephone/verbal orders, which are obtained by licensed HHA staff, in accordance with_____State scope of practice guidelines.

- Orders are obtained from the physician or other authorized individual according to applicable laws and regulations and professional practice acts prior to providing care, treatment and/or services.

- All orders for medical care, treatment and/or services are reviewed/evaluated for appropriateness and accuracy by an appropriately licensed individual (i.e., Registered Nurse, Licensed Therapist, Pharmacist) prior to providing care, treatment and/or services.

- Orders for care, treatment and/or services should be tailored to each patient's needs and include all elements required by law and regulation.

- Care, treatment and/or services are provided according to the most recent order/ prescription.

☐ All orders are renewed or updated to reflect:

- Changes in the care, treatment and/or services being provided
- Changes in the patient's physical or psychosocial condition
- The patient's response to care, treatment and/or services
- The patient's outcome related to care, treatment and/or services
- Changes in diagnosis, treatment (including procedures and medications) and equipment

☐ Physician telephone/verbal orders are accepted by qualified staff and submitted to the physician for his/her signature within____days.

☐ Original and/or new/updated orders are transcribed onto a Physician Order/Prescription form or a plan of treatment form as appropriate, and mailed or faxed to the physician for signature within days of receipt of the order by HHA staff.

☐ Telephone/verbal orders shall signed by the physician as soon as possible within the receipt of the orders by HHA staff. (Check state-specific regulations.)

☐ Facsimile copies of signed orders must be supported by the original signed orders prior to billing Medicare, Medicaid or other third-party payer.

SUBJECT: TELEPHONE/VERBAL ORDERS	REFERENCE #8013
DEPARTMENT: HOME HEALTH	PAGE: 3 OF: 5
	EFFECTIVE:
APPROVED BY:	REVISED:

PROCEDURE:

- Telephone/verbal physician orders are accepted by licensed staff, in accordance with the _____ State scope of practice guidelines. All orders for medications shall include the following:
  - Date and time of the order
  - Medication name
  - Dosage
  - Route
  - Frequency
  - Name of prescriber
- All orders for treatment shall include the following:
  - Type of treatment
  - Specific requirements, i.e., wet to dry dressings
  - Frequency and duration of treatment
- Each telephone/verbal order shall be written down or entered into the computer and then read-back to the individual delivering the order, by an appropriately qualified HHA staff member receiving the order.
- The staff member shall document the following statement on the telephone/verbal order form: “Order written down and read-back to and verified with (full name of the individual providing the order)”, as well as the date and time the order was read-back.
- The telephone/verbal order is communicated to the Clinical Supervisor and appropriate members of the healthcare team.

- The staff member who accepts the order:
  - Reduces the order to writing
  - Ensures the appropriateness, accuracy and completeness of the order
  - Signs and dates the order
- The telephone/verbal order may initially be transcribed onto one of the following forms:
  - Referral sheet
  - Physician order/prescription form
  - Communication sheet
- A copy of the Physician Telephone/Verbal Orders Form is filed in the patient's medical record.
- The Medical Records Department maintains a log of and monitors outstanding, i.e., unsigned, physician orders.
- A report of the outstanding, i.e., unsigned, orders is submitted to the Patient Care Services Director on a monthly basis.
- The Patient Care Services Director notifies Clinical Supervisors of outstanding orders and requests follow-up with physicians.
- HHA staff may be assigned to visit physician offices to obtain the signed orders.

- If the physician is unwilling/unable to comply with the request for signed orders, the following actions may be instituted:

  - The Patient Care Services Director may contact the physician's office regarding order(s) outstanding more than___days.
  - The Administrator contacts physicians unwilling/unable to cooperate with HHA policy for timely signed orders.
  - The Medical Director may be asked to contact the physician to explain the necessity of the signed order and to request compliance with the request for signed order(s).
  - Another physician may be identified and requested to provide signed orders for the patient's care, treatment and/or services.
  - Read-back of telephone/verbal orders is tracked and trended as part of the HHA's Quality Assessment and Performance Improvement (QAPI) program, and aggregated results are reported monthly to the Patient Care Services Director/Management Committee, and quarterly to the Governing Body.
  - Root cause analysis is conducted on any identified variances, and a plan of correction is developed, implemented and evaluated.

PHYSICIAN TELEPHONE/VERBAL ORDERS

Patient Name:_____ MR #: _____

Physician Name: _____

Addition to/or Change of Previous Orders: _____

_____

_____

_____

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_____

_____ _____

Signature of Nurse/Therapist Date

_____ _____

Signature of Physician Confirming Orders Date

All orders must be signed by physician within_____days. *(Varies from state to state. Check with your state.)*

SUBJECT: MEDICATION ORDERS AND ADMINISTRATION	REFERENCE #8015
	PAGE: 1 OF: 6
DEPARTMENT: HOME HEALTH	EFFECTIVE:
APPROVED BY:	REVISED:

PURPOSE:

- To promote the integrity of medication management when patients are receiving care, treatment and/or services from the HHA.
- To ensure accurate, safe and effective administration of prescribed medications by qualified HHA staff.
- To adhere to applicable laws, regulations and standards of practice.

POLICY:

- The HHA adheres to Federal and State laws and regulations governing prescription medications.
- Acceptable Specific Medication Orders/Prescriptions:
  - All medication orders must contain all the elements of a complete and clear medication order
  - Standing Orders (i.e., anaphylaxis management):
    - Must be verified with and signed by the physician each time they are to be utilized
  - As Needed (PRN) Orders:
    - Must include the specific indications for use along with the maximum dose allowed within a specific time period
  - Range Orders/Titrating Orders:
    - Must include the indications for increases/decreases in dosage along with the maximum dose allowed within a specified time period. Any test results pertinent to the order, i.e., blood sugar test results, PT/PTT, INR results are to be included in the order.

- Taper Orders (i.e., prednisone therapy):
  - Must include the specific dosage to be administered at the appropriate time period.
- Resume Care Orders:
  - When a patient returns to the HHA following hospitalization, all medication orders must be written in detail. “Resume previous medications” is not an acceptable order.
- Transfer/Discharge Orders:
  - When a patient is transferred/discharged to another provider, medications prescribed and any OTC medications, including herbal remedies being administered at the time of transfer/discharge are to be documented with the name of the medication, dosage, and frequency of administration. This includes a patient discharge to self-care under the supervision of the physician.

- Licensed nurses, as permitted by state law and regulations, may accept orders for and administer patient medications.

- All medication orders, whether written by HHA staff or by the ordering physician, should be reviewed by the Case Manager/Clinical Supervisor to ensure that the orders are appropriate for the diagnosis/indication for use and/or symptoms; that the orders are complete, legible and clear. Correct and complete orders shall be initialed by the Case Manager/Clinical Supervisor.

- All prescribed and OTC medications, including herbal remedies, are to be documented on the patient's Medication Profile. Although OTC medications and herbal remedies that are self-administered by the patient do not require a physician’s order/prescription, the prescribing physician should be made aware of these medications. Physician notification should be documented in the patient’s medical record. HHA staff may not initiate the administration of OTC medications and/or herbal remedies without a physician order.

- All HHA nurses are qualified by education and experience to administer prescribed medications including controlled substances via the following routes: oral, rectal, sublingual, subcutaneous and intramuscular.

- Only nurses qualified by education and experience are permitted to administer medications via intravenous and/or intrathecal routes.

- All nurses are competency tested on medications during orientation and at least annually thereafter to ensure they are qualified. Competency evaluation includes a written test, along with demonstration of skills in either a simulated or clinical situation.

PROCEDURE:

- Medication orders include the following information:

  - Ordering physician's name, address and telephone number
  - Patient name
  - Medical record number
  - Diagnosis
  - Reason medication has been prescribed/indications for use
  - Medication name
  - Dose
  - Route
  - Frequency of administration
    - Route and frequency of administration should be documented in understandable language.

- Any medication orders written on the physician's prescription form are checked by the Case Manager/Clinical Supervisor as per the above mentioned policy.

- Any medication orders that are questionable, i.e., unclear, incomplete, illegible, whether written by HHA staff or by the physician, must be clarified with the physician, rewritten and submitted to the physician for verification and signature.

    - The rewritten medication order(s) shall contain documentation that the order was clarified with the physician, the date of clarification, and full signature and professional designation of the licensed nurse who obtained the clarification order.

        - The licensed nurse who obtains the clarification order must be the same nurse who documents the order.

- Medication order changes received by the HHA should be documented on the patient's medication record and in the visit note as applicable.

Note: All medication orders must be verified with the ordering physician and must contain the phrase "Orders read back and verified with_____", the date of verification and the signature of the nurse verifying the orders.

- The nurse discusses any unresolved, significant concerns about the medication with the prescribing physician, licensed independent practitioner and/or other HHA staff involved in the patient's care, treatment and/or services.

- Medications identified during the initial assessment visit and throughout the certification period are documented via the OASIS Data Set, as appropriate, on the initial and recertification plans of care, as well as in the clinical visit note and the Medication Administration Record (MAR).

- The patient's apical pulse is assessed for one full minute before the administration of cardiotonic glycosides, i.e., digoxin. If the pulse is less than 60 per minute or below the parameters established by the physician, the medication will be held and the physician contacted for orders.

- Prior to administering any medication, the nurse verifies the following information based on the medication order and product label:
  - Correct medication and strength
  - Correct dose
  - Correct time
  - Correct route
  - Correct frequency
  - Correct patient
    - To validate the identity of the patient, the nurse must use two (2) identifiers. These may be, but are not limited to, asking the patient or a responsible individual in the place of residence, the patient's name and his/her date of birth.
  - Correct reason
  - That the medication is stable, based on visual examination for particulates or discoloration, and that the medication has not expired
  - That there is no contraindication for administering the medication, based on current knowledge
  - Expiration date of the medication
  - For all compounded IV admixtures and parental nutrition solutions, the date prepared and the diluent, as well as directions for use, and any applicable cautionary statements either on the label or accompanying instructions, i.e., "requires refrigeration", "for IM use only"

- Each prefilled syringe, i.e., insulin, calcimar, prepared by the nurse to be administered by the patient/family, should be labeled with the following information:
  - Patient name and identification, i.e., medical record number, date of birth
  - Name of drug, strength and dosage
  - Expiration date
  - Date syringes prepared
  - Any cautionary information, i.e., “Keep refrigerated”, “Remove from refrigerator 15 minutes prior to administration”
  - Name/signature of the nurse preparing the syringes
- The nurse adheres to Standard Precautions when administering medications.
- The nurse adheres to applicable laws and regulations and uses safety materials and equipment when preparing hazardous medications, i.e., chemotherapy medications, in the patient’s place of residence.
- The nurse instructs the patient/family in an understandable format and language about any clinically significant adverse reaction, potential unanticipated outcomes or any other concerns about the medication to be administered, along with actions to be taken should any reaction or unanticipated outcomes occur when the nurse is not present.

DOCUMENTATION:

- Documentation of medication administration will include:
  - Date, time, name of medication, dose, route of administration
  - Patient response to the medication, including adverse reactions
  - Instructions provided to the patient/family and their response to/understanding of those instructions. Instructions should include the occurrence of any adverse reactions and/or unanticipated outcomes
  - Signature of nurse with appropriate professional designation

SUBJECT: PATIENT SELF-ADMINISTRATION OF MEDICATION	REFERENCE #8016
DEPARTMENT: HOME HEALTH	PAGE: 1 OF: 2
	EFFECTIVE:
APPROVED BY:	REVISED:

PURPOSE:

To promote correct administration of medication by patients and families.

POLICY:

The HHA shall encourage patient/family participation in care and shall explain the correct administration of medications ordered by the attending physician or purchased over the counter.

PROCEDURE:

- The HHA RN shall provide an opportunity for the patient to administer his/her own medications. The medications listed at the time of admission and recertification shall be considered part of the plan of care. The RN shall:
  - Instruct the patient about purpose and side effects of medications.
  - Instruct how to administer medications, i.e., process time, frequency, route of administration, dose.
  - Instruct how to monitor the effects of the medications on the patient.
  - Help the patient in setting up medications for the first time.
  - Assess patient's ability to self-administer medications correctly and to document usage before being allowed to administer medications.
  - Answer questions/concerns expressed by the patient/family regarding patient's self-administration of medications.
  - Document information given to the patient regarding the medication, date and time to give the medication, teaching of side effects and any pertinent observations made during the information session, such as patient's needs, outcome in the patient's plan of care, as appropriate.

- Complete the Medication Reconciliation/Verification Form at admission and recertification.
- Assess patient's use of over the counter (OTC) medications, document with start date.
- Instruct the patient/family regarding safe storage of medications and consider the following:
  - Store medications separately from other poisonous drugs and chemicals.
  - Remove medication from storage during instruction and administration times.
  - Medications are kept out of the reach of children, pets and confused or disoriented patients.

☐ Evaluate the patient's/family's competency in adhering to the medication regimen and the instructions provided. The evaluation may include, but is not limited to, the following:

- Counting the number of remaining units of the medication remaining to determine whether the correct frequency and dosage has been followed
- Having the patient/family repeat the instructions during a subsequent visit
- Having the patient/family demonstrate adherence to the instructions provided at a subsequent visit

☐ During the assessment process the RN plans with the patient/family for the safe therapeutic storage of drugs.

- Store drugs requiring refrigeration safely in the refrigerator and put in a container that will prevent children getting to the medication.
- Urine testing and other diagnostic materials are to be stored away from all medications, heat, light and moisture.

SUBJECT: INFLUENZA AND PNEUMOCOCCAL VACCINE STANDING ORDERS	REFERENCE #8017
	PAGE: 1 OF: 2
DEPARTMENT: HOME HEALTH	EFFECTIVE:
APPROVED BY:	REVISED:

POLICY:

- _____ HHA shall allow standing orders. Standing orders must meet specified criteria and must be approved by the medical staff. Standing orders are written documents containing medical directives for the provision of patient care in selected stipulated clinical situations.

- The administration of influenza and pneumococcal polysaccharide vaccines, per standing orders, is governed by the physician-approved policies and procedures of the HHA.

- The influenza and pneumococcal polysaccharide vaccine standing order must be:

  - Developed with input from the Medical Director or a physician
  - Be approved for use in this institution through the appropriate medical staff and nursing processes

PROCEDURE:

- The administration of the influenza and pneumococcal polysaccharide vaccine shall be conducted by a licensed healthcare professional trained to:

  - Screen patients for contraindications to vaccination
  - Administer the vaccines
  - Monitor for adverse events

- Prior to the administration of the influenza and/or pneumococcal polysaccharide vaccine, the licensed healthcare professional will:

- Assess the patient for appropriateness for receiving the influenza and/or pneumococcal polysaccharide vaccine

  - Assess the patient for contraindications to the vaccine, including:

    - Anaphylactic hypersensitivity to vaccine components

    - Acute febrile illnesses

  - Provide the patient/family with information regarding the risks for and benefits of the vaccine

- The influenza and/or pneumococcal polysaccharide vaccine shall be administered per this HHA's approved standing orders.

- Administration of the influenza and/or pneumococcal polysaccharide vaccine shall be documented in the patient's medical record.

  - Document in the patient's medical record that the patient/family received the CDC's Vaccine Information Statement (VIS) for the influenza vaccine and/or the pneumococcal polysaccharide vaccine

- In the event that a change in the order is deemed necessary for the well-being of the patient, the ordering physician shall be notified, and new orders shall be followed.

NOTE:

Check with state and local laws and regulations prior to implementation of influenza and pneumococcal polysaccharide vaccine standing orders

SUBJECT: MULTIPLE DOSE VIALS (MDVs) - USE OF	REFERENCE #8018
DEPARTMENT: ORGANIZATIONWIDE	PAGE: 1 OF: 4
	EFFECTIVE:
APPROVED BY:	REVISED:

NOTE:

Vaccines that are a part of the Centers for Disease Control and Prevention's and state immunization programs, which have separate requirements for when multiple dose vials must be discarded, are not subject to the dating expectation in this policy.

POLICY:

- Pharmacy Services shall verify that MDVs are stored and labeled correctly when inspecting medication storage areas in the Pharmacy and on patient care units/departments.

- Only vials clearly labeled by the manufacturer for multiple dose use can be used more than once.

- Limit the use of a multiple dose vial to only a single patient, whenever possible, to reduce the risk of contamination

  - Multiple use of preservative-free MDVs shall be avoided whenever possible.

- When multiple dose vials are used more than once, staff shall use a new needle and new syringe for each entry.

  - Do not leave needles or other objects in vial entry diaphragms between uses. This may contaminate the contents of the vial.

- The beyond-use date (BUD) for an opened or entered (i.e., needle-punctured) multiple dose container with antimicrobial preservatives shall be **28 days**, unless otherwise specified by the manufacturer.

- The healthcare provider shall write the expiration date on the vial, when it is opened.

  - This revised expiration date replaces the manufacturer's original expiration date **unless** the original expiration date occurs earlier than the 28-day date.

- For multiple dose vials, the expiration will occur **28 days** after the vial has been opened/ punctured, providing:
  - There is no obvious contamination.
  - Aseptic technique has been followed when withdrawing the medication.
  - The MDV is stored according to the manufacturer.
- Multiple dose vials shall be refrigerated after they are opened, unless contraindicated by the manufacturer.
- MDVs shall be discarded:
  - When empty
  - When suspected contamination occurs
  - When contamination/particulates are visible
  - When the beyond-use date has been reached or the manufacturer's established expiration date is reached, whichever is earlier, as long as the MDV has been stored according to manufacturer's instructions
- Opened single-dose ampuls shall not be stored for any period of time.
- Staff shall discard any vial if its sterility has been compromised or is in question, including those vials on a procedure tray or used during an emergency procedure, even if the vial is unopened/unused.
- The Infection Preventionist shall report clusters of infections or other adverse events to the appropriate local and state public health authorities.

  Note: While reporting of adverse events is usually voluntary, outbreak reporting is typically required by state public health departments.

PROCEDURE:

- The healthcare provider shall perform hand hygiene before handling the multiple dose vial.
- A new, sterile needle and syringe shall be used each time medication is drawn from the vial.
- The integrity of the stopper shall be checked and the medication in the vial checked for any particulate matter prior to use. If the integrity of the stopper or sterility of the medication is in question, discard the vial.
- The stopper or vial gum shall be swabbed with 70% alcohol before each puncture. Allow the stopper/vial gum to dry before inserting a needle or other device into the vial.
- Avoid touching the stopper of the MDV during this process.
- Once a multiple dose vial has been punctured, the staff member shall assign a "beyond-use" date to the vial and place this date on the vial's label.

ADDITIONAL TOOL:

1 Needle, 1 Syringe, Only 1 Time Campaign, http://www.oneandonlycampaign.org/content/audio-video

REFERENCES:

- The Joint Commission. (June 16, 2014). Preventing Infection From The Misuse of Vials. *Sentinel Event Alert*, Issue 52. Retrieved from http://www.jointcommission.org/assets/1/6/SEA_52.pdf and https://www.jointcommission.org/sea_issue_52/
- Centers for Disease Control and Prevention (CDC). (February 9, 2011). Injection Safety. *Frequently Asked Questions (FAQs) regarding Safe Practices for Medical Injections.* Retrieved from http://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html
- The Joint Commission. (March 2006). Errata: Multiple Dose Vials. *Joint Commission Perspectives on Patient Safety*.

- The Joint Commission Resources. (January 2006). Switching to Single-Dose Containers, Moving Away From Multiple Dose Vials. *Joint Commission Perspectives on Patient Safety*, Volume 6, Number 1, pages 10-11.

- USP General Chapter <797>. Pharmaceutical Compounding - Sterile Preparations.

SUBJECT: USE OF INVESTIGATIONAL TREATMENTS/TRIALS	REFERENCE #8019
DEPARTMENT: HOME HEALTH	PAGE: 1 OF: 1
	EFFECTIVE:
APPROVED BY:	REVISED:

POLICY:

- _____ HHA does not conduct drug investigational studies or allow HHA staff to administer investigational drugs/treatments.

- The HHA will accommodate the patient's participation in investigational drug treatments/trials as deemed appropriate.

- Investigational drugs are those drugs which have not yet been released by the Federal Food and Drug Administration (FDA) for general use. Therefore, they include drugs bearing the following cautionary labeling "CAUTION New Drug - Limited by Federal Law to Investigational Use."

PROCEDURE:

- In the event that a patient is accepted by the HHA and is currently enrolled in a clinical drug trial, or the attending physician determines that the patient may benefit from use of an investigational drug or treatment, the physician:

  - Must submit a request with supporting documentation and investigational protocol to the Executive Director and the HHA Governing Body for approval

  - Must be approved by the FDA to administer the investigational drug

  - Must have an Investigational Drug Informed Consent form signed by the patient and a copy placed in the medical record

  - Must provide a copy of the protocol being followed and information about the drug, including all relevant policies and procedures to_____HHA; a copy of this information is to be placed in the patient's medical record.

- The dispensing pharmacy, in conjunction with the Medical Director, shall develop all relevant policies and procedures for the handling, storing and distribution of any investigational drugs.

SUBJECT: FIRST DOSE HOME IV ANTIMICROBIAL ADMINISTRATION AND MANAGEMENT OF ANAPHYLAXIS	REFERENCE #8020
	PAGE: 1
DEPARTMENT: HOME HEALTH	OF: 7
	EFFECTIVE:
APPROVED BY:	REVISED:

DEFINITIONS:

- Adverse Reaction, often called side effect, is a predictable pharmacological effect that is either drug, non-drug or dose related.
- Allergic Reaction is a physiologic response to a specific antigen.
- Anaphylaxis is an acute, often fatal systemic reaction resulting from re-injection in a previously sensitized individual.

PURPOSE:

To assess and manage the administration of antimicrobial medications in the home in a safe and effective manner.

POLICY:

- The first dose of any IV medication must be administered under the supervision of a physician.
- Medications are administered by licensed staff only in accordance with State Scope of Practice.
- Where possible the first dose should be administered in the hospital prior to discharge to home health services.
- First dose of investigational drugs must be given under the direct supervision of the physician.
- Patients receiving drugs that have a high potential for causing anaphylaxis must not be given the first dose in the home, i.e., amphotericin B, chemotherapy agents.
- The Registered Nurse assigned to administer IV medications shall be qualified by education and experience and shall have been assessed as being competent by the HHA.

☐ All nurses supervising IV medication infusions in the home must be competent in anaphylaxis management, certified in CPR (preferably ACLS) and proficient in starting peripheral IVs.

☐ Adherence to all other existing candidate selection criteria for home antimicrobial therapy is essential and must include knowledge of patient's complete medical, drug and allergy history, as well as a family allergy history.

☐ If the patient has a history of allergy to the prescription drug, it must be changed to an appropriate alternate to minimize risk of anaphylaxis.

Note: Prior exposure may have sensitized the individual; subsequent doses can elicit an allergic response.

☐ A physician's plan of treatment must include an order which states, "first dose of _____ to be administered in the home", the dose, route, rate of administration, any pretreatment or preinfusion lab work, emergency protocol, specific parameters for adverse drug reaction, postinfusion monitoring and physician's location and phone number during initial infusion.

☐ An anaphylaxis kit must be readily available per a physician's order during the entire infusion. A kit will typically contain, but is not limited to:

- Adult:

1 - administration set
2 - 21 g butterfly
1 - 90 mm airway
2 - tongue blade (for airway insertion)
1 - diphenhydramine (Benadryl) 50 mg per mL IV, IM or PO
1 - 0.3 mg EpiPen-Injector
2 - epinephrine 1:1,000 (IM)
6 - prep pads
3 - pairs gloves
1 - D_5W 500 mL

- Pediatric:

1 - microdrip set	1 - 0.15 mg EpiPen Junior Injector
2 - 23 g butterfly	1 - epinephrine 1:2,000 (IM)
1 - 60 mm airway	6 - prep pads
2 - tongue blade (for airway insertion)	3 - pairs gloves
1 - diphenhydramine (Benadryl) 12.5-25 mg PO, 1.25 mg/kg IV or IM	1 - D_5W 500 mL

☐ The Registered Nurse remains with the patient for the duration of the infusion and for at least one-half (1/2) hour after the infusion is completed.

☐ Preinfusion Nursing Responsibilities:

- Prior to initiating the infusion, review with the patient his/her medical history, drug history and previous allergies. Document the types of allergy, the severity of previous symptoms and prior response to treatment. Any questionable allergies must be brought to the attention of the physician.
- Assess current medications for the potential of cross-reactions. Document and report pertinent findings to the physician.
- Obtain baseline vital signs (T, P, R, B/P) and continue to monitor every 15 minutes or as prescribed by the physician for the duration of the infusion.
- Draw any lab work that has been ordered.
- Check medication label with physician orders for:
  - Correct drug - be alert for sound-alike drugs
  - Correct dose and rate
  - Correct route

- Correct time
- Correct frequency
- Correct patient
- Correct reason

- Check all equipment (pumps, tubing, medication containers, access devices) to ensure all are in good working order and free of any defects.
- Check that IV solution is free of any particulate matter.
- Instruct patient/family in any potential adverse reactions that may occur during administration of the medication.
- Prepare equipment using standard precautions and aseptic technique.

□ During Infusion:

- Remain with the patient for the entire duration of the infusion and for at least one-half (1/2) hour after the completion of the infusion.
- Monitor and document the patient's vital signs every 15 minutes, as designated by clinical practice guidelines or as ordered by the physician.
- Monitor, assess and document the patient's response to the infusion.

□ Post Infusion:

- Discontinue the infusion and dispose of any used equipment in accordance with standard precautions.
- Draw post-infusion lab work as ordered.
- Instruct the patient/family in any precautions, potential side effects/adverse reactions and appropriate actions to be taken.

- Document:
  - Instructions and patient/family understanding of and response to instructions
  - Patient's condition
  - Condition of the infusion site
- Management of Anaphylaxis:
  - Anaphylaxis is an acute, often fatal systemic reaction that can occur in spite of all precautions taken. Since the reaction occurs quickly characterized by respiratory distress and vascular collapse, it is essential to institute treatment immediately.
  - The home health nurse must have the anaphylaxis protocol readily available for use in case of an emergency.
  - Medications are to be given in accordance with the physician's orders.
  - While specific treatment regimens will vary, essential common elements will include:
    - For localized or mild reaction - rash itching:
      - Stop the infusion immediately
      - Maintain the intravenous line
      - Administer Benadryl as directed
      - Monitor for vital signs
      - Notify physician

- For generalized or severe reaction - itching, tightness in the chest, chills, agitation, dizziness, nausea, abdominal cramping, respiratory distress, hypotension, edema, flushed appearance or generalized urticaria:
  - Stop the infusion immediately
  - Initiate CPR if necessary
  - Call EMS (911) and physician
  - Institute anaphylaxis protocol per physician's orders:
    - Administer Epinephrine
    - Administer Benadryl
    - Maintain intravenous infusion
    - Monitor vital signs every five (5) minutes
    - Keep patient supine
  - Remain with the patient until the paramedic arrives; initiate CPR if necessary
  - Document the incident, then notify the appropriate members of the healthcare team

NOTE:

ACHC requires that the nurse administering the first dose of a medication stay with the patient a minimum of one (1) hour following administration to monitor and ensure the patient appropriately tolerates the medication.

REFERENCES:

- Vallerand, April. (2017). *Davis's Drug Guide for Nurses, 15th Edition*. Philadelphia, Pennsylvania: F.A. Davis Company.

- Infusion Nurses Society (INS). (2016). *Policies and Procedures for Infusion Nursing*, Fifth Edition. Norwood, MA: Infusion Nurses Society.

SUBJECT: MEDICATION MONITORING	REFERENCE #8021
DEPARTMENT: HOME HEALTH	PAGE: 1 OF: 2
	EFFECTIVE:
APPROVED BY:	REVISED:

PURPOSE:

- To ensure that the medication therapy ordered is appropriate to meet the patient's clinical needs, thereby promoting achievement of positive patient outcomes.

- To minimize the occurrence of adverse events relative to medication administration either by_____HHA staff or by the patient/family.

POLICY:

- The patient's response to medications shall be monitored by the skilled nurse/therapist on a regular basis.

- The results of the monitoring process shall be communicated to the ordering physician, licensed independent practitioner and the HHA staff involved in the patient's care, treatment and/or services.

- The physician shall be immediately notified of any medication discrepancies, side effects, concerns, or reactions.

PROCEDURE:

- The skilled nurse/therapist monitors the patient's response to medications at least once a week, and more frequently if needed, based on the patient's clinical needs and/or response to care, treatment and/or services.

- The monitoring process includes at least the following elements:

  - Eliciting from the patient/family a determination of the effectiveness of the medication regimen and whether or not any side effects have occurred

  - Reviewing and evaluating laboratory results, if applicable

  - Reviewing and evaluating the medication profile

  - Objectively assessing the patient's clinical response to medications

- The skilled nurse/therapist shall immediately report to the patient's physician any medication discrepancies, side effects, concerns, or reactions.

- The findings, conclusions and recommendations of medication monitoring are communicated to the physician.

- The findings, conclusions and recommendations of medication monitoring are documented in the patient's medical record.

SUBJECT: CONTROLLED DRUG DISPOSAL	REFERENCE #8022
	PAGE: 1 OF: 1
DEPARTMENT: HOME HEALTH	EFFECTIVE:
APPROVED BY:	REVISED:

POLICY:

- When a patient no longer requires the controlled drug, the nurse will inform the family of the need to destroy the remaining medication.

- The nurse will dispose of the drug in the presence of another witness and according to state and local rules and regulation. Suggestions for disposal include:

  - Take the medications out of their original container and mix the medications with an undesirable substance, such as cat litter or coffee grounds
  - For any unused IV controlled drugs, take the bag and tubing back to the nursing station or HHA office and dispose of under the observance of another licensed professional, i.e., RN
  - Before throwing out a drug container, remove any personal identification information or refill information so as to prevent the illegal re-ordering of the medication or a privacy violation
  - Follow FDA guidelines for medication flushing

- In the event there are no state requirements, the Pharmacy and a Registered Nurse shall dispose of the controlled drugs and document the following:

  - Name of drug
  - Amount disposed
  - Name of the Pharmacist
  - Name of the RN
  - Date and time

- Documentation reflecting the name and amount of the drug, method of disposal and witnesses will become part of the medical record.

- Should the patient/family refuse to destroy the drug(s), the nurse will document this refusal in the medical record and notify the physician and Patient Care Services Director.

SUBJECT: DISPOSAL OF CONTROLLED SUBSTANCE PATCHES IN THE HOME	REFERENCE #8023
	PAGE: 1 OF: 2
DEPARTMENT: HOME HEALTH	EFFECTIVE:
APPROVED BY:	REVISED:

POLICY:

_____ HHA shall ensure that patients and family members are educated on proper disposal of controlled substances contained in topical patches, such as fentanyl. All controlled substance topical patches removed from the patient must be disposed of in a manner that reduces risk to others.

PROCEDURE:

- Patient and family members shall be educated on the proper disposal of controlled substance patches by_____.

- In addition to providing the patient with the manufacturer product label with instructions for use, the following information shall be conveyed to the patient and family members and documented in the medical record:

  - FDA recommends disposing of used patches by folding them in half so that the sticky sides meet, and then flushing them down a toilet. Patches should not be placed in the household trash where children or pets can find them.

  - The FDA has included fentanyl patches on a list of medicines that should be flushed down a toilet because they could be especially harmful, and possibly fatal, in a single dose if used by someone other than the person for whom the medicine was prescribed.

    Note: While the FDA recognizes that there are environmental concerns about flushing medicines down the toilet, at this time the FDA believes that the risk associated with accidental exposure to this strong narcotic medicine outweighs any potential risk associated with disposal by flushing. When the patches are no longer needed, disposing by flushing completely eliminates the risk of harm to people in the home.

- Patients shall also be advised of the risk of medication exposure to children in the event a patient's partially detached patch transfers onto the skin of a child.

ADDITIONAL TOOL:

Food and Drug Administration (FDA). (April 2016). Disposal of Unused Medicines: What You Should Know. *Medications Recommended for Disposal by Flushing*. Retrieved from https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm

REFERENCES:

- Food and Drug Administration (FDA). (November 1, 2016). *FDA Reminds the Public about the Potential for Life-Threatening Harm from Accidental Exposure to Fentanyl Transdermal Systems ("Patches")*. Retrieved from http://www.fda.gov/Drugs/DrugSafety/ucm300747.htm

- Food and Drug Administration (FDA). (November 1, 2016). *Fentanyl Patch Can Be Deadly to Children*. Retrieved from http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm

SUBJECT: DECREASING MEDICATION ERRORS	REFERENCE #8024
DEPARTMENT: HOME HEALTH	PAGE: 1 OF: 4
	EFFECTIVE:
APPROVED BY:	REVISED:

POLICY:

- _____ HHA has instituted a “Medication Safety Awareness Program” and takes a proactive approach by focusing Quality Assessment and Performance Improvement (QAPI) activities on medication use.

- The HHA maintains a current knowledge base of, and implements best practices based on current knowledge to maintain safety of the HHA’s medication management system.

    - Medication errors can occur at any step of the process, i.e., prescribing, ordering, dispensing, administering or monitoring the effects of medications.

- The HHA has developed standardized practices for documenting medication orders and for administering medications to patients receiving care, treatment and/or services from the HHA.

- The Institute for Safe Medical Practices has identified some common sources of medication errors:

    - Patient information, i.e., lab values, allergies, unavailable prior to dispensing or administering a medication

    - Unavailable medication information from written sources

    - Miscommunication of medication orders, i.e., similar names, misuse of zeros, inappropriate abbreviations, poor handwriting

    - Labeling and/or packaging problems

    - Medication device use and monitoring, i.e., lack of standardization in medication delivery devices, unsafe equipment

    - Environmental stressors, i.e., distractions, noise during transcription or dispensing

    - Limited staff education (on problem prone drugs)

    - Limited patient/family education

- The Institute of Safe Medical Practices has also determined that a majority of medication errors resulting in death or serious injury were caused by "high alert medications".
    - Antiretroviral agents
    - Insulin
    - Chemotherapeutic agents
    - Opiates and narcotics
    - Pediatric liquid measurements that require measurement
    - Injectable potassium chloride (or phosphate) concentrate
    - Intravenous heparin
    - Sodium chloride solutions above 0.9%
    - Antithrombotic agents

PROCEDURE:

- The HHA shall adopt the following procedures to decrease the incidence of medication orders:
    - Medication orders shall be documented in accordance with HHA policy.
    - Medication orders must include the name of the medication, dosage, frequency and route of administration.
    - All drug orders will include a brief notation of purpose unless considered a breach of confidentiality by the prescriber (medications for certain disease states).
    - All drug orders must be written in the metric system. Units must be spelled out.
    - Medication orders must include the name of the drug, dosage amount and form.
    - All verbal orders received (orally or via telephone) will include the read-back verification process by the individual receiving the order.

- A leading zero (0) must always precede a decimal point for a dose less than one (1); a trailing zero (0) is never to be used after a decimal.
- The use of abbreviations is to be avoided, both for drug names (i.e., MOM) and for Latin directions for use (i.e., QD, SC).
- The patient is identified using two (2) patient identifiers before the administration of all medications.
- The right drug, right patient, right dose, right time, right route, right reason are evaluated prior to administration of the medication.
- Any questionable medication orders received in the HHA must be clarified with the prescribing physician/licensed independent practitioner prior to medication administration.
- All medication orders shall be reviewed for accuracy and completeness by the Clinical Supervisor/Case Manager.
- Medication errors shall be reported, tracked and trended via the QAPI process of the HHA.
- The Patient Care Services Director and Pharmacy Consultant shall review and evaluate literature, i.e., intermediary alerts, journal articles, regularly for new technologies or successful practices that have been demonstrated to enhance safety in other organizations. These practices are incorporated into the HHA's medication management system as appropriate.

- All HHA staff, including contracted staff, involved in the HHA's medication management system receive education about the risks of medication errors and strategies to reduce such errors during orientation and at least annually thereafter, or more often if necessary.

- Appropriate HHA staff are tested for competency in medication administration, monitoring and documentation during the probationary period, and at least annually thereafter, or more often if necessary.

REFERENCES:

- Institute for Safety Medication Practices (ISMP). (2015). ISMP Safe Practice Guidelines for Adult IV Push Medications: A compilation of safe practices from the ISMP Adult IV Push Medication Safety Summit. Retrieved from http://www.ismp.org/Tools/guidelines/ivsummitpush/ivpushmedguidelines.pdf

- Institute for Safe Medication Practices (ISMP). (n.d.). ISMP High-Alert Medications. Retrieved from http://www.ismp.org/tools/highalertmedicationLists.asp

SUBJECT: MEDICATION ERRORS	REFERENCE #8025
DEPARTMENT: HOME HEALTH	PAGE: 1 OF: 3
	EFFECTIVE:
APPROVED BY:	REVISED:

PURPOSE:

To standardize the process for reporting medication errors.

DEFINITIONS:

- A Medication Error is any preventable event that may cause or lead to inappropriate medication use or patient harm.

- Significant Medication Errors are those which require medical intervention and/or result in possible or confirmed morbidity or mortality.

  - Level 0 No error occurred, potential error (near miss)
  - Level 1 Error occurred without harm to patient
  - Level 2 Error occurred, increase monitoring but no change in vital signs or any patient harm
  - Level 3 Error resulted in need for increased monitoring, there was change in vital signs but no ultimate patient harm; any error needing increased laboratory monitoring
  - Level 4 Error resulted in need for treatment with another drug, increased length of stay, patient transfer to a higher level of care (i.e., ICU) or required intervention to prevent permanent impairment of damage
  - Level 5 Error resulted in permanent patient harm
  - Level 6 Error resulted in patient death

- Types of medication errors include:

  - Wrong: drug, dose, route, time, reason, documentation
  - Omission (not administered before next schedule dose due)
  - Unordered dose

SUBJECT: MEDICATION ERRORS	REFERENCE #8025
DEPARTMENT: HOME HEALTH	PAGE: 2 OF: 3
	EFFECTIVE:
APPROVED BY:	REVISED:

POLICY:

- _____ HHA shall have a process to respond to actual or potential medication errors. All actual or potential errors identified shall be documented through the HHA's risk management system. All significant medication error reports shall be reviewed by_____.

- The Medication Use Task Force (MUTF) shall review all medication error data as part of the HHA's improvement process.

- All adverse medication events requiring notification through external state, federal, USP or FDA channels, shall be reported according to the requirements of the specific organization.

PROCEDURE:

- When a medication error occurs the following shall occur in this order:

  - Evaluate the patient and notify the attending physician and HHA.
  - Perform any necessary clinical interventions, within the patient care provider's scope of practice to reduce the negative effects of the identified error.
  - Record the medication as given in the medical record.
  - Record the observed and assessed outcome of the patient in the medical record.
  - Record notification of physician in the medical record with any resultant orders.
  - Record any actions and clinical interventions taken and the patient's response to same.
  - Report the error in detail on a medication inadvertent incident report.

- The practitioner who identifies an error shall document all relevant particulars on the incident report form.

- All medication error reports shall be reviewed by the MUTF and categorized according to severity, type, cause and drug class involved.

SUBJECT: MEDICATION ERRORS	REFERENCE #8025
DEPARTMENT: HOME HEALTH	PAGE: 3 OF: 3
	EFFECTIVE:
APPROVED BY:	REVISED:

- All medication error reports evaluated as significant (Level 4 or above) shall be referred to _____.

- Summary data and trend analysis shall be performed by MUTF. Reports of actions taken and appropriate follow-up shall be made by MUTF to Administration.

- Actual or potential medication errors shall be tracked and trended as part of the Quality Assessment and Performance Improvement (QAPI) activities of the HHA. Summary reports of findings, conclusions, actions taken and recommendations for improvement shall be generated by the QAPI Committee. Summary reports shall be submitted to the Governing Body.

MEDICATION INCIDENT REPORT
CONFIDENTIAL - QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT

❑ Actual Incident ❑ Potential for Incident

Patient Name:_____MR#: __ WHERE incident occurred:____

_____Who DISCOVERED incident? _____ DATE when occurred:

_____TIME:_____Staff involved with incident _ DATE when discovered:

_____TIME: _____ _____

Name of MEDICATION INVOLVED: _____

Cause of Incident	Type of Incident

❑ Dose Omitted
❑ Incorrect Patient
❑ Incorrect Time
  ❑ Administered Early
  ❑ Administered Late
❑ Incorrect Dosage
  ❑ Overdosage
  ❑ Underdosage
❑ Incorrect Route
❑ Incorrect Medication
  ❑ Ordered by: _____
  ❑ Given by: _____
❑ Delay in Administration
  ❑ Drug Unavailable
  ❑ Other: _____
	❑ Nursing
	❑ Pharmacy
	❑ Documentation
	❑ Physician Order
	❑ Other:_____
	Please explain details of incident:

Name of Physician Notified:_____Date and Time Notified: _____

Notified by Whom:_____Adverse Reaction: _____

Signature of Supervisor:_____Severity of Incident: _____

Follow-up by Department Manager:

Recommendations to prevent future situations of this nature:

QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT ANALYSIS
MEDICATION INCIDENT

Current policy requires that this form be completely filled out and returned to the Performance Improvement Director at the end of the shift on the date that the medication incident was identified. This form is necessary to determine the possible causes leading to the medication incident, thus preventing future errors:

Responsible Party's Name:_____ Date of Incident: _____

Patient Name:_____ MR#: _____

Brief Description of Incident: (Including type of medication and time incident committed):

_____

_____

Why Was Medication/Treatment Ordered for the Patient?

_____

_____

Possible Untoward Effects of the Incident for the Patient:

_____

_____

Medication Incident Was Felt to be Due to:

- ❑ Unavailable patient information prior to dispensing or administering drug (lab values, allergies, etc.)
- ❑ Unavailable drug information (written resources)
- ❑ Miscommunication of drug orders (similar names, inappropriate abbreviations, illegible handwriting, etc.)
- ❑ Problems with labeling, packaging
- ❑ Drug standardization, storage (look-alike containers, etc.)
- ❑ Drug device use and monitoring (equipment malfunction, etc.)
- ❑ Environmental stress (distractions, noise during transcription or dispensing, extended shifts, etc.)
- ❑ Staff knowledge regarding medication
- ❑ Other: _____

Suggestions for Future Prevention of this Type of Incident:

_____

_____

_____

PERFORMANCE IMPROVEMENT USE ONLY

Date forwarded to the Risk Manager: _____

Risk Manager Recommendations:

_____

_____

_____

SUBJECT: ADVERSE DRUG REACTION REPORTING	REFERENCE #8028
DEPARTMENT: HOME HEALTH	PAGE: 1 OF: 9
	EFFECTIVE:
APPROVED BY:	REVISED:

PURPOSE:

- To promote patient safety through a standardized process for managing and reporting actual or potential adverse drug reactions and medication sentinel events.
- To educate _____ HHA staff, including contracted staff, about adverse drug reactions.
- To respond appropriately to actual or potential adverse drug reactions.
- To identify, track and measure trends and institute corrective actions designed to improve patient outcomes by minimizing the potential for adverse drug reactions.

DEFINITIONS:

- According to the FDA, an adverse event is any undesirable experience associated with the use of a medical product in a patient. The event is serious and shall be reported when the patient outcome is:
  - Death: Report if the patient's death is suspected as being a direct outcome of the adverse event.
  - Life Threatening: Report if the patient was at substantial risk of dying at the time of the adverse event, or it is suspected that the use or continued use of the product would result in the patient's death.
  - Disability: A significant, persistent or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life.
  - Hospitalization: Requires inpatient hospitalization or a prolonged hospitalization.
  - Congenital Anomaly: Report if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child.

- Requires Intervention to Prevent Permanent Impairment or Damage: Report if it is suspected that the use of a medical product may result in a condition which required medical or surgical intervention to preclude permanent impairment or damage to a patient.
- The American Society of Health-System Pharmacists (ASHP) defines an adverse drug reaction (ADR) as any unexpected, unintended, undesired or excessive response to a drug that:
  - Requires discontinuing the drug (therapeutic or diagnostic)
  - Requires changing the drug therapy
  - Requires modifying the dose (except for minor dosage adjustments)
  - Necessitates admission to a hospital
  - Prolongs stay in a healthcare facility
  - Necessitates supportive treatment
  - Significantly complicates diagnosis
  - Negatively affects prognosis
  - Results in temporary or permanent harm, disability or death

☐ High Risk Drugs that are Associated with Adverse Drug Events include:

- Aminoglycosides
- Amphotericin
- Antineoplastics
- Corticosteroids
- Digoxin
- Heparin
- Lidocaine
- Phenytoin
- Theophylline
- Thrombolytic agents
- Warfarin
- Other

- Trigger Alert List:

- Antihistamines
- Atropine
- Benzotropine
- Blood Transfusions
- Calcium chloride
- Calcium gluconate
- Dantrolene
- Dextrose 50% in water
- Diazepam
- Digoxin immune fab (Digibind)
- Dimethyl Sulfoxide (DMSO)
- Diphenhydramine
- Epinephrine
- Flumazenil
- Fosphenytoin
- Glucagon
- Hyluronidase
- Lorazepam
- Naloxone
- Nitroglycerin
- Phenobarbital
- Phentolamine
- Phenytoin
- Physotigmine
- Phytonadione
- Protamine
- Sodium polystyrene sulfonate (Kayexelate)
- Steroids (injectable)
- Steroids (topical)

SUBJECT: ADVERSE DRUG REACTION REPORTING	REFERENCE #8028
DEPARTMENT: HOME HEALTH	PAGE: 4 OF: 9
	EFFECTIVE:
APPROVED BY:	REVISED:

POLICY:

- Adverse drug reactions shall be documented and reported in compliance with applicable laws and regulations.

- _____ HHA shall document any potential or actual adverse medication reactions, review the reports and institute a plan of correction/action plan in response to the reports.

- Potential or actual adverse reactions to medications may be identified through:

  - HHA incident reports
  - Patient/family reports
  - Concurrent or retrospective medical record audits

- As part of the HHA's overall Medication Management Program, all significant adverse drug reactions (ADRs) shall be reviewed by_____.

- ADR monitoring and reporting shall be a component of the HHA's Quality Assessment and Performance Improvement (QAPI) Program. Components of ADR monitoring and reporting includes:

  - Feedback and education to all appropriate clinical staff
  - Continuous monitoring for trends, clusters or significant individual ADRs
  - Education of programs for the prevention of ADRs
  - Evaluation of prescribing patterns
  - Evaluation of patient monitoring practices
  - Evaluation of the ADR monitoring and reporting procedure's effect on overall and individual patient outcomes

- Assessment of the safety of drug therapies, especially new drugs
- Educating healthcare professionals and patients on drug effects and increase their level of awareness regarding adverse drug reaction
- Identifying and measuring trends and institute corrective actions designed to improve patient outcomes by minimizing potential adverse drug reaction
- Providing quality assurance/improvement screening findings for use in drug use evaluation programs

- The HHA's ADR monitoring and reporting process shall include a concurrent surveillance system:
  - Based on the reporting of suspected adverse drug reaction by pharmacists, physicians, nurses or patients.
  - For drugs or patients with a high risk for adverse drug reaction.
  - Monitoring the use of "tracer" drugs that are used to treat common adverse drug reaction (i.e., orders for immediate doses of antihistamine, epinephrine and corticosteroids).

- The prescriber shall be contacted immediately in the event of a potential adverse drug reaction which is identified concurrently.

- Patients and families, as appropriate, shall be informed about suspected adverse drug reactions.

- All concurrently reported potential adverse drug reaction reports shall be investigated by _____. Concurrent reports of potential adverse drug reaction can be submitted by telephone (adverse drug reaction hotline) or in writing (Potential Adverse Reaction Form or Quality/Risk/Security Report).

- A description of each suspected adverse drug reaction and outcomes shall be documented in the patient's medical record.

  - In addition to documenting the ADR in the patient's medical record, the ISMP suggests that physicians should communicate ADRs in a standardized fashion, such as writing the ADR on an order form. This communicates the information to nurses and pharmacists, which allows for entry in the appropriate fields in the computer system and in other nursing and pharmacy records. The ISMP suggests that this documentation aids in the timely discontinuation of the drug that is suspected of causing the ADR.

- An adverse drug reaction can also be identified retrospectively by medical record abstraction.

- The Pharmacist shall assign a severity rating to each adverse drug reaction report according to the following scale:

  - Non-adverse drug reaction: An event unrelated to drug therapy.

  - Minor: An adverse drug reaction which requires no medical treatment or has no effect on continuation of therapy.

  - Significant: An adverse drug reaction which results in hospital admission, increases length of hospital stay, requires medical treatment or requires discontinuation of therapy.

  - Severe: An adverse drug reaction which is life-threatening or causes permanent injury or death.

- Adverse drug reaction reports shall be further analyzed by:

  - Method of reporting (spontaneous or retroactive medical record abstraction)

  - Type of adverse drug reaction (dose related or non-dose related)

  - Time of occurrence (before admission or during hospitalization)

REPORTING:

- _____ shall produce periodic adverse drug reaction summary reports. The focus shall be on identifying risk factors, trends in reporting and educational needs of the organization. Emphasis shall be placed on concurrent reporting which can influence patient care and result in documentation in the medical record, rather than retrospective reporting. The results of adverse drug reaction analysis may be of use in drug use evaluation programs and other quality assurance/improvement efforts. Drugs which are frequently encountered in adverse drug reaction analysis may be targeted for more intense evaluation or education.

- Adverse medication reaction summary reports shall be presented to the QAPI Committee and Governing Body.

- ADR report information shall be disseminated to clinical staff for educational purposes.

- If_____determines that the findings may be relevant to an individual's performance, corrective actions appropriate to the severity of the findings will be instituted by the Clinical Supervisor.

- Serious or unexpected adverse drug reaction shall be reported to the Food and Drug Administration (FDA). The FDA Form 3500 should be used by healthcare professionals and consumers for voluntary reporting of adverse events noted spontaneously in the course of clinical care, not events that occur during clinical trials under an Investigational New Drug (IND) application. Those mandatory reports are to be submitted to the FDA as specified in the investigational new drug/biologic regulations or investigational device exemptions. For instructions on mandatory reporting, go to http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm

PROCEDURE:

- In the event of a possible or actual adverse reaction to a medication while in the patient's place of residence, the Registered Nurse is to:
  - Notify the physician immediately for orders.
  - Implement the anaphylaxis protocol, if ordered.
  - Activate the Emergency Medical System (911) if necessary. Initiate first aid measures to provide for an open airway.
  - Administer CPR if required.
  - Complete the Incident Report and forward it to the Risk Manager/Patient Care Services Director.
  - Document in the patient's medical record:
    - A description of the type of reaction
    - Patient's vital signs
    - Time of physician notification and order
    - Interventions implemented
    - Patient's response to the interventions

REFERENCES:

- U.S. Food and Drug Administration (FDA). (February 1, 2016). *What Is A Serious Adverse Event?* Retrieved from http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm

- Schatz, Stephanie N. & Weber, Robert J. (2015). Adverse Drug Reactions. CNS/Pharmacy Practice - PSAP 2015. Retrieved from https://www.accp.com/docs/bookstore/psap/2015B2.SampleChapter.pdf

- Institute for Safe Medication Practices (ISMP). (September 6, 2000). Adverse Drug Reactions: Documentation is Important But Communication is Critical. *Acute Care ISMP Medication SafetyAlert!* Retrieved from http://www.ismp.org/newsletters/acutecare/articles/20000906.asp

- Institute for Safe Medication Practices (ISMP). (September 6, 2000). ISMP Trigger Alert List. *Acute Care ISMP Medication SafetyAlert!* Retrieved from http://www.ismp.org/newsletters/acutecare/articles/20000906_3.asp

- American Society of Hospital Pharmacy. (February 1, 1995). ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting. *Medication Misadventures*. Retrieved from https://www.ashp.org/Pharmacy-Practice/Policy-Positions-and-Guidelines/Browse-by-Topic/Medication-Misadventures

- U.S. Food and Drug Administration (FDA). (n.d.). MedWatch Online Voluntary Reporting Form. Retrieved from https://www.accessdata.fda.gov/scripts/medwatch/

ADVERSE DRUG REACTION REPORTING FORM (INTERNAL)

REPORT ANY REACTION OR INCIDENCE THAT MAY BE A DETRIMENTAL RESPONSE TO A MEDICATION WHICH IS UNDESIRED, UNINTENDED OR UNEXPECTED IN DOSES ACCEPTED IN MEDICAL PRACTICE.

Patient Name:_____ MR#: _____

Date of Reaction:_____ Known Allergies/Sensitivities: _____

Suspected Drug (manufacturer, strength, dose, frequency, route): _____

Start Date:_____ Concurrent Drugs: _____

Describe Reactions: _____

Circle all that apply:

GI	SKIN	CV	CNS	LABS	OTHER
Nausea	Rash	Hypertension	Headache	LFTs	Short of Breath
Vomiting	Itching	Hypotension	Confusion	Scr/BUN	Wheezing
Diarrhea	Flushing	Chest Pain	Anxiety	Neutropenia	Fever
Constipation	Swelling	Arrhythmias	Sedation	Anemia	Chills
GI Upset	Phlebitis	Bradycardia	Depression	Electrolyte	Seizures
GI Pain	Erythema	Tachycardia	Malaise		Shock

Was the Physician Notified: ❑ Yes ❑ No

Treatment of reaction: (Circle or list drugs prescribed or actions taken.)

Discontinued drug	Epinephrine	Kayexalate	Benztropine	Vancomycin PO
Decrease dose	Hydroxyzine	Naloxone	Physostigmine	Other: _____
Obtain drug level	Insulin	Phytonadione	Blood Products	_____
Diphenhydramine	Digibind	Protamine	Romazicon	_____
Dextrose	Glucagon	Meclizine	Steroids	_____

OUTCOMES ATTRIBUTED TO ADVERSE EVENT (Check all that apply)

❑ Death ❑ Life-threatening ❑ Hospitalization (initial or prolonged) ❑ Disability or permanent damage

❑ Congenital anomaly/birth defect ❑ Required intervention to prevent permanent impairment/damage (devices)

❑ Necessitates supportive treatment ❑ Negatively affects prognosis ❑ Significantly complicates diagnosis

❑ Other serious (important medical events) _____

Confirmed Diagnosis of the Event/Disease: _____

Patient Medical History: _____

Patient's Baseline Status: _____

PREVENTABILITY ASSESSMENT

1. Was the drug involved in the ADR inappropriate for the patient's clinical condition?
2. Were the dose, route and frequency of administration appropriate for the patient's age, weight, organ function and disease state?
3. If the reaction was due to a drug allergy, was this allergy previously documented?
   ❑ Admitting orders ❑ Pharmacy computer ❑ Patient's Medical Record
4. Were appropriate therapeutic drug monitoring or other laboratory tests performed, which may have predicted this reaction? (include toxic serum levels)
5. Reaction involved a drug-drug, drug-food or drug-lab interaction.

SEVERITY ASSESSMENT

1. An ADR occurred but required no change in treatment with the suspected drug.
2. The ADR required that treatment with the suspected drug be held, discontinued or otherwise changed. No antidote or other treatment required. No increase in length of stay.
3. The ADR required that treatment with the suspected drug be held, discontinued or otherwise changed **AND/OR** an antidote or other treatment was required.
4. Serious ADR, but drug's benefits outweigh the adverse effects; drug is continued.
5. The ADR was the reason for admission.
6. ADR treatment required intensive medical care. Increase length of stay.
7. The ADR caused permanent harm to the patient.
8. The ADR directly or indirectly led to the death of the patient.

This information will remain confidential. Upon completion of the form, return to the_____ Department.

Completed by:_____ Date: _____

SUBJECT: MEDICATION MANAGEMENT PROGRAM	REFERENCE #8030
DEPARTMENT: HOME HEALTH	PAGE: 1 OF: 6
	EFFECTIVE:
APPROVED BY:	REVISED:

PURPOSE:

- To support patient safety and to improve the quality of care, treatment and services provided by_____HHA.

- To improve the performance of medication management processes, thereby continuously improving patient health outcomes and reducing the occurrence of medication-related errors and medication-related adverse patient outcomes, including adverse drug reactions.

POLICY:

- The Quality Assessment and Performance Improvement (QAPI) Committee, acting on behalf of the HHA and its Governing Body, shall implement a Medication Management Assessment and Evaluation Program to provide a system to ensure medication use within the organization is conducted in a safe and optimal manner.

- The Medication Management Assessment and Evaluation program shall require the routine evaluation of literature for new technologies and best practices that have been demonstrated to enhance safety in other organizations to determine if these practices are conducted successfully within the organization or if they should be implemented to improve the medication management system.

- The Medication Management Assessment and Evaluation Program shall identify risk points (including medication errors and adverse drug reactions) and identify areas to improve patient safety as well as the overall use of medications throughout the organization.

- For the purposes of this program the definition of medication shall include:

  - Prescription medications
  - Sample medications
  - Herbal remedies
  - Vitamins
  - Nutraceuticals (substances not controlled by the FDA, not proven beneficial by authoritative sources, however, the public commonly utilizes, i.e., Ingestible Shark Cartilage

- Over-the-counter medications
- Vaccines
- Radioactive medications
- Respiratory therapy treatments
- Parenteral nutrition
- Blood derivatives
- Intravenous solutions (plain, with electrolytes and/or other drugs)
- Any product designated by the FDA as a drug

☐ The QAPI Committee shall maintain oversight for the Medication Management Assessment and Evaluation Program. The program shall be based on the principles of quality assessment and performance improvement, with a focus on identification and measurement of processes and activities that are high-volume, high-risk, problem-prone and patient safety related. The program shall include data collection and measurement of medication management processes, identification of opportunities or areas of improvements, the testing of incremental improvements and the recommendation of improvements to the organization's leaders.

☐ The following essential processes shall be conducted to adequately assess and evaluate how medication is managed throughout the organization.

- Process Design
- Performance Measurement
- Performance Assessment
- Performance Improvement

- The Quality Assessment and Performance Improvement (QAPI) Director/Risk Manager shall be responsible for reporting medication management processes to the QAPI Committee, whose members in turn are responsible for assessing, monitoring and evaluating the processes and outcomes of the medication management throughout the organization.

PROCEDURE:

- The QAPI Committee shall collaborate with other designated members of the organization, to develop, implement and evaluate the organizationwide Medication Management Assessment and Evaluation Program. As appropriate to the setting, individuals involved in the system of medication management shall include licensed independent practitioners, healthcare professionals and staff involved in medication management processes.

- Assessment and Evaluation Process:

  - The following core medication management processes carried out by the organization shall be measured, assessed and evaluated:
    - Selection and procurement
    - Storage
    - Ordering and transcribing
    - Preparing and dispensing
    - Administration, including new technologies
    - Documentation in the CPOE and EHR systems
    - Monitoring the effects and side effects on patients
  - Over time, data shall be collected on all of the above processes.

- To adequately monitor and evaluate the medication management system in place within the organization the QAPI Director/Risk Manager shall collect data on the following:
    - Processes and outcomes
    - Medication errors (real and potential)
    - Adverse drug reactions
    - High-risk, high-volume and problem-prone processes
    - Patients needs, expectations and department specific patient satisfaction questionnaires and/or surveys
    - Infection prevention and control activities
    - Patient safety reports
    - Current literature for new technologies and best practices
    - Risk management issues and findings

- Performance Measures:

  - Administration of medication is of high-risk and therapeutic benefit to the patient. Medication management processes shall be measured on an ongoing basis. The following shall be performance measures or categories of measures for which data is collected, aggregated, reviewed and analyzed in an effort to identify risk points and areas to improve patient safety. The list is not exhaustive and may be revised in accordance with data collected, which may indicate the benefit of inclusion or exclusion of a performance measure from the monitoring and evaluation cycle. Measures shall include, but may not be limited to:

    - Medication errors - wrong drug, dosage, time, route or rate of administration, wrong patient, omission, duplication or administration without an order, adverse reaction to medication (includes potential errors or "near misses")
    - Medication order filled incorrectly
    - Medication order prepared incorrectly
    - Occurrences that have an adverse result on a patient
    - Equipment breakage/failure that has an adverse result on a patient
    - Equipment not available
    - Expired, recalled or otherwise unusable drug dispensed
    - Labeling of drugs
    - Education of patients and family
    - Drug recall measures
    - Infection prevention and control
    - Research investigational drugs

- Management of Human Resources (i.e., licensure requirements and entry level qualifications)
- Patient outcomes; long and short range continuing education
- Technical quality control activities
- Adverse drug reactions

☐ The organization shall systematically improve the performance of its medication management system. The QAPI Committee shall assess and evaluate data provided and shall determine and implement strategies to improve performance. The QAPI Committee shall implement actions that result in desired, measurable changes in processes. To achieve improvements and improve patient safety, the Committee shall participate in the following quality assessment and performance improvement activities:

- Planning
- Implementing
- Assessing the effectiveness of implemented actions and redesigning if necessary
- Reevaluation as deemed necessary to assure gains made are sustained

ANNUAL REVIEW:

☐ The Medication Management Assessment and Evaluation Program shall be assessed and measured annually for its effectiveness and consistency within the improving organization performance framework. If the identified improvements are not realized within a defined time period, the organization shall reexamine the process within the function that is being monitored. The QAPI Committee shall submit its findings, conclusions, recommendations and actions to the following:

- Governing Body
- Administration and the HHA Management Team

MEDICATION COMPOUNDING

- Effective January 1, 2018, The Joint Commission has released a Medication Compounding Chapter applicable to home care organizations.

- Contained within is the Medication Compounding Services policy and procedure.

- Please see MCN Healthcare's Compounded Sterile Preparation - USP 797 Compliance Manual for additional policies and procedures not contained within this manual.

SUBJECT: MEDICATION COMPOUNDING SERVICES	REFERENCE #8102
DEPARTMENT: HOME HEALTH	PAGE: 1 OF: 12
	EFFECTIVE:
APPROVED BY:	REVISED:

SCOPE OF SERVICES:

_____ (organization name's) medication compounding services shall ensure safe medication compounding practices in accordance with the highest quality standards for nonsterile, sterile and hazardous medication compounding preparation and distribution to the patient population served.

OBJECTIVE:

The objective of the organization's medication compounding services shall include safe provision of compounded medications in accordance with State laws and regulations, including State Board of Pharmacy requirements, accrediting agency standards and quality standards set by USP chapters <795>, <797>, <800> and other USP Chapters, as applicable, to the compounding of medications.

DEFINITION:

Compounding - The practice of combining, mixing, or altering ingredients of a drug to create a medication tailored to the needs of an individual patient. Compounding is generally performed by a licensed Pharmacist, a licensed Physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed Pharmacist (FDA).

RESPONSIBILITY:

- Leadership Responsibilities:
  - The Home Health Agency's (HHA's) Administration, in collaboration with the pharmacy's Pharmacy Director, shall be responsible for ensuring the safety and quality of medication compounding services provided to patients under its care.
  - The Pharmacy Director, in collaboration with the HHA's Administrator, Patient Care Services Director and Medical Director, shall develop and approve medication compounding policies and procedures.
  - The Pharmacy Director shall participate in the HHA's Quality Assessment and Performance Improvement (QAPI) and Quality Control activities.

- The Pharmacy Director shall be responsible, at minimum, for ensuring the following:
  - Safe medication preparation
  - Accurate medication strength
  - Precise medication labeling
  - Integrity of compounded medication
  - Sterility of all compounded medication
- The Pharmacy Director shall be responsible for establishing and implementing quality assurance policies and procedures to meet current requirements of USP chapters <795>, <797>, <800> and other USP Chapters, as applicable, as well as applicable State laws and regulations, including State Board of Pharmacy requirements.
- At minimum, the Pharmacy Director shall establish policies and procedures that provide for the following:
  - Aseptic technique
  - Beyond-use dating (BUDs)
  - Individual facility requirements
  - Environmental monitoring
  - Equipment maintenance and cleaning
  - Compounding ingredients' identity, quality and purity
  - Labeling
  - Packaging
  - Quality assurance/control

- Selection, handling and storage of all components used for sterile and nonsterile compounding
- Standard operating procedures (SOPs)
- Sterility and sterilization techniques
- Staff training and competency assessment
- All other USP requirements

- Staff Responsibilities:

  - Staff shall follow all procedures, as established by the Pharmacy Director, related to the following (not all inclusive):
    - Medication order/prescription adherence
    - Compounded preparation strength, quality and purity
    - Following applicable State agencies and Board of Pharmacy laws and regulations pertaining to:
      - Packaging
      - Labeling
      - Dispensing
  - Compounding staff shall be responsible for completing appropriate ongoing training and education, competency assessment(s) and performance evaluation(s).

STAFF ORIENTATION, EDUCATION, COMPETENCY, AND EVALUATION:

- Staff shall attend orientation upon hire, and ongoing inservice training shall be provided as needed.

- The Pharmacy Director shall be responsible for establishing pharmacy-specific procedures for initial and ongoing training and education for all compounding staff.

- Staff education, at minimum, shall include the following:

  - State Board of Pharmacy laws, regulations, and requirements
  - USP Chapters <795>, <797> and <800>
  - Safety Data Sheets (SDSs) (i.e., accessing, retrieving, reviewing information)
  - Safe handling, storage and disposal of hazardous medications
  - Aseptic techniques, including aseptic manipulation skills
  - Compounding equipment
  - Compounding environment
  - Safe Labeling
  - Storage
  - Dispensing
  - Minimizing occupational exposure to hazardous medications
  - OSHA regulations

- All education and training activities shall be documented and maintained by the Pharmacy Director.

- Staff Competency:
  - Staff must demonstrate competency in compounding procedures prior to independently performing such procedures.
  - The Pharmacy Director shall be responsible for developing specific staff competency assessments per risk level for sterile and nonsterile compounding.
  - Staff competency assessments must be performed in accordance with applicable USP chapters <795>, <797>, <800> and other UPS chapters as applicable, as well as applicable State Board of Pharmacy laws and regulations.
  - The Pharmacy Director or his/her designee shall observe staff performing compounding procedures and inspect final preparations to ensure appropriate techniques.
  - The Pharmacy Director or his/her designee shall sign appropriate initial competency documentation confirming the staff member has achieved the required knowledge and competency to satisfactorily complete each skill.
  - Ongoing staff competency shall be monitored and assessed every _____and as needed.
  - Documentation of the staff member's completed competency assessment shall be maintained in the staff member's personnel file located in_____.
- See Sterile Compounding - Staff Competency policy and procedure in MCN Healthcare's Compounded Sterile Preparation - USP <797> Compliance Manual for additional policies and procedures.

- Staff Performance Evaluation:
  - The Pharmacy Director or his/her designee shall maintain a list of all staff performing medication compounding to facilitate ongoing staff performance monitoring and evaluation.
  - The Pharmacy Director or his/her designee shall complete individual staff member's performance evaluations per appropriate timeframes.
    - Staff performing nonsterile preparation compounding shall be evaluated at least once every 12 months and as needed.
    - Staff performing high-risk sterile compounding shall be evaluated at least once every six (6) months and as needed.
    - Staff performing low- and medium-risk sterile compounding shall be evaluated at least once every 12 months and as needed.
  - Compounding staff shall be evaluated in accordance with:
    - USP requirements
    - Current and evidence-based literature
    - Practical skills, including aseptic manipulation
  - Staff involved in cleaning and disinfecting procedures, such as cleaning and disinfecting the clean room, buffer area, and anteroom, shall demonstrate competency in the following procedures, at minimum:
    - Hand hygiene
    - Garbing
    - Cleaning and disinfecting procedures in compliance with USP chapter <797>
  - Competency of cleaning and disinfection shall be assessed, at minimum, upon hire, with change in job responsibility and with cleaning/disinfection procedural changes.
  - Performance evaluations shall be documented in the patient's personnel record.

COMPOUNDING ENVIRONMENT:

- Compounding shall only be performed in a dedicated space within the Pharmacy equipped for compounding medications.

- Work practices and the compounding environment shall be maintained in accordance with applicable USP standards and State Board of Pharmacy laws and regulations.

- The Pharmacy Director shall be responsible for developing and implementing policies and procedures to ensure quality assurance practices and environmental quality control in accordance with applicable USP chapters, and local laws and regulations, including the State Board of Pharmacy requirements.

- The following work practices and environmental control procedures, at minimum, shall be followed (not all inclusive):

  - Food, gum and drinks are strictly prohibited in the compounding area.
  - Personal cell phones are prohibited.
  - Wearing or removing outerwear (i.e., hats and sweaters) is prohibited in restricted areas.
  - Makeup and nail polish are prohibited.
  - Any jewelry that may interfere with the efficacy of personal protective equipment (PPE) is prohibited.
  - Staff shall be prohibited from coming to work with infectious conditions such as upper respiratory infections, rashes and conjunctivitis.
  - Frequently used supplies must be readily available, decontaminated and stored in the ante-area.
  - Paper-related items (i.e., paper syringe overwraps, work records) shall not be allowed in the buffer area until they are wiped with the appropriate disinfecting agent.

- Nonessential supplies shall be prohibited in the compounding area.
- Nonessential supplies that shed particles (i.e., pencils, cardboard, paper towels, cotton items, gauze pads) shall be strictly prohibited in the buffer area.
- Containers and closures for compounded preparations shall be compatible with physical and chemical properties of the preparation, per applicable USP requirements.
- Supplies shall be maintained in a manner within the compounding area so as to provide maximum workflow efficiency and decrease clutter.
- Traffic into and out of the compounding area shall be controlled and minimized.
- Hand hygiene, including hand scrub and forearm cleansing, shall be performed appropriately, per organizational policy and procedure.
- Garb and personal protective equipment (PPE) shall be used appropriately, per organizational policy and procedure.
- Cleaning and disinfection of the compounding area shall meet all requirements of USP chapter <797>.

 Compounding equipment:

- Equipment and supplies used for compounding shall be selected based on correct type and size to safely prepare compounded medications with accuracy and integrity.
- Equipment shall be located and stored in a manner that facilitates use, maintenance, and cleaning while protected from contamination.
- Specific facility standard operating procedures (SOPs), as developed by the Pharmacy Director, shall be followed for all compounding equipment and related supplies.
- Performance of equipment maintenance shall be documented and readily available.

PROCEDURES RELATED TO COMPOUNDING PRACTICES:

- Compounded sterile preparations (CSPs) for immediate use (i.e., low risk-level CSPs) shall not be batch-compounded or stored for future use.
    - Hazardous medications (i.e., antineoplastics) shall never be prepared as immediate use CSPs.
- High risk-level CSPs shall be sterilized by filtration, steam, dry heat or other techniques as permitted in applicable USP chapters.
- The accuracy and sterility of CSPs shall be verified in accordance with USP chapter <797> as well as applicable State Board of Pharmacy requirements and State laws.
- Use of single-dose and multiple-dose containers shall follow safety practices outlined in USP chapter <797>.
- Nonsterile compounding procedures shall be performed in accordance with USP chapter <795> and all applicable State laws, regulations and State Board of Pharmacy requirements.
- Should the Pharmacy administer radiopharmaceuticals, the Pharmacy Director shall ensure policies and procedures for compounding, handling, storing, dispensing and transporting radiopharmaceuticals meet appropriate requirements of USP chapters <797> and <823>.
- Pharmacy staff shall assign beyond-use dates (BUDs) to sterile and nonsterile preparations, per organizational policy and procedure.
- Prior to dispensing compounded preparations Pharmacy staff shall:
    - Check each procedure at each stage of the compounding process at least two (2) times.
    - Document any deviation(s) from procedure as required by Pharmacy policy, the master formulation record, or the compounding record.

- The Pharmacy Director shall inspect final preparations for appearance.
- The Pharmacy Director shall review each procedure in the compounding process, investigate any discrepancies, and correct any action prior to dispensing the compounded preparation to the patient.

PATIENT/CAREGIVER EDUCATION:

- Patients and their caregivers, as appropriate, shall receive education and training for safe storage, handling and administration of compounded sterile preparations (CSPs) in the home setting.

- Competent staff (i.e., Registered Nurses) providing patient education within their scope of practice shall provide training to the patient and his/her caregiver, as appropriate, including:
  - Hands-on demonstration
  - Return demonstration with the devices and equipment needed to administer the CSP
  - Return demonstration of aseptic and injection technique, as appropriate

- Patients and/or their caregivers, as appropriate, shall be required to demonstrate skills and competencies, as defined by the organization, for self-administration of CSPs prior to receiving compounded preparations in the home without the immediate supervision of health care staff.

- Patient/caregiver education shall include, at minimum, the following:
  - Pertinent diagnosis
  - Goals of medication therapy
  - Side effects of medication
  - How to inspect and handle the compounded preparation, supplies, and equipment
  - Storage requirements, including refrigerator or freezer requirements

- Complications
- Signs of infection
- When to contact emergency services, the patient's physician or the Home Health Agency/Pharmacy
- Safe disposal of compounded preparation(s) and related supplies
- Cleaning practices

- The patient and/or patient's caregiver shall be reassessed for ongoing CSP competency as needed.
- Validation of patient/caregiver competency and any education provided shall be documented in the patient's medical record.
- See Patient/Caregiver Education policy and procedure and Patient/Caregiver CSP Competence Assessment Form in MCN Healthcare's Compounded Sterile Preparation - USP 797 Compliance Manual.

DOCUMENTATION:

- ☐ Compounding documentation shall meet all applicable laws and regulations, State Board of Pharmacy requirements and USP standards.
- ☐ Compounding documentation records shall be retained for_____, per applicable State laws and regulations.

QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT (QAPI):

- The organization shall monitor and evaluate medication compounding services in accordance with its Quality Assessment and Performance Improvement (QAPI) Plan. (See the Performance Improvement Plan for Compounded Sterile Preparations policy and procedure in MCN Healthcare's Compounded Sterile Preparation - USP <797> Compliance Manual).

- The Pharmacy Director shall be responsible for establishing and implementing a Quality Assessment and Performance Improvement (QAPI) Plan for compounding procedures, as well as a QAPI Plan for the entire department. The Plan shall integrate the organization's Quality Assessment and Performance Improvement (QAPI) and Quality Control activities into a system that will foster improvement in patient care. The Pharmacy Director also shall delegate responsibilities for monitoring, action, evaluation and reporting.

- The Pharmacy Director shall report all Pharmacy Quality Assessment and Performance Improvement activities to the Home Health Agency's QAPI Committee for their review and recommendations. The agencywide QAPI Committee shall in turn report their evaluations to the Medical Director and Pharmacist for further review.

NOTE:

See MCN Healthcare's Compounded Sterile Preparation - USP <797> Compliance Manual for additional policies and procedures.