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PURPOSE

The purpose of this course is to review some of the requirements / regulations and policies within the Home Health Care setting, to educate and reinforce the knowledge of nurses; ARNP, RN, LPN and CNA/ HHA who are working in the Home health care environment, as well as other individuals who would like to work within the Home Health care setting. This course is great for nurses interested in RN Case management or supervisory position. Review of Home Health care services that are usually provided by home Health care agencies /organizations, case management and nursing supervision in home health. Review of Policies regarding acceptance of patients, admission and coordination of patient services. Review of the requirements for the plan of care and the Outcome and Assessment Information Set (OASIS), the Comprehensive assessments. Review of the guideline for proper documentation and legal aspects. The course also reviews the clinical record review requirements, the Physician Face to Face encounter, the CNA /HHA role with assisting with the activities of daily living, assistance with self-administration of medication, the requirements for the comprehensive emergency management plan (CEMP), the Background screening requirements, the importance of the drug review, medication management, monitoring for side / adverse effects of some commonly used medications and the home bound status definition in the home health care setting.

OBJECTIVE

After successful completion of this course the students will be able to:

1. Describe Home Health care services that are usually provided by home Health care Agencies /organizations
2. Discuss Policy regarding Acceptance of patients
3. Discuss admission and coordination of patient services
4. Describe the requirements for the plan of care
5. Discuss the Outcome and Assessment Information Set (OASIS)
6. Describe the Comprehensive assessments
7. Discuss the guideline for proper documentation and legal aspects
8. Describe clinical record review requirements
9. Discuss the Physician Face to Face encounter
10. Describe the CNA /HHA role with assisting with the activities of daily living
11. Define Assistance with self-administration of medication
12. Discuss the requirements for the comprehensive emergency management plan (CEMP)
13. Describe the Background screening requirements
14. Discuss the importance of the medication/drug review
15. Discuss case management and nursing supervision in home health
16. Define home bound status

INTRODUCTION

HOME HEALTH CARE

There has been an increase in the number of patients who require continuing professional medical services when they return home. Professional home health care services include a variety of care and support services for patients;

- Who are disabled,
- who are recovering from a hospital stay,
- who are chronically ill and
- who are terminally ill.

These patients need medical, nursing, social, or therapeutic treatment and assistance with their day to day activities of daily living.

Home health care services are usually provided by home Health care agencies /organizations.

There are many home health care organizations, such as:

- Medicare certified home health care agencies,
- Medicare and Medicaid certified home health care agencies,
- Hospices,
- Homemaker agencies,
- Staffing and private duty nursing agencies.

There are also many other companies that the home health care organizations may use to deliver specialized services and products including but not limited to:

- Medical equipment (DME) and supplies,
- pharmaceuticals, and
- Drug infusion / IV therapy.

Home health care agencies provide care for patients of all ages, from infants to the elderly population. Often times they offer comprehensive services ranging from maternal-child health programs to hospice care.

These services may include, but are not limited to the following:

- Skilled nursing
- Rehabilitation therapies: physical therapy, occupational therapy & speech-language
- Medical social services
- counseling
- Case management
- Home health aide services

Home health care agencies may also offer specialized care such as:

- Infusion therapy
- Hospice and palliative care
- Parental and enteral nutritional therapy
- Home safety instructions
- Telemedicine
- Vaccination
- Behavioral and mental health counseling
- Educational advice
- Wound care
- Home medical equipment
- Pain management

PHYSICIAN'S ORDER

The physician may order home health care services for:

- Patients who return home from the hospital, skilled nursing facility. Nursing home or return home after surgery, and they need care, assistance and /or supervision.
- Older adults who have health problems, but want to stay at home and maintain their independence with the support of a license nurse (RN, LPN, ARNP) and a Certified Nursing Assistant (CNA), Home Health Aid (HHA) or/caregiver.
- Patient who has complex treatments and requires medication monitoring and /or the use of medical equipment.
- Mothers and their newborn baby, home from the hospital who are in need of further support, education and clinical assessment skills of a licensed professional nurse.
- Adults with mentally illness who need support to remain in their community
- Young adults who are recovering from accidents and /or injuries, who are in need of further support, education and clinical assessment skills of a licensed professional nurse and /or assistance of a CNA/HHA.
- And individuals with chronic diseases and disabilities, such as heart failure, diabetes, kidney disease, or Alzheimer's who need careful monitoring but do not want or need to enter a nursing home or skilled care facility.

SOME POLICIES WITHIN THE HOME HEALTH ENVIRONMENT A-Z

ACCEPTING PATIENTS

Patients are accepted for treatment within a home health care agency on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence.

Care follows a written plan of care established and periodically reviewed by a physician of medicine, osteopathy, or podiatric medicine.

When the Agency receives a verbal or written physician's order, patient eligibility will be verified and authorization for service/s will be obtained.

ACCEPTANCE OF PATIENTS

When the agency accepts a patient or client for service, there shall be a reasonable expectation that the services can be provided safely to the patient or client in his place of residence. This includes being able to communicate with the patient, or with another person designated by the patient, either through a staff person or interpreter that speaks the same language, or through technology that translates so that the services can be provided.

The responsibility of the agency is also to assure that the patient or client receives services as defined in a specific plan of care, for those patients receiving care under a physician, physician assistant, or advanced registered nurse practitioner's treatment orders, or in a written agreement.

This responsibility includes assuring the patient receives all assigned visits.

At the start of services the agency has to establish a written agreement between the agency and the patient or client or the patient's or client's legal representative, including the information described in Section 400.487(1), F.S.

The written agreement must be signed and dated by a representative of the home health agency and the patient or client or the patient's or client's legal representative. A copy of the agreement must be given to the patient or client and the original must be placed in the patient's or client's file.

The written agreement shall serve as the home health agency's service provision plan, pursuant to Section 400.491(2), F.S., for clients who receive homemaker and companion services or home health aide services which do not require a physician, physician assistant, or advanced registered nurse practitioner's treatment order. The written agreement for these clients shall be maintained for one year after termination of services.

TERMINATING SERVICES WHEN PATIENT STILL NEED HOME HEALTH CARE

When the agency terminates services for a patient or client needing continuing home health care, as determined by the patient's physician, physician assistant, or advanced registered nurse practitioner, for patients receiving care under a physician, physician assistant, or advanced registered nurse practitioner's treatment order, or as determined by the client or caregiver, for clients receiving care without a physician, physician assistant, or advanced registered nurse practitioner's treatment order, a plan must be developed and a referral made by home health agency staff to another home health agency or service provider prior to termination.

The patient or client must be notified in writing of the date of termination, the reason for termination, and the plan for continued services by the agency or service provider to which the patient or client has been referred.

This requirement does not apply to patients paying through personal funds or private insurance who default on their contract through non-payment. The agency will need to provide social work assistance to patients to help them determine their eligibility for assistance from government funded programs if their private funds have been depleted or will be depleted.

Admission /Coordination of Patient Services

All personnel who are providing services need to maintain liaison to ensure that their efforts are coordinated effectively and support the objectives outlined in the plan of care.

The clinical record or minutes of case conferences establish that effective interchange, reporting, and coordination of patient care does occur and a written summary report for each patient is sent to the attending physician at least every 60 days.

ASSISTANCE WITH ACTIVITIES OF DAILY LIVING (ADL)

Assistance with activities of daily living means a certified nursing assistant (CNA) or a home health aide (HHA) provide to the patient individual assistance with activities of daily living, including the following:

AMBULATION

Providing physical support to enable the patient to move about within or outside of the patient's place of residence. Physical support includes holding the patient's hand, elbow, under the arm, or holding on to a support belt worn by the patient to assist in providing stability or direction while the patient ambulates.

BATHING

Helping the patient in and out of the bathtub or shower being available while the patient is bathing. Can also include washing and drying the patient.

DRESSING

Helping patients, who require assistance in dressing themselves, put on and remove clothing.

EATING

Helping with feeding patients who require assistance in feeding themselves.

PERSONAL HYGIENE

Helping the patient with shaving. Assisting with oral, hair, skin and nail care.

TOILETING

Reminding the patient about using the toilet, assisting him to the bathroom, helping to undress, positioning on the commode, and helping with related personal hygiene, including assistance with changing of an adult brief. Also includes assisting with positioning the patient on the bedpan, and helping with related personal hygiene.

ASSISTANCE WITH PHYSICAL TRANSFER

Providing verbal and physical cueing, physical assistance, or both while the patient moves from one position to another, for example between the following: a bed, chair,

wheelchair, commode, bathtub or shower, or a standing position. Transfer can also include use of a mechanical lift, if a home health aide is trained in its use.

Assistance with self-administered medication, as defined in subsection 59A-8.0095(5), F.A.C. (refers to the unlicensed assistive personnel)

Assistance with self-administration of medication includes:

- Taking the medication from where it is stored and bringing it to the patient. Make sure the medication container has the label that can be read; if unable to read, you cannot assist with the medication and you must notify your supervisor,
- While you are in the presence of the patient, read the label and make sure that the information is accurate for example, the right patient and other vital information we will discuss later in this course. Open the container for the patient, remove the prescribed amount of medication from the container, and then close the container,
- Place the oral dose that is prescribed, in the patient's hand or in another container and help the patient by lifting the container to his or her mouth,
- Application of topical medications,
- Returning the medication container to proper storage and
- Keeping a record of when a patient receives assistance with self-administration.

See the Florida Statues below:

Legal Standards

The Florida State Statute (Chapter 465.003) states that administration means the obtaining and giving of a single dose of medicinal drugs by a legally authorized person to a patient for her or his consumption." (Florida State Statute, 2014).

Florida State Statute (Chapter 400.488) lists what assisting with the self-administration of medicines is and the laws about it when the person is cared for in their own home.

400.488 Assistance with self-administration of medication

Terminology:

(a) Informed consent means advising the patient, or the patient's surrogate, guardian, or attorney in fact, that the patient may be receiving assistance with self-administration of medication from an unlicensed person.

(b) Unlicensed person means an individual not currently licensed to practice nursing or medicine who is employed by or under contract to a home health agency and who has received training with respect to assisting with the self-administration of medication as provided by agency rule.

(2) Patients who are capable of self-administering their own medications without assistance shall be encouraged and allowed to do so. However, an unlicensed person may, consistent with a dispensed prescription's label or the package directions of an over-the-counter medication, assist a patient whose condition is medically stable with the self-administration of routine, regularly scheduled medications that are intended to be self-administered. Assistance with self-medication by an unlicensed person may occur only upon a documented request by, and the written informed consent of, a patient or the patient's surrogate, guardian, or attorney. For purposes of this section, self-administered medications include both legend and over-the-counter oral dosage forms, topical dosage forms, and topical ophthalmic, otic, and nasal dosage forms, including solutions, suspensions, sprays, and inhalers.

(3) Assistance with self-administration of medication includes:

(a) Taking the medication, in its previously dispensed, properly labeled container, from where it is stored and bringing it to the patient.

(b) In the presence of the patient, reading the label, opening the container, removing a prescribed amount of medication from the container, and closing the container.

(c) Placing an oral dosage in the patient's hand or placing the dosage in another container and helping the patient by lifting the container to his or her mouth.

(d) Applying topical medications.

(e) Returning the medication container to proper storage.

(f) Keeping a record of when a patient receives assistance with self-administration under this section.

(4) Assistance with self-administration **does not** include:

(a) Mixing, compounding, converting, or calculating medication doses, except for measuring a prescribed amount of liquid medication or breaking a scored tablet or crushing a tablet as prescribed.

(b) The preparation of syringes for injection or the administration of medications by any injectable route.

(c) Administration of medications through intermittent positive pressure breathing machines or a nebulizer.

(d) Administration of medications by way of a tube inserted in a cavity of the body.

(e) Administration of parenteral preparations.

(f) Irrigations or debriding agents used in the treatment of a skin condition.

(g) Rectal, urethral, or vaginal preparations.

(h) Medications ordered by the physician or health care professional with prescriptive authority to be given “as needed,” unless the order is written with specific parameters that preclude independent judgment on the part of the unlicensed person, and at the request of a competent patient.

(i) Medications for which the time of administration, the amount, the strength of dosage, the method of administration, or the reason for administration requires judgment or discretion on the part of the unlicensed person.

(5) Assistance with the self-administration of medication by an unlicensed person as described in this section does not constitute administration as defined in s. 465.003.

(6) The agency may by rule establish procedures and interpret terms as necessary to administer this section.

ADVANCE DIRECTIVES

The agency has to provide each adult patient, in advance of receiving services, with a copy of “Health Care Advance Directives – The Patients’ Right to Decide”, as prepared by the Agency for Health Care Administration.

Providing each adult patient, in advance of receiving services, with written information concerning the home health agency’s policies respecting advance directives; and the requirement that documentation of whether or not the patient has executed an advance directive shall be contained in the patient’s medical record and not kept solely at another location in the agency.

If an advanced directive has been executed, a copy of that document shall be made a part of the patient’s medical record.

If the agency does not receive a copy of the advanced directive for a patient, the agency will document that it has requested a copy in the patient’s record.

Pursuant to Section 400.487(7), F.S., the agency may honor a DNRO as follows:

Cardiopulmonary resuscitation may be withheld or withdrawn from a patient only if a valid Do Not Resuscitate Order (DNRO) is present, executed pursuant to Section 401.45, F.S.

Home health personnel and agencies shall not be subject to criminal prosecution or civil liability, nor be considered to have engaged in negligent or unprofessional conduct for withholding or withdrawing cardiopulmonary resuscitation pursuant to such a Do Not Resuscitate Order (DNRO) and rules adopted by the agency, pursuant to Section 400.487(7), F.S.

Any licensed professional home health agency personnel, who, in good faith, obeys the directives of an existing DNRO, executed pursuant to Section 401.45, F.S., will not be subject to prosecution or civil liability for his/her performance regarding patient care.

BACKGROUND SCREENING:

408.809 Background screening; prohibited offenses

(1) Level 2 background screening pursuant to chapter 435 must be conducted through the agency on each of the following persons, who are considered employees for the purposes of conducting screening under chapter 435:

(a) The licensee, if an individual.

(b) The administrator or a similarly titled person who is responsible for the day-to-day operation of the provider.

(c) The financial officer or similarly titled individual who is responsible for the financial operation of the licensee or provider.

(d) Any person who is a controlling interest if the agency has reason to believe that such person has been convicted of any offense prohibited by s. 435.04. For each controlling interest who has been convicted of any such offense, the licensee shall submit to the agency a description and explanation of the conviction at the time of license application.

(e) Any person, as required by authorizing statutes, seeking employment with a licensee or provider who is expected to, or whose responsibilities may require him or her to, provide personal care or services directly to clients or have access to client

funds, personal property, or living areas; and any person, as required by authorizing statutes, contracting with a licensee or provider whose responsibilities require him or her to provide personal care or personal services directly to clients. Evidence of contractor screening may be retained by the contractor's employer or the licensee.

(2) Every 5 years following his or her licensure, employment, or entry into a contract in a capacity that under subsection (1) would require level 2 background screening under chapter 435, each such person must submit to level 2 background rescreening as a condition of retaining such license or continuing in such employment or contractual status.

In addition to the offenses listed in s. 435.04, all persons required to undergo background screening pursuant to this part or authorizing statutes must not have an arrest awaiting final disposition for, must not have been found guilty of, regardless of adjudication, or entered a plea of nolo contendere or guilty to, and must not have been adjudicated delinquent and the record not have been sealed or expunged for any of the following offenses or any similar offense of another jurisdiction: (follow the links for more details):

(a) Any authorizing statutes, if the offense was a felony.

(b) This chapter, if the offense was a felony.

(c) Section 409.920, relating to Medicaid provider fraud.

(d) Section 409.9201, relating to Medicaid fraud.

(e) Section 741.28, relating to domestic violence.

(f) Section 777.04, relating to attempts, solicitation, and conspiracy to commit an offense listed in this subsection.

(g) Section 817.034, relating to fraudulent acts through mail, wire, radio, electromagnetic, photoelectronic, or photooptical systems.

(h) Section 817.234, relating to false and fraudulent insurance claims.

(i) Section 817.481, relating to obtaining goods by using a false or expired credit card or other credit device, if the offense was a felony.

(j) Section 817.50, relating to fraudulently obtaining goods or services from a health care provider.

(k) Section 817.505, relating to patient brokering.

(l) Section 817.568, relating to criminal use of personal identification information.

(m) Section 817.60, relating to obtaining a credit card through fraudulent means.

(n) Section 817.61, relating to fraudulent use of credit cards, if the offense was a felony.

(o) Section 831.01, relating to forgery.

(p) Section 831.02, relating to uttering forged instruments.

(q) Section 831.07, relating to forging bank bills, checks, drafts, or promissory notes.

(r) Section 831.09, relating to uttering forged bank bills, checks, drafts, or promissory notes.

(s) Section 831.30, relating to fraud in obtaining medicinal drugs.

(t) Section 831.31, relating to the sale, manufacture, delivery, or possession with the intent to sell, manufacture, or deliver any counterfeit controlled substance, if the offense was a felony.

(u) Section 895.03, relating to racketeering and collection of unlawful debts.

(v) Section 896.101, relating to the Florida Money Laundering Act.

CLINICAL RECORD REVIEW

At least quarterly, the appropriate health professionals, representing at least the scope of the program, needs to review a sample of both active and closed clinical records to determine whether established policies are followed in furnishing services directly or under arrangement.

There is a continuing review of clinical records for each 60-day period that a patient receives home health services to determine adequacy of the plan of care and appropriateness of continuation of care.

Quarterly reviews need not be performed at a joint, sit-down meeting of the professionals performing the review. Each professional may review the records separately, at different times.

The Agency will evaluate all services provided for consistency with professional practice standards for Home Health Agency's and the HHA's policies and procedures, compliance with the plan of care, the appropriateness, adequacy, and effectiveness of the services offered, and evaluations of anticipated patient outcomes. Evaluations should be based on specific record review criteria that are consistent with the home health Agency (HHA) admission policies and other HHA specific patient care policies and procedures.

CLINICAL RECORDS

A clinical record needs to be maintained for each patient receiving nursing or therapy services that includes all the services provided directly by the employees of the home health agency and those provided by contracted individuals or agencies.

No information may be disclosed from the patient's file without the written consent of the patient or the patient's guardian. All information received by any employee, contractor, or Agency For Health Care Administration (AHCA) employee regarding a patient of the home health agency is confidential and exempt from Chapter 119, F.S.

If the patient transfers to another home health agency, a copy of his record must be transferred at his request.

All clinical records must be retained by the home health agency as required in Section 400.491, F.S. Retained records can be stored as hard paper copy, microfilm, computer disks or tapes and must be retrievable for use during unannounced surveys.

Clinical records must contain the following:

Source of referral;

Physician, physician assistant, or advanced registered nurse practitioner's verbal orders initiated by the physician, physician assistant, or advanced registered nurse practitioner prior to start of care and signed by the physician, physician assistant, or advanced registered nurse practitioner as required in Section 400.487(2), F.S.

Assessment of the patient's needs;

Statement of patient or caregiver problems;

Statement of patient's and caregiver's ability to provide interim services;

Identification sheet for the patient with name, address, telephone number, date of birth, sex, agency case number, caregiver, next of kin or guardian;

Plan of care or service provision plan and all subsequent updates and changes;

Clinical and service notes, signed and dated by the staff member providing the service which shall include:

1. Initial assessments and progress notes with changes in the patient's condition;
2. Services rendered;
3. Observations;
4. Instructions to the patient and caregiver or guardian, including administration of and adverse reactions to medications;

(i) Home visits to patients for supervision of staff providing services;
(j) Reports of case conferences;
(k) Reports to physicians, physician assistants, or advanced registered nurse practitioners;

(l) Termination summary including the date of first and last visit, the reason for termination of service, an evaluation of established goals at time of termination, the condition of the patient on discharge and the disposition of the patient.

(6) The following applies to signatures in the clinical record:

(a) Facsimile Signatures - The plan of care or written order may be transmitted by facsimile machine. The home health agency is not required to have the original signature on file. However, the home health agency is responsible for obtaining original signatures if an issue surfaces that would require certification of an original signature.

(b) Alternative Signatures

1. Home health agencies that maintain patient records by computer rather than hard copy may use electronic signatures. However, all such entries must be appropriately authenticated and dated. Authentication must include signatures, written initials, or computer secure entry by a unique identifier of a primary author who has reviewed and approved the entry. The home health agency must have safeguards to prevent unauthorized access to the records and a process for reconstruction of the records in the event of a system breakdown.

2. Home health agencies may accept a physician's rubber stamp signature. The individual whose signature the stamp represents must place in the administrative offices

of the home health agency a signed statement attesting that he/she is the only one who has the stamp and uses it.

Condition of Participation Regarding Clinical Records

A clinical record containing pertinent past and current findings in accordance with accepted professional standards is maintained for every patient receiving home health services.

In addition to the plan of care, the record contains appropriate identifying information; name of physician; drug, dietary, treatment, and activity orders; signed and dated clinical and progress notes; copies of summary reports sent to the attending physician; and a discharge summary.

DOCUMENTATION

Some of the purposes of documentation include:

- Fulfilling professional responsibility and establishing accountability
- Legal standards
- Compliance with standard of practice
- Communication among the health care team and providing education to staff
- To provide continuity of care
- Providing information for research
- For reimbursement.

A COMPLETE MEDICAL RECORD

A complete medical record must have an accurate and complete representation of the actual care/experience of the resident/patient in the facility. It needs to have enough information to demonstrate that the institution knows the status of the resident/patient, has care plans identified to meet the resident's/patient's conditions, and provides enough documentation of the effects of the care provided.

Documentation should provide a picture of the resident /patient and the results of treatment and the resident's/ patient's response to the treatment. Documentation should also show the changes in status or condition of the resident/patient and any changes in orders or treatments.

THE CERTIFIED NURSING ASSISTANT (CNA)

THE SCOPE OF PRACTICE FOR THE CERTIFIED NURSING ASSISTANT (CNA)

Check with your state to detail your role as a CNA/HHA. The Florida Statutes describe below, provides specific guidelines regarding the role of the nursing assistant within the long term and home health care settings.

Chapter 464 of the Florida Statues

Practice of a certified nursing assistant means providing care and assisting persons with tasks relating to the activities of daily living. Such tasks are those associated with:

- personal care,
- maintaining mobility,
- nutrition and hydration,
- toileting and elimination,
- assistive devices,
- safety and cleanliness,
- data gathering,
- reporting abnormal signs and symptoms,
- postmortem care,
- patient socialization and reality orientation,

- end-of-life care,
- cardiopulmonary resuscitation and emergency care,
- residents' or patients' rights,
- documentation of nursing-assistant services, and other tasks that a certified nurse assistant may perform after training beyond that required for initial certification and upon validation of competence in that skill by a registered nurse.

FLORIDA STATUES 464

A certified nursing assistant shall complete 12 hours of in service training during each calendar year. The certified nursing assistant shall be responsible for maintaining documentation demonstrating compliance with these provisions. The Council on Certified Nursing Assistants, in accordance with s. 464.2085(2)(b), shall propose rules to implement this subsection.

CONFIDENTIALITY

Confidentiality is defined as a set of rules or a promise that limits access or place restrictions on certain types of information. Within the health care setting, confidentiality is a major issue in patient/resident care.

Certified nursing assistants as well as everyone who works with the patient has to maintain confidentiality of patient information. For example: you cannot talk about the patient with others who are not working with the patient and you cannot leave patient's chart at the bedside for unauthorized personnel to view. Legally, you can be fined or imprisoned; if you talk about the patient or share patient information. HIPAA laws must be followed and maintained.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

Confidentiality of patients' information.
HIPAA violations involves both civil and criminal penalties which include fines and imprisonment. The fines can range from $100 for each violation of the law to a limit of $25,000 per year for multiple violations. For misusing or disclosing any of the patient's information, criminal sanctions carry fines of 50,000 to 250,000 and one to ten years imprisonment.

Always maintain confidentiality of patients' information. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security and Breach Notification Rules:

The Office for Civil Rights enforces the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, which protects the privacy of individually identifiable health information; the HIPAA Security Rule, which sets national standards for the security of electronic protected health information; the HIPAA Breach Notification Rule, which requires covered entities and business associates to provide notification following a breach of unsecured protected health information; and the confidentiality provisions of the Patient Safety Rule, which protect identifiable information being used to analyze patient safety events and improve patient safety.

The HIPAA Privacy Rule provides Federal protections for individually identifiable health information held by covered entities and their business associates and give the patient an array of rights with respect to that information. At the same time, the Privacy Rule is balanced so that it allows the disclosure of health information needed for patient care and other important purposes.

Protected Health Information (PHI)

The HIPAA Privacy Rule protects most "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form; electronic, on paper, or oral. The Privacy Rule calls this information protected health information (PHI). Protected health information is information, including demographic information, which relates to:

- the person's present, past, or future physical, mental health or condition,
- the provision of health care to the individual, or
- the present, past, or future payment for the provision of health care to the individual, and that identifies the person or for which can be used to identify the individual.

Protected health information includes many common identifiers such as name, address, Social Security Number, date of birth when they can be associated with the health information.

A medical record, hospital bill or laboratory report, would be Protected health information because each document would contain a patient's name and the other identifying information associated with the health data content.

LEGAL DOCUMENTATION

Certified Nursing Assistant (CNA)

Legal documentation involves:

- Careful and accurate charting, never document a task if it was not done, this too is illegal (always notify the nurse for assistance as needed),
- Never document for another CNA, this is illegal,
- Always document the facts,
- Do not place personal feelings in the chart
- If you observe something abnormal with the patient, do not just write it down; make sure the charge nurse is notified so that the patient can be assessed,
- only document care when it is given,
- Avoid using abbreviations, Potential for errors (refer to the Do not use list)
- Make sure hand writing is clear and can be read by others of the health care team, everything that you document or chart can be used in court and the lawyers and everyone involved in the legal team must be able to read it.

NURSE

Nurses need to know the state law, the policies and the professional standards that relates to the specialty in which they are practicing. If there is any doubt or lack of knowledge consult with a supervisor or an expert to assist.

THE NURSE PRACTICE ACT

The 2015 Florida Statues 464 states:

464.002 Purpose: The sole legislative purpose in enacting this part is to ensure that every nurse practicing in this state meets minimum requirements for safe practice. It is the legislative intent that nurses who fall below minimum competency or who otherwise present a danger to the public shall be prohibited from practicing in this state.

Members of the Health care Team

As previously mentioned, it is very important to complete appropriate documentation within the patient's medical record because other members of the healthcare team will also be reviewing and reading the document. Therefore always provide information about the patient that is current, accurate, factual, complete, and it reflects a picture of the resident/patient while under the care of each health care worker (nurse, CNA, physician etc.)

Goal of Documentation

The overall goal of the nursing documentation is to:

- Ensure that there is documented timeline for the care that the patient receives. Every entry that is completed by each nursing staff or members of the healthcare team has to be coordinated. This coordinated documentation will allow members of the health care team and other who need to review the chart, to see the patient's status at specific times and assist the health care team in determining if changes have occurred within the patient and at what time the changes were observed, reported and documented.
- Always remember that documentation is considered a legal document which reflects the care the patient received and should reflect that patient care was given in accordance with appropriate standards of care.

Personnel completing the documentation

As a health care worker, you are also documenting for your own purpose. When you have appropriately documented, this documentation will be available for you to access as needed, if you need to recall complete details of what did for the patients.

If there is a lawsuit or claim filed within a year or more, you might not remember all the details of care given to that patient or even the time that care or medications were administered therefore your complete and accurate documentation will be useful at that time. See your state for the statute of limitation (time frame); within some states, the statute of limitations allows lawsuits within 2 years or more of the date of the event resulting in a claim. The timeframe may be extended as much as 20 years if the patient involved is a minor.

Everyone within the health care team must document and the documentation should be at the time of patient care so that the information is accurate and complete. Never leave your shift without documenting; never say “I will come back in the morning and document.”

Lawyers, consultants, Judge and Jury

When there is a lawsuit, all of the documentation of the patient’s medical record will be reviewed by the lawyers, consultants, nurses and other experts involved. The team will look for what was not done per standard of care, what could have been done better, what was not accurately done, what was not done that should have been completed etc. The documentation will be read by the jurors involved in the case.

Follow the nursing process

The nursing process should always be followed. The nursing process requires :

- Assessment,
- Nursing diagnosis,
- Planning,
- Implementation, and
- Evaluation.

Assessment

Assessment is the first step in delivering nursing care.
Nursing assessment is defined as the gathering and analyzing of information about a patient's physiological, economic, psychological, sociological, cultural and spiritual status.

Diagnosis

The nursing diagnosis is the nurse's clinical judgment about the patient's response to actual or potential health status/conditions.

Planning

Based on the assessment and diagnosis, the nurse establishes measurable and achievable short- and long-term goals and expected outcomes for the patient. The information is placed in the plan of care.

Implementation
Implementation involves carrying out the nursing care according to the plan of care.

Evaluation
Ongoing evaluation is completed to check the patient's status and the effectiveness of the nursing care. The care plan is then modified as needed.

State nurse practice acts may vary from state to state so follow the established guidelines for documentation. Some tips for accurate and complete documentation are listed below:

- Always write clearly (legibly), everyone within the health care team needs to be able to read what you have documented. This is vital to accurate and continuity of care for the patient. It is good to use block printing if your handwriting is illegible.

- Avoid charting in advance, this too is illegal and can lead to devastating errors.

- Always complete your documented entry using a chronological documentation format. This will provide separate entries for each narrated item because you want to provide a clear picture of the events and times surrounding the care that was provided for that patient.

- Document timely; charting should be done every 1-2 hours for routine care. Medication administration and other interventions or changes in condition should be documented immediately. If medications are not recorded in a timely manner, there is a possibility that the patient may receive that medication again.
- When standard time is used, always include AM or PM with notations. Some healthcare facilities use military time to reduce errors.
- Your Signature is very important. The healthcare worker must always sign for every notation in the patient's medical record.
- If you are to assess the patient's baseline mental status, document it because if there is a change or deviation noted from baseline this could indicate an injury or an acute illness.
- If you completed a task or an intervention, always document the intervention followed by an evaluation; did the intervention help the patient, was it effective? If intervention was not effective, what was done? Was the physician updated, all basis covered? Patient's needs met?
- Also document any complaints of the patient and/ or family and ensure follow up is done with the supervisor, with timely resolution and documentation.

- If you document a body system abnormality, always note the details because over a period of time the abnormality may become worse.

- Always accurately document how your assessment was done. For example, if you watch the chest of the patient rise and fall, you cannot document that the patient has normal breath sounds unless you have used the stethoscope to listen to the lungs.
- Do not use abbreviations unless they are approved, acceptable and included in your facility's policy and procedure. Therefore if you are unable to complete an entry on that page, do not shorten the word (do not make up your own word) move to the next page; follow your facility's policy and procedure for continuing an entry on the next page.
- Do not use slangs within the patient's medical record. As mentioned before the patient's medical record is a legal document. All documentation should be in Standard English with accurate grammar. Accurate spelling is also required because misspelled words may lead to different interpretations.

- Writing must be done using permanent ink pen (dark ink, blue or black) and writing needs to be neat and legible. Do not use pencil or pen that can be erased. Check your facility policy, some only allow black ink.
- Always assess the patient at the time of admission, transfer and discharge. You need to know the status of a patient when he/she enters your care and before he/she leaves.

- Avoid leaving spaces in charting. If blank spaces are left, this will allow others to make additions to the patient's medical record, to your notation. Make a straight line through any empty space.

- Make sure if you have to complete a late entry, always follow your facility's policy. Late entries must indicate the date and time they were actually entered into the patient's medical record, and you have to include the notation -*Late entry*; followed by the date and time of the event.

- When medications or treatments are delayed, the healthcare worker must document in the patient's medical records, noting the reason for the delay. For example, the patient may be completing a diagnostic examination and has not yet returned to the unit. If aware that the patient is scheduled for the examination,

prioritize and make plans to complete the treatment before the patient leaves for the examination; if possible.

- When you have to continue notes from one page to another, make a notation that the entry is continued on the next page, this is to indicate that the note is not complete. Then document also on the next page to indicate that it is a continuation. Both of the pages have to contain your signature.(Follow your facility's Policy).
- When making corrections in the medical record, the error cannot be white-out, erased, scratched out to make illegible. The error can be corrected by drawing a line through the text and writing the word "error." sign your name and date the cross off. Follow your facility policy.

ALWAYS REMEMBER !!

• Writing has to be legible –clear for others to read and understand
• Use dark ink pen on the patient's medical records
• Whenever you make an error, use your pen and cross it off with **one thin line**. Write error, sign your name and date the cross off. Do not try to cover up the mistake with marker or scribble. Do not rewrite over the error; just one straight line through the error. White out cannot be used when you make a mistake.

Documentation Variations among health care institutions

Healthcare workers often work in various settings. Physicians, nurses, CNAs and other healthcare personnel often work in more than one facility at the same time. Therefore it is very important to understand the basic formats for effective documentation. Appropriate and accurate documentation requires the nurse to have an understanding of the nursing process and nursing diagnosis.

NANDA International (formerly the North American Nursing Diagnosis Association) is a professional organization of nurse's standardized nursing terminology that develops researches, disseminates, refines the nomenclature, criteria, and taxonomy of nursing diagnoses.

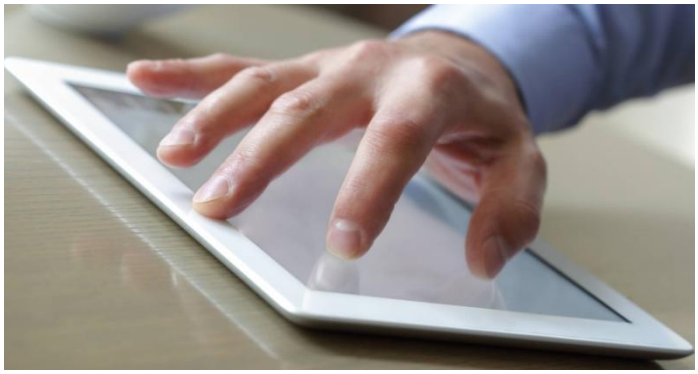
NANDA International sets the standards for nursing diagnoses with a taxonomy that includes domains, classes, diagnoses, based on health patterns; domains such as:

Activity/Rest
Comfort
Coping/Stress Tolerance
Elimination
Growth/Development
Health Promotion
Life Principles
Nutrition
Perception/Cognition
Role Relationships
Safety/Protection
Self-perception
Sexuality

Nursing Interventions Classification (NIC) and Nursing Outcomes Classification (NOC)

Nursing Interventions Classification; a standardized list of several of different interventions and activities needed to implement the interventions. The patient outcomes related to the nursing interventions classification are detailed in the Nursing Outcomes Classification (NOC), which contains several outcomes, each with measures to determine if outcomes are met.

NANDA International Nursing Diagnoses: Definitions and Classification 2015-2017 is available and approved by NANDA-I. The new 2015-2017 edition has been updated and revised throughout. There are 235 diagnoses presented and are supported by definition, defining characteristics, related factors, or risk factors. The new / revised diagnosis is based on latest global evidence, and approved by expert nurse diagnosticians, educators and researchers. (See the new 2015-2017 edition for updates).



Computerized documentation systems

Computerized documentation systems often incorporate nursing diagnoses into the system, which produces lists of interventions and expected outcomes. More institutions are utilizing computerized systems for documentation. These computerized systems however vary from one facility to another; however security is a common factor for all systems. Training has to be provided for the staff, which usually include securing patient information from unauthorized persons whether the computer is at the nurses' station or

at the bedside, security of password information; no one is allowed to share their password with their co-worker etc. Computer systems usually track the use of the system, therefore it is documented who is logged on and time and date. There has to be training regarding how to correct errors when an entry error is made.

Computerized documentation systems have many advantages, including but not limited to:

- Eliminates handwritten orders,
- The records are legible; no need to worry about unclear handwriting,
- Enters signatures automatically,
- Security of patient information; need password to log in to access patient information,
- Orders can be automatically transmitted to pharmacy and medication is ordered quickly,
- Reduction in errors,
- Prevents tampering of the medical record,
- Difficult to delete information from the record.

Computerized documentation systems may include:

Electronic medical record (EMR)

Electronic medical record is the computerized patient medical record. With the use of the computerized documentation system, computer terminals may be located in the patient's room, therefore healthcare providers / workers, professionals have to be educated/ trained regarding the importance of logging off the computer system so that persons who are not authorized will not be able to access and view the patient's information. The computerized documentation system usually has computerized physician order entry, clinical decision support system; therefore the notes can be entered electronically.

Clinical decision support system (CDSS)

Clinical decision support system refers to the interactive software systems which has evidence based medical information. Clinical decision support system can be used for different purposes such as providing diagnosis and treatment options when the symptoms are imputed into the computer system. Clinical decision support system may also monitor the orders and the treatments to prevent repetitions or duplications.

Computerized physician or provider order entry (CPOE)

Computerized physician or provider order entry (CPOE) refers to the interactive software application that automates ordering for medications or treatments. Orders must be entered in a prompted format that eliminates many errors. These systems usually include Clinical decision support system to provide alerts if there is an inaccurate dose

or duplication order. Computerized physician or provider order entry eliminates handwritten orders and the information is automatically transmitted to the pharmacy, reducing errors and medication is ordered quickly.

Documentation Formats

Many institutions utilize the narrative format when documenting in the clinical record. Healthcare workers must utilize the system that is in place / follow the policy and procedures of the facility that they work in.

Some of the formats that are available include:

- Narrative format
- Focus
- Charting by exception (CBE)
- Problem Oriented medical record (POMR)
- Flow Sheet, Assessment, Concise, Timely (FACT)
- Problem/ intervention/ Evaluation (PIE)
- Core

Narrative format

Narrative format is used in the most of the institutions. Narrative charting involves recording data using progress notes, with the flow sheets supplementing the notes. Narrative charting does not follow a specific outline and follows the thought process of the healthcare worker who is documenting.

Focus

Organized into patient centered topics, the Focus system encourages integrating assessment data to evaluate the patient's condition on an ongoing basis. The Focus system is best used where the procedures are repetitive and is utilized primarily in acute care settings. Progress notes are written utilizing the DAR (Data, Action, and Response) format.

Charting by exception (CBE)

Charting by exception requires the development and use of practice standards or protocols for each body system. The forms utilized in the documentation are developed following specific guidelines. Developing the standards and forms eliminates the need to document in narrative format standard nursing care. The healthcare worker check off the areas on the flow sheet through which the patient has met the established standard, then writes a narrative note when the patient's condition deviates from the established standard.

Problem Oriented medical record (POMR)

Problem oriented medical record (POMR) is utilized in many health care institutions. The POMR system follows a problem list format, identifying all areas (both positive and negative) that are impacting the patient. The notes and all the documentation refer back to the problem list, using the Subjective, Objective, Assessment, Plan (SOAP), the Intervention, Evaluation (SOAPIE) and/or SOAPIER (Revision) format.

Flow Sheet, Assessment, Concise, Timely (FACT)

Flow Sheet, Assessment, Concise, Timely (FACT) developed to help eliminate repetitive notes, irrelevant data, inconsistency and to reduce amount of time required to complete documentation. Flow sheets are designed to address the redundant activities in caring for a resident. The narrative documentation utilizes the Data, Action, Response (DAR) format of the Focus charting system.

Problem/ intervention/ Evaluation (PIE)

Problem/ intervention/ Evaluation (PIE) organize information according to the patient's problems to simplify the documentation system. Problem/ intervention/ Evaluation (PIE) utilize flow sheets which have been developed for daily documentation supplemented with structured narrative documentation. This system also integrates the care plan into the daily documentation.

Core

Core focuses on the nursing process. The Core framework utilizes the data base, flow sheets, care plan, progress notes, discharge summary to chart the patient's needs and progress. Progress notes follow the data, action, evaluation/response (DAE) for each of the problems.

Use of abbreviations

Abbreviation is a shortened form of a word or phrase. Abbreviations can lead to some serious or life threatening errors, therefore there are guidelines in place. The Joint Commission has set guidelines and rules; all healthcare settings has to standardize abbreviations, acronyms and symbols that they are using. They are also required to adhere to a Do Not Use list.

The Do Not Use List includes some of the following:

Do Not Use u, or for unit. Mistaken some times for zero. You must write "unit"
Do Not use iu for international unit. Mistaken for IV. Write "international unit"
Do Not Use Q.D., QD, q.d., qd (Daily). Mistaken for each other. Write "Daily".
Do Not Use Q.O.D. QOD, q.o.d., qod (every other day). Write "every other day"
See the complete Do Not Use List (The Joint Commission http://www.jointcommission.org/assets/1/18/Do_Not_Use_List.pdf**)**

Timely Documentation

Time is a very crucial factor within the nursing process. Healthcare workers; Physicians, Nurses, CNA have to document the time of all interventions and notations.

Documentation /Physician orders

Telephone order and Verbal order

Always follow the institution's Policy when noting orders on the physician order sheet. When the nurse receives a telephone order (the physician telephones and gives an order) then it has to be documented as a Telephone Order (T.O.) The telephone order should indicate a telephone order with the time, date, physician's name and that the order has been repeated to the physician, also Verbal orders, must be documented as V.O. and must be written exactly as dictated and then verified.

Vital Information

Some information such as allergies/ sensitivities, Patient's identification; name and other identifying information should be on every page of every document in the patient's medical record.

Notation of Medications and treatments

When medications and treatments are administered, the healthcare worker has to document in the patient's medical record. Also If the wrong medication or treatment is administered, this also has to be documented. The nursing note has to indicate all treatments and medications given to the patient, even if it was the wrong medication or

treatment. The individual who administers the wrong medication or treatment has to document the:

- Name of the medication
- the dose of medication,
- Name of physician notified
- time the physician was notified,
- Nursing interventions or physician orders to prevent or treat adverse effects,
- Patient's response to treatment.

Follow the facility policy and procedure regarding with medication and treatment errors. An incident report will also be completed.

LONG TERM CARE DOCUMENTATION

Home health care agencies are also allowed to see patients within the Assisted living and Senior community settings. Complete and accurate documentation within the long term care setting is also very vital due to several factors such as:

- Regulations
- Surveys conducted by The Agency For Health Care Administration (AHCA)
- Litigations (laws suits)
- Documentation based on reimbursement/ payment systems
- Increased legal challenges
- Complex clinical needs
- Complex patient decision making

Federal Regulations and Clinical Record guidelines

Long-term care facilities such as Skilled Nursing Facilities (SNF), rehab. centers often review their documentation policies and procedures/ guidelines. They frequently have to incorporate accreditation requirements, payer requirements (for reimbursement purposes) and state regulations into the documentation systems.

Federal regulation requires that the facility has to maintain clinical records on each resident/patient in accordance with accepted professional standards and practices that are:

- Accurately documented,
- Complete,
- Readily accessible and
- Systematically organized.

CORRECTION OF CLINICAL RECORDS

When corrections are needed in the clinical records; the correction needs to be made using an addendum/ which will note that a correction has been made. If in the event of staff turnover or staff schedules changes and the original clinician is no longer available, the Director of nursing or a designated clinician will be assigned to make the necessary corrections.

It is important for the home health agency to include latitude for correction of records in the event of staff turnover or staff schedules. For example, a clinical supervisor may be permitted by agency policy to make corrections when the original clinician is no longer available due to staff turnover.

When a comprehensive assessment is corrected, the Agency will maintain the original assessment record as well as all subsequent corrected assessments in the patient's clinical record for five years, or longer, in accordance with the clinical record requirements at 42 CFR 484.48.

Clinical Implications of Corrected Assessment Records

When corrections are made to an assessment already submitted to the state system, the Agency will determine if there is an impact on the patient's current care plan.

If there is an impact, in addition to the correction made to the assessment, the Agency will make corresponding changes to the current plan of care. If there are any other records where the correction has an impact , the agency will make corresponding changes to that record, as applicable.

The agency review the impact of any corrections made to assessment records and make corresponding changes to other records that are affected.

AUTHORIZATION FOR SERVICES ORDERED

The agency often needs to obtain authorization from payer source such as insurance companies regarding services ordered. Authorizations can be given verbally or written. If authorization is not granted, the Agency should discuss with physician and patient to decide the next course of action.

CASE MANAGEMENT

Case management means:

- The initial assessment of the patient and caregiver for appropriateness of and acceptance for home health services
- Establishment and periodic review of a plan of care
- Implementation of medical treatment when ordered
- Referral, follow-up, provision of, evaluation of and supervision of care
- Coordination of services given by other health care providers
- Documentation of all activities and findings.

Within the home health care agencies the Director of nursing or designated personnel will work with other health care providers to ensure that case management is conducted for each patient.

COMPREHENSIVE ASSESSMENT

Each patient will receive, and the Agency will provide, a patient specific, comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement of desired outcomes. The comprehensive assessment must identify the patient's continuing need for home care and meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs.

For Medicare beneficiaries, the Agency will verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment.

The comprehensive assessment must also incorporate the use of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items.

The comprehensive assessment will also identify the patient's continuing need for home care, medical, nursing, rehabilitative, social, and discharge planning needs.

The comprehensive assessment should incorporate the use of the Outcome and Assessment Information Set (OASIS) items, and /or the nursing /therapy assessments, progress notes and the attestation of a Face to Face encounter with the physician.

Completion of the comprehensive assessment

The comprehensive assessment will be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care.

For patients to whom OASIS applies, when a patient is admitted to the Agency, a start of care comprehensive assessment that includes certain required OASIS data items, will be completed no later than 5 calendar days after the start of care date.

MEDICATION /DRUG REVIEW

The comprehensive assessment has to include a review of all medications the patient is currently using (including over the counter and supplements) in order to identify any potential adverse effects and drug reactions, including:

- Ineffective drug therapy,
- significant side effects,
- significant drug interactions,

- Duplicate drug therapy, and
- noncompliance with drug therapy.

This requirement applies to all patients being serviced by the Agency, regardless of whether the specific requirements of Outcome and Assessment Information Set (OASIS) apply.

For patients to whom OASIS does not apply, the drug regimen review must be conducted in conjunction with the requirement Condition of Participation: Acceptance of patients, plan of care, and medical supervision.

The drug regimen review must include documentation of ALL medications the patient is Taking (including over the counter and supplements).

Review medications on the current physician plan of care and in clinical record notes to determine the accuracy of the medication regimen. This may be included as part of the case-mix, stratified sample of clinical records.

DIRECT EMPLOYEE

Within the home health care setting “Direct Employee” means one of the following pays the withholding taxes for the employee: the home health agency; a management company which has a contract to manage the home health agency; or an employee leasing company which has a contract with the home health agency to handle the payroll and payroll taxes for the home health agency.

DISCHARGE SUMMARY

When the patient is due for discharge from the home health care agency, the Agency may call the physician’s office to report that the Discharge summary is available or may fax to Physician’s office and document update on Discharge summary. The physician discharge order needs to be documented.

Patients may be discharged with admission to Hospital, Skilled Nursing facility or other settings. Each discharge planning will be done on an individual basis.

Unexpected discharge should be called in to physician and Discharge Outcome and Assessment Information Set (OASIS) needs to be completed.

When a Medicare beneficiary elects to transfer to a different HHA or is discharged and returns, a new clock for purposes of payment, Outcome and Assessment Information Set (OASIS) assessment, and physician certification of the new plan of care.

When a new 60-day episode begins, the original 60-day episode payment is proportionally adjusted to reflect the length of time the beneficiary remained under the Agency’s care before the intervening event. The proportional payment is the Partial Episode Payment (PEP) adjustment.

EMERGENCY MANAGEMENT

Each home health agency shall prepare and maintain a written comprehensive emergency management plan, in accordance with criteria shown in the Comprehensive Emergency Management Plan (CEMP). This document is available from the Agency for Health Care Administration at http://ahca.myflorida.com and shall be used as the format for the home health agency's emergency management plan.

(1)The plan needs describe how the home health agency establishes and maintains an effective response to emergencies and disasters.

(2) The plan, once completed, will be forwarded electronically for approval to the contact designated by the Department of Health.

(3) The agency shall review its emergency management plan on an annual basis and make any substantive changes.

(4) Changes in the telephone numbers of those staff who are coordinating the agency's emergency response must be reported to the agency's county office of Emergency Management and to the local County Health Department.

For agencies with multiple counties on their license, the changes must be reported to each County Health Department and each county Emergency Management office. The

telephone numbers must include numbers where the coordinating staff can be contacted outside of the agency's regular office hours.

All home health agencies must report these changes, whether their plan has been previously reviewed or not, as defined in subsection (2) above.

(5) When an agency goes through a change of ownership the new owner shall review its emergency management plan and make any substantive changes, including changes noted in subsection (4) above. Those agencies which previously have had their plans reviewed, as defined in subsection (2) above, will need to report any substantive changes to the reviewing entity.

(6) In the event of an emergency the agency shall implement the agency's emergency management plan in accordance with Section 400.492, F.S. Also, the agency must meet the following requirements:
(a) All staff who are designated to be involved in emergency measures must be informed of their duties and be responsible for implementing the emergency management plan.

(b) If telephone service is not available during an emergency, the agency shall have a contingency plan to support communication, pursuant to Section 400.492, F.S. A contingency plan may include cell phones, contact with a community based ham radio group, public announcements through radio or television stations, driving directly to the employee's or the patient's home, and, in medical emergency situations, contact with police or emergency rescue services.

(7) Home health agencies which are exempt from this requirement are listed in Section 400.497(8)(e), F.S.

(8) On admission, each home health agency shall, pursuant to Section 252.355, F.S., inform patients and patient caregivers of the home health agency's procedures during and immediately following an emergency and inform patients of the special needs registry maintained by their county Emergency Management office. The home health agency must document in the patient's file if the patient plans to evacuate or remain at home; if during the emergency the patient's caregiver can take responsibility for services normally provided by the home health agency; or if the home health agency needs to continue services to the patient.

If the patient is a resident of an assisted living facility or an adult family care home, the home health agency must contact the assisted living facility or adult family care home administrator or designated emergency management personnel and find out the plan for evacuation of the resident in order to document the resident's plans in the home health agency's file for the patient. If it is determined the home health agency needs to provide continued services, it will be the responsibility of the home health agency to provide the same type and quantity of care for the patient in the special needs shelter during and after the emergency, equal to the care received prior to the shelter assignment as specified in Section 400.492, F.S., except in certain situations as specified in Section 400.492(3), F.S.

(9) Upon eminent threat of an emergency or disaster the home health agency must contact those patients needing ongoing services and confirm each patient's plan during and immediately following an emergency. The home health agency must also contact every assisted living facility and adult family care home where patients are served to confirm the plans during and immediately following the emergency.

(10) During emergency situations, when there is not a mandatory evacuation order issued by the local Emergency Management agency, some patients may decide not to evacuate and will stay in their homes. The home health agency must establish procedures, prior to the time of an emergency, which will delineate to what extent the agency will continue care during and immediately following an emergency.

The agency shall also ascertain which patients remaining at home will need care from the home health agency and which patients have plans to receive care from their family or caregivers. The agency shall designate staff to continue the services specified in the treatment orders to residents in the assisted living facility or adult family care home during and following the emergency.

If the assisted living facility or adult family care home does relocate the residents to another assisted living facility or adult family care home within the geographic area the home health agency is licensed to serve, the agency will continue to provide services to the residents, except in certain situations as specified in Section 400.492(3), F.S. If the residents should go to a special needs shelter outside the licensed area of the home health agency, the home health agency may provide services to the residents at the shelter pursuant to Section 400.492(4), F.S.

(11) If the agency at some point ceases operation, as defined in Section 400.492(3), F.S., the agency must inform those patients whose services will be discontinued during the emergency. The agency must also notify assisted living facilities and adult family care homes where residents are served and make arrangements for nursing personnel to continue essential services, such as insulin and other injections, as ordered in treatment orders to residents.

If the agency has assisted living facility, adult family care home or other patients in special needs shelters, then the agency will call the local emergency operation center as soon as possible after the disaster and report on the status of the agency's damage, if any, and the post-disaster availability to continue serving their patients in the special needs shelters and during discharge from the special needs shelters.

(12) When a home health agency is unable to continue services to special needs patients registered under Section 252.355, F.S., that patient's record must contain documentation of the efforts made by the home health agency to comply with their emergency management plan in accordance with Section 400.492(3), F.S. Documentation includes, but is not limited to, contacts made to the patient's caregivers, if applicable; contacts made to the assisted living facility and adult family care home, if applicable; and contacts made to local emergency operation centers to obtain assistance in reaching patients and contacts made to other agencies which may be able to provide temporary services.

(13) Each home health agency is required to collect registration information for special needs patients who will need continuing care or services during a disaster or emergency, pursuant to Section 252.355, F.S. This registration information shall be submitted, when collected, to the county Emergency Management office, or on a periodic basis as determined by the home health agency's county Emergency Management office.

(14) Home health agency staff shall educate patients registered with the special needs registry that special needs shelters are an option of last resort and that services may not be equal to what they have received in their homes.

(15) **The prioritized list of patients maintained by the home health agency shall be kept current and shall include information as defined in Section 400.492(2), F.S**. The prioritized list shall also include residents in assisted living facilities and adult family care homes who require nursing services. This list will assist home health agency staff during and immediately following an emergency which requires implementation of the

emergency management plan. This list also shall be furnished to local County Health Departments and to the county Emergency Management office, upon request.

(16) The patient record for each person registered as a special needs patient shall include information as listed in Section 400.492(1), F.S.

(17) The home health agency is required to maintain in the home of the special needs patient a list of patient-specific medications, supplies and equipment required for continuing care and service should the patient be evacuated.

The list must include the names of all medications, their dose, frequency, route, time of day and any special considerations for administration. The list must also include any allergies; the name of the patient's physician and the physician's phone number(s); the name, phone number and address of the patient's pharmacy. If the patient permits, the list can also include the patient's diagnosis.

FACE TO FACE ENCOUNTER

It is allowable for the certifying physician to use the discharge summary or referral as documentation of the face-to-face encounter if:

• The discharge summary or referral meets all the documentation requirements for face-to-face documentation, and

• The discharge summary or referral, which is serving as the face-to-face documentation, is dated and clearly titled as such, and

• The certifying physician signs the discharge summary or referral, demonstrating that the certifying physician received that information from the teaching physician supervising the resident who performed the face-to-face encounter, and that the certifying physician is using that discharge summary or referral as his or her documentation of the face-to-face encounter.

It is allowable for the certifying physician to use the ER physician's documentation as documentation of the face-to-face encounter:

• If that ER physician's documentation meets all the documentation requirements for face-to-face documentation; and

• The ER physician's documentation, which is serving as the face-to-face documentation, is dated and clearly titled as such; and

• The certifying physician signs the ER physician's documentation, demonstrating that the certifying physician received that information from the physician who performed the face-to-face encounter, and that the certifying physician is using that ER physician's documentation as his or her documentation of the face-to-face encounter.

HOMEBOUND STATUS

A physician who is enrolled as a Medicare provider must certify the patient's eligibility for the benefit. The physician must certify that:

1. The home health services are or were needed because the patient is or was confined to the home.

2. The patient needs or needed skilled services on an intermittent basis,

3. A plan of care has been established and is periodically reviewed by a physician; and

4. The services are or were furnished while the patient is or was under the care of a physician.

MD COMPLETES FACE TO FACE ENCOUNTER and Medicare eligibility and homebound status are determined.

For the patient to be eligible to receive covered home health services under both Part A and Part B, the law requires that the physician certify in all cases that the patient is confined to his / her home.

To determine whether homebound criteria are met, it is necessary to look at the patient's condition over a period of time rather than for short periods within the home health visits.

CMS makes clear that the aged individuals who do not often travel from home because of increased age and insecurity brought on by feebleness or advanced age would not be considered confined to the home for purposes of receiving home health services unless they meet the specific criteria outlined listed.

CRITERIA FOR HOMEBOUND STATUS

CMS advises that an individual shall be considered “confined to the home” (homebound) if the following two criteria are met:

Criteria #1

The patient must either:

- Because of injury or illness, need the aid /assist of a supportive device such as crutches, cane, wheelchair, and walker, the use of special transport or the assistance of another individual in order to leave their place of residence or
- Have the individuals has a condition such that leaving his or her home is medically contraindicated.

If the patient meets one of the Criteria #1 conditions, then the patient must also meet two additional requirements defined in Criteria #2.

Criteria #2:

There has to exist a normal inability to leave home and leaving the home must require a considerable and taxing effort.

Temporary Absence on Homebound Status

CMS also provides examples of temporary absences from the home that are acceptable for a homebound patient. A patient could still be considered homebound if absences from the home are:

- Not often (Infrequent)
- For periods of relatively short duration, or
- Attributable to the need to receive health care treatment,

Absence for Health Care Treatment:

Absences attributable to the need to receive health care treatment include:

Attendance at adult day centers for the purpose of receiving medical care

Ongoing receipt of outpatient kidney dialysis

For outpatient chemotherapy therapy or radiation therapy,

And other reasons not listed.

ADULT DAY CARE CENTER

Regular absences for the reason or purpose of participating in therapeutic, medical treatment or psychosocial treatment in an adult day-care program that is licensed, certified or accredited by the State shall not disqualify an individual from being considered to be confined to his home.

SHORT DURATION/ INFREQUENT

If an absence is of relatively short duration / infrequent a patient will not lose their homebound designation.

NON-MEDICAL ABSENCE

Absences from the home that occur will be for the purpose of receiving health care treatment, most of the time. Sometimes occasional absences from the home for example funeral, a walk around the block, an occasional trip to the hairdresser/ barber, attendance at a family reunion, graduation, or other infrequent / unique event would not necessitate a finding that the patient is not homebound if other criteria are met.

MEDICAL TREATMENT OUTSIDE THE HOME

Sometimes the service that the patient needs cannot be provided at the residence of the homebound patient because equipment is required that cannot be made available there. If the services required by an individual involve the use of such equipment, the HHA may make arrangements with a hospital, skilled nursing facility or a rehabilitation center to provide these services on an outpatient basis. However, even in these situations, for the services to be covered as home health services the patient must be considered as confined to home; and to receive such outpatient services a homebound patient will generally require the use of supportive devices, special transportation, or the assistance of another person to travel to the appropriate facility.

GEOGRAPHICAL AREA

Geographic service refers to the area, as specified on the license, in which the home health agency may send its personnel to provide home health services to patients in their places of residence

(1) All home health agencies must apply for a geographic service area on their initial license application. Home health agencies may apply for a geographic service area which encompasses one or more of the counties within the specific AHCA area boundaries in which the main office is located provided that the license application includes a plan for:

(a) Coverage of the professional staff which takes into account the projected number of clients in the requested geographic service area, and

(b) Supervision of the staff in the requested geographic service area. AHCA shall authorize a geographic service area if there are a sufficient number and type of staff and supervision to meet the needs of the geographic service area.

(2) In any request for expansion of the geographic service area, the home health agency's previous history of survey results and administrative actions including fines, suspensions, revocations or injunctions will be reviewed to establish the home health agency's ability to provide quality services within the requested area. In addition, the application for an expanded geographic service area must include a plan for:

(a) Coverage of the professional staff which takes into account the projected number of clients in the requested geographic service area, and
(b) Supervision of the staff in the requested geographic service area.

(3) The counties listed on the home health agency license should reflect counties in which the home health agency expects to provide services. If an agency refuses to serve residents of a specific county and that county is listed on the agency's license, AHCA shall remove that county from the agency's license. Refusal to provide services to a resident solely based on their residence in a specific county must be verified by AHCA prior to removing the county from the license.

HOURS OF OPERATION

The agency has the following responsibility in terms of hours of operation:
The home health agency administrator and director of nursing, or their alternates, must be available to the public for **any eight consecutive hours** between 7:00 a.m. and 6:00 p.m., Monday through Friday of each week, excluding legal and religious holidays. Available to the public means being readily available on the premises or by telecommunications

When the administrator and the director of nursing are not on the premises during designated business hours, a staff person must be available to answer the phone and

the door and must be able to contact the administrator and the director of nursing by telecommunications. This individual can be a clerical staff person

INFUSION THERAPY SERVICES

Home infusion therapy services means teaching, assessment, evaluation and clinical services related to the administration of intravenous substances provided by a professional licensed under Chapter 464, 458 or 459, F.S.

LABORATORY SERVICES

CLIA certificate must be maintained by the Agency.

A certificate of waiver are limited to performing only those tests determined to be in the waived category. Some tests that an home health agency (HHA) may perform that fall into the waived category include:

- Dipstick/tablet reagent urinalysis
- Blood glucose by glucose monitoring devices cleared by the Food and Drug Administration (FDA) specifically for home use;
- Some prothrombin time tests; and
- Some glycosolated hemoglobin tests.

For a complete listing of waived tests, refer to CMS' website at http://www.cms.hhs.gov/.

For a complete listing of provider-performed microscopy procedures, refer to CMS' website at http://www.cms.hhs.gov/.

For a complete listing of moderate and high complexity tests, refer to CMS' website at http://www.cms.hhs.gov/. (follow the link).

LICENSED NURSE

Licensed nurse, as defined in Sections 464.003(4) and 464.003(5), F.S., means a registered nurse licensed to practice professional nursing or a licensed practical nurse licensed to practice nursing under the direction of a physician or registered nurse pursuant to Chapter 464, F.S.

Medical Device Reporting

The Agency needs to adhere to the following regulation and will comply with applicable reporting requirements:

According to D. Bruce Burlington, M.D. Director Center for Devices and Radiological Health, the Center for Devices and Radiological Health (CDRH), part of the Food and Drug Administration (FDA), develops and implements national programs and regulations to protect the public health in the fields of medical devices and radiological health.

These programs are intended to assure the safety, effectiveness, and proper labeling of medical and radiation emitting devices.

The Safe Medical Devices Act of 1990 (SMDA) imposed significant new reporting requirements on the medical device industry and users of medical devices. SMDA requires user facilities to report device-related deaths and serious injuries to the Food and Drug Administration (FDA) and/or the manufacturer.

Much of the information in this document is general in nature and may not apply to a

specific situation. Questions should be sent by facsimile (FAX) to (240) 276-3454 or mailed to:

Food and Drug Administration
Center for Devices and Radiological Health
Division of Surveillance Systems (HFZ-530)
Medical Device Reporting (MDR) Inquiries
1350 Piccard Drive
Rockville, MD 20850

In 1990, Congress enacted the Safe Medical Devices Act (SMDA) to increase the information that the Food and Drug Administration (FDA) and manufacturers receive about serious problems with medical devices.

Although manufacturers and importers of medical devices have been required since 1984 to report to FDA all device-related deaths, serious injuries, and certain malfunctions, numerous reports show widespread under reporting. A 1986 General Accounting Office (GAO) study showed that hospitals reported less than one percent of problems with medical devices and, the more serious the problem with a medical device, the less likely it was to be reported. A GAO follow-up study in 1989 concluded that despite full implementation of the Medical Device Reporting (MDR) regulation, serious under reporting still existed.

Under SMDA, device user facilities and manufacturers **must report deaths and serious injuries** to which a device has or may have caused or contributed and must establish and maintain adverse event files. A device user facility is defined as a hospital, an ambulatory surgical facility, a nursing home, an outpatient treatment facility, or an outpatient diagnostic facility which is not a physician's office.

A medical device is any item that is used for the diagnosis, treatment, or prevention of a disease, injury, or other condition and is **not** a drug or biologic. The user facility reporting section of SMDA became effective on November 28, 1991.

To implement SMDA, FDA published a tentative final rule in the November 26, 1991, *Federal Register* and invited comments on the regulation. Over 300 comments were received. Then, on June 16, 1992, the President signed into law the Medical Device Amendments of 1992 (Public Law 102-300; the Amendments of 1992), amending certain provisions (section 519 of the Food, Drug, and Cosmetic Act) relating to reporting of adverse events. The primary impact of the 1992 Amend-ments on user

facility reporting was to establish a single reporting standard for user facilities, manufacturers, and importers. The final medical device reporting rule published in the December 11, 1995, *Federal Register* addresses the comments received by FDA and the changes mandated by the Amendments of 1992.

All individual reports of death and serious injury must be submitted within 10 work days from the time that any medical personnel of the facility becomes aware of a reportable event.

The Food and Drug Administration Modernization Act (FDAMA) was signed on 11/21/97 and became effective on 2/19/98. There were four changes that affected MDR:

- Manufacturers and distributors/importers do not need to submit annual certification.
- Domestic distributors are no longer required to file MDR reports, but must continue to maintain complaint files. [Importers (initial distributors for devices manufactured overseas and imported into the USA) must continue to file MDR reports.]
- User facilities must now file an annual report instead of semiannual reports to summarize their adverse event reports.
- Sentinel reporting by user facilities was proposed.

Medical Device Reporting (MDR) - Contact Information for User Facilities and Manufacturers

To Report a Significant Emergency (outside of normal East Coast business hours):

FAX	(301) 847-8543
Voice (24 hr/day)	(301) 796-8240 or 866-300-4374

To Report an MDR:

Voluntary Reporting Program	1-800-FDA-1088

For information on reporting Voluntary and Mandatory Medical Device Reports, visit: (LINK)

- Where to Submit a Medical Device Report

For Questions about Medical Device Reporting, including Interpretation of policy:

Address	Phone
Food and Drug Administration Center for Devices and Radiological Health Reporting Systems Monitoring Branch 10903 New Hampshire Avenue WO Bldg. 66, Rm. 3217 Silver Spring, MD 20993-0002	Email: RSMB@fda.hhs.gov (301) 796-6670 (voice)

How to Report a Medical Device Problem

VOLUNTARY MedWatch Reporting for Health Professionals and Consumers (Form FDA 3500)

Health professionals and consumers may submit reports of device adverse events or product problems to FDA through the MedWatch program in one of the following ways:

- online at: **MedWatch** Online Reporting Form 3500
- by telephone at 1-800-FDA-1088
- by fax at 1-800-FDA-0178
- by mail to:
    - MedWatch
      Food and Drug Administration
      5600 Fishers Lane
      Rockville, MD 20857
- **Update on FDAMA**
- **Update on FDAMA**
- **Update on FDAMA**

MANDATORY MedWatch Reporting for User Facilities, Importers and Manufacturers (Form FDA 3500A)

Manufacturers, User Facilities, and Importers are required to submit certain adverse events to FDA.

Find reporting information at: (SEE LINKS)

- Medical Device Reporting
- Instructions for Completing Form FDA 3500A
- Form FDA 3500A
- MDR Coding Tools / Resource Files

Forms must be mailed to:

FDA
Center for Devices and Radiological Health
Medical Device Reporting
P. O. Box 3002
Rockville, MD 20847-3002

Alternatively, for carrier service deliveries:

FDA
Center for Devices and Radiological Health
Medical Device Reporting
16071 Industrial Drive, Room 258
Gaithersburg, Maryland 20877-1462

To Report an Emergency

FDA Office of Crisis Management, Emergency Operations Center

- Voice (24hr/day) phone: 866-300-4374 or 301-796-8240
- FAX: 301-847-8543

Form 3419 Annual User Facility Report

- Medical Device Reporting Annual User Facility Report - Form FDA3419 (PDF - 30KB)
- Instructions for Completing the Medical Device Reporting Annual User Facility Report, Form FDA3419

For Questions about Medical Device Reporting, including interpretation of MDR policy:

- Call: (301) 796-6670 (voice)
- Email: MDRPolicy@fda.hhs.gov
- Or write to:
    - Food and Drug Administration
      Center for Devices and Radiological Health
      MDR Policy Branch
      10903 New Hampshire Avenue
      WO Bldg. 66, Room 3217
      Silver Spring, MD 20993-0002

For general device questions, please contact the DSMICA (Division of Small Manufacturing, Industry and Consumer Assistance) by telephone at 301-796-7100, or by email at industry.devices@fda.hhs.gov.

MEDICARE ELIGIBILITY

Eligibility for the Medicare home health benefit is defined in the Medicare Benefit Policy Manual, CMS Pub.100-2 :
(see http://www.cms.hhs.gov/manuals/102_policy/bp102index.asp) and includes conditions patients must meet to qualify for coverage, such as:

- Patient is confined to the home;
- Services are provided under a plan of care established and approved by a physician;
- Patient is under the care of a physician; and
- Patient needs skilled nursing care on an intermittent basis or physical therapy or speech therapy services or has continued need for occupational therapy.

MEDICAID

Medicaid is a joint federal and state program that helps with medical costs for some people with limited income and resources. Medicaid also offers benefits not normally covered by Medicare, like nursing home care and personal care services.

MEDICAID CONTACT

- When you have questions about Medicaid letters you receive, prior authorization, other Medicaid policy:
  - Contact the Medicaid area office - see the web site for phone # & email link http://ahca.myflorida.com/Medicaid
- When you have questions about your Medicaid audit:
  - Call the person that sent the letter at the telephone number in the letter. Ask to speak to that person's supervisor too, if needed.

Outcome and Assessment Information Set (OASIS)

OASIS is a group of data items designed for the purpose of enabling the rigorous and systematic measurement of patient home health care outcomes, with appropriate adjustment for patient risk factors affecting those outcomes.

Outcomes have been defined in many ways, but those derived from OASIS items have a very specific definition: they measure changes in a patient's health status between two or more time points.

The OASIS was designed to provide the necessary data items to measure both outcomes and patient risk factors. The OASIS is therefore key to outcome measurement and performance improvement using outcomes. OASIS data items address socio - demographic, environmental, support system, health status, functional status, and health service utilization characteristics of the patient. The data are collected at start of care, 60-day follow-ups, and discharge (and surrounding an inpatient facility stay).

OASIS PRIVACY ACT STATEMENT

During admission, on the patient's initial evaluation visit, or the patient's first professional visit the Agency needs to provide written information to the patients regarding the patient's rights, and will also include the statement concerning the collection and reporting of OASIS information.

The OASIS database is subject to the requirements of the Federal Privacy Act of 1974. The Privacy Act allows the disclosure of information from a system of records without an individual's consent if the information is to be used for a purpose that is compatible with the purposes for which the information was collected. However, under existing patient's rights regulations, the Agency must provide the patient with a written notice of this collection of information, i.e., OASIS in advance of furnishing care to the patient.

Before comprehensive assessments (that include collection of OASIS data items) are conducted, the HHA must tell patients about OASIS and explain their rights with respect to the collection and reporting of OASIS information.

These rights include:

1. The right to be informed that OASIS information will be collected and for what purpose;
2. The right to have the information kept confidential and secure;
3. The right to be informed that OASIS information will not be disclosed except for legitimate purposes allowed by the Privacy Act;
4. The right to refuse to answer a specific question; and
5. The right to see, review, and request changes on their assessment.

A standard notice to patients that explains these rights in plain language was published in the "Federal Register" on June 18, 1999, (64 FR 32984) and is available in English and Spanish on the OASIS website (http://www.cms.hhs.gov/oasis/). The Agency must present and explain this required notice to beneficiaries before their initial OASIS assessment.

Condition of Participation: Release of Patient Identifiable OASIS Information.
The Agency and agent acting on behalf of the HHA in accordance with a written contract must ensure the confidentiality of all patient identifiable information contained in the clinical record including OASIS data, and may not release patient

identifiable information to the public.

Protection of confidentiality of OASIS information is two-fold; the HHA has a responsibility to keep OASIS information confidential and CMS has a responsibility to keep it confidential, once it has been transmitted to the OASIS State system.
Under this condition of participation, the HHA is required to maintain the confidentiality of OASIS data while it is being used for patient care and may not release it without the consent of the patient for any reason other than for what it is intended, which is to appropriately deliver patient care.

COLLECTION OF OASIS DATA

The Agency will continue to collect OASIS data on all patients including non-Medicare/non-Medicaid patients as part of the comprehensive assessment of patients. The agency will collect, encode, and transmit OASIS data for the non-maternity Medicare and Medicaid patients that are age 18 and over and receiving skilled services.

Private pay patients are defined to include any patient for whom the Current Payment Source for Home Care does not include any of the following responses:
1- Medicare (Traditional fee-for-service)
2- Medicare (HMO/ managed care)
3- Medicaid (Traditional fee-for-service)
4- Medicaid(HMO/managed care).

If a patient has a private pay insurance and M0150 response 1, 2, 3, or 4 as an insurance to which the agency is billing the services, the comprehensive assessment including
OASIS must be collected and transmitted. Medicare (HMO/managed care) does include Medicare Advantage (MA), formerly known as Medicare+Choice (M+C) plans and Medicare PPO plans.

Reporting OASIS data

The Agency or contracted entities acting on behalf of the HHA will report OASIS data to the State agency using the HAVEN software CMS provides free of charge or by using HAVEN-like software that conforms to the same specifications used to develop HAVEN.

Encoding OASIS Data

The Agency will encode and be capable of transmitting OASIS data for each agency patient within 7 days of completing an OASIS data set.

Rejected data

A complete listing of current record rejection criteria is available in the Agency Error Message Guide on the OASIS website (http://www.cms.hhs.gov/oasis/usermanu.asp).

Rejected data that requires correcting and re-transmitting must be received by the OASIS State system within the **same required time frame**. Submission of data with identified fatal errors does not justify extending the required time frame. While overdue assessments will be accepted, the Agency (or the contracted vendors) may not wait until the end of the month to transmit their OASIS data in case errors are identified that require re- transmittal or system problems develop that prevent transmission.
Entities submitting OASIS data to the State agency or CMS OASIS contractor on behalf of the Agency, such as corporate offices or vendors under contract, must share the feedback reports with the Agency in order for Agency to monitor the encoding and transmission process.

Correction of errors

The Agency will electronically correct the errors found in the production of OASIS submissions that has been transmitted to the SA or CMS OASIS contractor. There is no current time limit to correcting errors in previously submitted records.

To correct assessments containing key field errors:

HAVEN 5.0 or above gives the Agency the ability to electronically correct nearly any kind of assessment errors. A description of key fields vs. non-key fields is available on the OASIS website (http://www.cms.hhs.gov/oasis/).

Transmission of OASIS data:

The Administrator, Alternate Administrator, DON or any designated Registered nurse may be assigned to transmit OASIS data.
Transmit data using electronic communications software that provides a direct telephone connection from the Agency to the State agency or CMS OASIS contractor.

The Agency will have a computer system that supports dial-up communications for the transmission of OASIS data to the State agency or CMS OASIS contractor, transmits the

export files, and receives validation information.
Corporate offices or contracted vendors submitting OASIS data on behalf of the HHA must provide the HHA with either an electronic copy of the validation information received from the State agency or CMS OASIS contractor, or a summary of that information.

The Agency will use the Medicare Data Communication Network (MDCN) to connect to the State agency for submission of OASIS data. When incorporation is complete, OASIS data from branch locations may be submitted directly by the branch as long as the
appropriate user identification and passwords have been obtained.

Data Format

The HHA will encode and transmit data using the software available from CMS or software that conforms to CMS standard electronic record layout, edit specification, and data dictionary, and that includes the required OASIS data set.

To correct transmission problems, the Agency may:
notify the State, or use HAVEN as a backup software program or change software Vendor and notify the State.

ON-CALL /24 Hr Availability

The home health agency shall have written policies and procedures governing 24 hour availability to licensed professional nursing staff by active patients of the home health agency receiving skilled care.

These procedures shall describe an on-call system whereby designated nursing staff will be available to directly communicate with the patient. For agencies which provide only home health aide and homemaker, companion and sitter services and who provide no skilled care, written policies and procedures shall address the availability of a supervisor during hours of patient service.

Failure to be available or to respond, as defined in paragraphs (a) through (c) above, will result in a $500 fine, pursuant to Section 400.474(1), F.S. A second incident will be grounds for denial or revocation of the agency license.

PHYSICIANS

Medical director – only 1 per HHA permitted

- ✓ Must have written contract, at least 1 year term
- ✓ Payment must be at fair market value for an hourly rate
- ✓ Invoices for medical director payment describe the work performed, the dates on which that work was performed, & the duration of that work

Federal regulations for Medicare & Medicaid HHAs require a group of professional personnel to advise on policies, participate in evaluation of the HHA's programs, maintain liaison with other community agencies, assist with community information…. One has to be a physician. (42 CFR 484.16).

PATIENT RIGHTS

The Agency has a responsibility to inform the patient of his or her rights. Patient rights should be explained to **ALL** patients admitted to the HHA. However, HHAs treat patients whose physical, mental, and emotional status varies widely. Overall, there should be evidence that the HHA has conscientiously tried, within the constraints of the individual situation, to inform the patient in writing, and orally of his/her rights.

If in a particular situation the HHA determines that the patient, despite the HHA's best efforts, is unable to understand these rights, a notation describing the circumstances should be placed in the patient's clinical record. The notation should be consistent with the patient's diagnosis, general state of physical or mental health, and/or other recorded clinical information, environmental information, or observations.

NOTICE OF RIGHTS

The HHA needs to provide the patient with a written notice of the patient's rights in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment.

HIRING OR CONTRACTING FOR AIDES:

The Agency may hire or contract for aides/ HHA who have already completed a training and competency evaluation or competency evaluation program, or make arrangements for home health aides to attend a training and competency evaluation or competency evaluation program provided by another entity.

A home health aide may receive training from different organizations if the amount of training totals 75 hours, the content of training addresses all subjects listed at and the organization, training, instructors, and documentation meet the requirements of the regulation.

Documentation of training should include:

A description of the training/competency evaluation program, including the qualifications of the instructors,

A record that distinguishes between skills taught at a patient's bedside, with supervision, and those taught in a laboratory using a volunteer or "pseudopatient," (not a mannequin) and indicators of which skills each aide was judged to be competent; and

How additional skills (beyond the basic skills listed in the regulation) are taught and tested if the admission policies and case-mix of HHA patients require aides to perform more complex procedures.

Competency Evaluation In-Service Training

The Agency must ensure that skills learned or tested elsewhere can be transferred successfully to the care of the patient in his/her place of residence. The Agency needs to give careful attention to evaluating both employees and aides who provide services under arrangement or contract.

This review of skills could be done when the nurse installs an aide into a new patient care situation, during a supervisory visit, or as part of the annual performance review.

PHYSICIAN ORDERS

Medicare & Medicaid HHAs - The *treating or attending physician* that ordered the service is to sign the order. (This is not necessarily the primary care physician.)

All Medicare & Medicaid services require a physician's order. Medicaid allows ARNP, PA if physician also signs the order.

Licensed-only HHAs – Nursing or therapy services requires an order from a physician, ARNP, or PA.

Treatment orders means written orders signed by a physician, physician assistant, or advanced registered nurse practitioner, acting within his or her respective scope of practice, which authorizes the provision of care or treatment to a patient in his place of residence by licensed Nurses, Physical Therapists, Occupational Therapists, Speech Therapists, or Dietitians/ Nutritionists.

Verbal orders are put in writing and signed and dated with the date of receipt by the nurse or qualified therapist responsible for furnishing or supervising the ordered services.
Verbal orders will be countersigned by the physician as soon as possible. Verbal orders can be faxed to MD office or dropped off at MD office for signatures.

All physician orders will be included in the patient's clinical record.

Physician Orders/ Admission Order

When a resident is admitted to the facility, the institution has to have physician orders for the resident's immediate care. These orders should include, at least, the resident's medications, diet and routine care to maintain or improve the resident's functional abilities until the healthcare worker/ staff can complete a comprehensive assessment and develop a comprehensive interdisciplinary plan of care.

When the transfer orders are confirmed with the attending physician, the physician may add or delete some of the orders provided via the transfer document. These should be documented, as appropriate, following documentation standards.

Content of the Order

The physician's order should include the medication or treatment, the correlating reason or medical diagnosis. The medication order should include dosage, strength, the route of administration, frequency, and reason for administration should be documented in the order.

Telephone Orders

All orders that were received by telephone should be countersigned by the physician in the required timeframe as defined by state law. The documentation should indicate that the verbal order was read back and was verified with the physician. Follow your facility's policy regarding the appropriate timeframe for countersignature (some state may not indicate timeframe).

Standing Order

Standing orders have to be used with caution. Standing orders should not be used in place of notification to the physician of a change in status; the nurse has to update the physician with changes in resident's status. Some states do not allow the use of standing orders.

Transcription of Orders and Noting Orders

Transcription of orders, for example telephone orders, is the responsibility of the professional nurses (RN, LPN/LVN per the scope of practice defined by State law/practice acts), can also be delegated to a trained individual if allowed by state law or practice acts. If the transcription of order was delegated, the nurse still has to sign off on the order and retain the responsibility for accurate transcription. When the telephone order or fax order is transcribed into the resident's medical record, it should be transcribed/ documented "verbatim" as given from the physician.

Contacting the physician and obtaining the order

Nurses, Therapists and other professionals designated to take orders has to first contact the physician to obtain the order. Each resident's medical care has to be supervised by a licensed physician. Licensed nurses are not authorized to independently write the physician orders without first contacting the physician and receive direction of the physician. It is not acceptable to write the telephone order, implement the order and then send the order for signature without contacting the physician. The nurse practitioner and physician assistant has the authority by law and scope of practice to write orders on behalf of a physician.

Documentation regarding discontinuing an order when a new order is obtained

Accurate and complete documentation has to be complete when the physician changes a physician order that is currently in use. The original physician order must be discontinued first then the new order has to be written that reflects the change.

Accepting orders from a Nurse Practitioner (NP)/Physician Assistant (PA)

Orders should only be accepted from a nurse practitioner or physician assistant if the state practice acts allows the nurse practitioner or physician assistant to give orders or prescribe and the attending physician has given authorization through a scope of care agreement. Both the scope of care agreement with the attending physician and a copy of the nurse practitioner or physician assistant's license should be kept on file by the facility.

Documentation in the Medication and Treatment Records

Medication administration record (MAR) and treatment administration record (TAR) are derived from the physician orders. Nurses are required to document the delivery of medications and treatments, by placing their initials in the blocks of the MAR and TAR

form when the medication or treatment has been administered. Some facility requires the initials to be circled if the medication or treatment was not administered / completed and to document the reason in the medical record, with appropriate to physician as needed. There should be no spaces or gaps noted in the Medication administration record (MAR) and treatment administration record documentation.

The medical record may also contain a legend that matches staff initials with full signature and title. Any medications and / or treatments given on a as needed (PRN) basis must be initialed, and the information pertaining to the need for the PRN, documented either on the back of the Medication administration record and treatment administration record or elsewhere in the resident's medical record as required by the facility's policy.

For electronic records; the Medication and Treatment Records may only have the initials on the Medication administration record and treatment administration record, either on print or view. Some electronic medication administration records (e-MARs) may be able to perform audit functions at the end of medication pass to make sure that all required documentation is in place.

Documentation regarding New Medication and Treatment Records on Readmission

Documentation of medications and treatments within the resident's medical record is crucial when the patient returns from another setting such as the hospital. To eliminate possible errors in transcription or administration of medications and treatments, new medication and treatment records should be initiated with a return from the hospital rather than continuing on the previous record. The new medication and treatment records would be based on the new orders received after hospitalization.

PLAN OF CARE

Plan of Care means a coordinated plan, which includes the treatment orders, prepared by the case manager in collaboration with each professional discipline providing service to the patient and caregiver.

The plan of care developed in consultation with the agency staff covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items.

(1) A plan of care shall be established in consultation with the physician, physician assistant, or advanced registered nurse practitioner, pursuant to Section 400.487, F.S., and the home health agency staff who are involved in providing the care and services required to carry out the physician, physician assistant, or advanced registered nurse practitioner's treatment orders. The plan must be included in the clinical record and available for review by all staff involved in providing care to the patient. The plan of care shall contain a list of individualized specific goals for each skilled discipline that provides patient care, with implementation plans addressing the level of staff who will provide care, the frequency of home visits to provide direct care and case management.

(2) Home health agency staff must follow the physician, physician assistant, or advanced registered nurse practitioner's treatment orders that are contained in the plan of care. If the orders cannot be followed and must be altered in some way, the patient's physician, physician assistant, or advanced registered nurse practitioner must be notified and must approve of the change. Any verbal changes are put in writing and signed and dated with the date of receipt by the nurse or therapist who talked with the physician, physician assistant, or advanced registered nurse practitioner's office.
(3) The patient, caregiver or guardian must be informed by the home health agency personnel that:
(a) He has the right to be informed of the plan of care;
(b) He has the right to participate in the development of the plan of care; and
(c) He may have a copy of the plan if requested.

If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modification to the original plan.

Orders for therapy services include the specific procedures and modalities to be

used and the amount, frequency, and duration.

The therapist and other agency personnel participate in developing the plan of care

The Agency may accept physician's orders on referral communicated verbally by an institution's discharge planner, nurse practitioner, physician's assistant, or other authorized staff member followed by written, signed and dated physician's orders, in order to begin HHA services as soon as possible.

The Agency will accept signed physician certification and recertification of plans of care, as well as signed orders changing the plan of care, by telecommunication systems (fax) which are filed in the clinical record.

The plan of care must be established and authorized in writing by the physician based on an evaluation of the patient's immediate and long term needs. The HHA staff, and if appropriate, other professional personnel, shall have a substantial role in assessing patient needs, consulting with the physician, and helping to develop the overall plan of care.

The patient has the right, and should be encouraged, to participate in the development of the plan of care before care is started and when changes in the established plan of care are implemented.

The total plan of care is reviewed by the attending physician and HHA personnel as often as the severity of the patient's condition requires, but at least once every 60 days or more frequently when there is a beneficiary elected transfer; a significant change in condition resulting in a change in the case-mix assignment; or a discharge and return to the same HHA during the 60-day episode.

Changes in the patient's condition that require a change in the plan of care will be documented in the patient's clinical record.

To monitor the delivery of services, including those provided under arrangement or contract, to ensure compliance with the specificity and frequency of services ordered in the plan of care -

All disciplines will provide visit notes, reports/progress to Agency in accordance to the Policy & procedures.

All disciplines will document in the patient's home chart on each visit.
The Agency will ensure that all disciplines communicate effectively with the Agency/ DON /supervisors. All disciplines will call Agency to update on any emergency or

change in status of the patient (s) and if patient is not home at time of visits/ missed visit.

Frequency of visits:

The Agency will ensure that the frequency of visits meets the clinical needs of the patient(s)

The Agency will follow the physician's order regarding the frequency of visits. If the need arise for changes to be implemented; the physician will be updated regarding the patient's status and the need for changes with the frequency of visits to ensure that the patient will attain and maintain his or her highest practicable functional capacity based on medical, nursing, and /or rehabilitative needs

Management and Evaluation of a Patient Care Plan

Skilled nursing visits for management and evaluation of the patient's care plan are also reasonable and necessary where underlying conditions or complications require that only a registered nurse can ensure that essential non - skilled care is achieving its purpose.

For skilled nursing care to be reasonable and necessary for management and evaluation of the patient's plan of care, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of skilled nursing personnel to promote the patient's recovery and medical safety in view of the patient's overall condition.

QUALITY ASSURANCE PLAN

Quality assurance plan means a plan which is developed and implemented by a home health agency:

1. To review and

2. Evaluate the effectiveness and appropriateness of service provision to patients and, upon identification of problems, requires specific action to correct the problems and deficiencies

SERVICES

In cases of patients requiring only nursing, or in cases requiring nursing and physical, respiratory, occupational or speech therapy services, or nursing and dietetic and nutrition services, the agency shall provide case management by *a licensed registered nurse directly employed by the agency*.

In cases of patients receiving only physical, speech, respiratory or occupational therapy services, or in cases of patients receiving only one or more of these therapy services and home health aide services, case management shall be provided *by the licensed therapist, who is a direct employee of the agency or a contractor*.

SATELLITE OFFICE

Satellite office means a secondary office established in the same county as the main office, pursuant to subsection 59A-8.003(7), F.A.C.

A satellite office must be located in the same county as the agency's main office. Supplies and records can be stored at a satellite office and phone business can be conducted the same as in the main office.

The satellite office shares administration with the main office and is not separately licensed. Signs and advertisements can notify the public of the satellite office location. If the agency wants to open an office outside the county where the *main office* is located, the second office must be separately licensed.

A licensed home health agency may operate a drop-off site in any county within the geographic service area specified on the license.

A drop-off site may be used for pick-up or drop-off of supplies or records, for agency staff to use to complete paperwork or to communicate with the main office, existing or prospective agency staff, or the agency's existing patients. Prospective patients cannot be contacted and billing cannot be done from this location.

The drop-off site is not a home health agency office, but merely a work station for direct care staff in large areas where the distance is too great for staff to drive back frequently to the home health agency office. A drop-off site shall not require a license.

No other business shall be conducted at these locations, including housing of records. The *agency name cannot appear at the location, unless required by law or by the rental contract, nor can the location appear on agency letterhead or in advertising*.

SOCIAL WORKER

Social Worker means a person who has a degree in social work and who works with patients and families to help them adjust to the social and emotional factors related to the patient's health problems.

SIGNIFICANT CHANGE IN CONDITION (SCIC)

A Significant Change In Condition (SCIC) adjustment occurs when a Medicare beneficiary experiences a significant change in condition during a 60-day episode that was not envisioned in the original plan of care.

In order to receive a new case-mix
assignment for purposes of SCIC payment during the 60-day episode, the HHA must complete an OASIS assessment and obtain the necessary physician change orders reflecting the significant change in treatment approach in the patient's plan of care. Refer to current policy for the use of the OASIS assessment for SCIC adjustments.

SPECIAL NEEDS

"Special needs patients" pursuant to Section 252.355, F.S., means those persons who have physical or mental conditions that require limited medical and nursing oversight during emergency evacuations. They are medically dependent individuals who are not acutely ill.

Special needs registry" pursuant to Section 252.355, F.S., means a registry maintained by the local emergency management agency of persons who need assistance during evacuations and sheltering because of physical or mental handicaps.

SURVEY

If an AHCA surveyor arrives on the premises to conduct an unannounced survey and the administrator, the director of nursing, or a person authorized to give access to patient records, are not available on the premises they, or the designated alternate, must be available on the premises **within an hour** of the arrival of the surveyor. A list of current patients must be provided to the surveyor **within two hours** of arrival if requested.

If you do not agree with the surveyor:

1. Ask the surveyor to show you the survey standard or law, rule

2. Discuss with surveyor at Exit Interview

3. Contact the AHCA Field Office Manager

   http://ahca.myflorida.com/MCHQ/areas

4. If still not resolved, contact Chief of Field Operations (850) 412-4301

When you have questions about your survey or any standard that was cited as not met:

- Call the Field Office Manager or Supervisor

  - When you have questions about laws, rules, the application form or requirements

- 1st check http://ahca.myflorida.com/homecare - select *Home Health Agency* or *Nurse Registry* - See *Frequently Asked Questions* or *State Regulation Set*
- Then call the Home Care Unit (850) 412-4403

or, send an email to

HQAHOMEHEALTH@ahca.myflorida.com

licensing or certification of home health aides/ In-Service Training

There is no state licensing or certification of home health aides in Florida. The State of Florida does not have a state-administered test of home health aides. There is no state law that requires the licensing or certification of home health aides in Florida.

Home Health Aides Who Were Licensed or Certified In Another State

Home health aides who were trained in another state must provide a copy of the course work and a copy of their training documentation, license or certification to the employing home health agency or nurse registry

To Work as Home Health Aide at the Agency
To work for a Medicare or Medicaid home health agency, a home health aide must **complete at least 75 hours of training and/or successfully complete a competency evaluation** given by the home health agency.

To work in a licensed-only agency the home health aide must complete at least 40 hours of training or successfully complete a competency test given by the home health agency. Some home health agencies require additional training above these minimum hours.

The agency may hire certified nursing assistants to work as home health aides. (See information below on certified nursing assistants.)

Please note: these are the ***minimum*** requirements. A home health agency may have its own additional requirements beyond the minimum for home health aides.

The Agency may provide training for persons that they employ as home health aides or offer a competency test to persons they employ instead of the training.

All home health aides employed by home health agencies and nurse registries must complete an HIV/AIDS training course. They also are required to obtain and maintain a current certificate in cardiopulmonary resuscitation (CPR).

Home health aides employed by Medicare and Medicaid home health agencies are required to have a total of 12 hours of in-service training during each 12-month period (this can be a calendar year or based on the date of hire). The HIV/AIDS training and CPR training may be counted toward meeting the 12 hours of in-service training.

MEDICATION MANAGEMENT

DRUG INDICATIONS FOR USE

An indication is a valid reason to use a certain medication, test, procedure, or surgery. The opposite of an indication is a contraindication; a reason to withhold a certain medication or medical treatment etc. due to the harm that it would cause the patient.

All medications have an indication for use. Most of the indications for use are related to the desired actions of the medication. If you do not know the indication for use of a medication that your patient is taking, use a reference such as a drug guide or ask your supervisor or a Pharmacist.

Some medications are not allowed to be used or they are contraindicated for some patients. Therefore, the medication should not be given to the patient. Other medications may only be used with some patients when they are used with extreme caution and with frequent monitoring.

A very common contraindication is an allergy or sensitivity to the medicines. Always check the patient's medical record for allergies and ask the patient before you assist. Sometimes you will observe NKA on the patient's medical record /chart; this indicates that the patient has no known allergies. Sometimes you may observe NKDA- this means no known drug allergies.

ALLERGY

Allergy involves hypersensitivity or an exaggerated response of the immune system, often to common substances such as medication, pollen or foods. A rash or a life threatening reaction such as Anaphylaxis can occur if the patient takes a medication that he/ she is allergic to.

Some types of Allergies include:

- Food allergies e.g. peanuts, peanut butter, shellfish
- Drug allergies
- Latex allergies e.g. latex gloves
- Seasonal allergies
- Animal allergy

Some signs of Allergic reactions include:

- Itching , Hives
- Redness of the skin
- Dyspnea, Shortness of Breath (SOB)
- Problems with breathing
- Throat swelling
- Loss of consciousness
- Irregular heart beat /rhythm
  Decrease in the blood pressure (BP)
  Abdominal discomfort / cramps

- Nausea and / or vomiting
- Death

Anaphylaxis

Anaphylaxis is a severe, whole-body *allergic reaction* to a chemical or substance that has become an allergen. An allergen is a substance that can cause an allergic reaction. Some drugs such as, Penicillin, aspirin, x-ray dye, morphine and others may cause an anaphylactic-like reaction when the patient is first exposed to them. Anaphylaxis is an emergency situation that requires medical attention immediately. Call 911 immediately.

Symptoms will develop very quickly, often within seconds or minutes. They may include:

- Difficulty breathing
- Facial swelling
- Redness of the skin
- Itchy /hives
- Light headed / dizziness
- Loss of consciousness
- Swelling of the face and eyes
- Chest tightness/ discomfort
- Palpitations
- High pitched abnormal breathing sounds
- Wheezing
- Coughing
- Speech becomes slurred
- Difficulty swallowing
- Swelling of the tongue
- Restlessness / anxiety
- Diarrhea
- Abdominal pain
- Nausea or vomiting
- Death

Medication interactions

Some medications may interact with other medications, various herbs, foods, supplements and drink for example; alcohol. Medication interactions can cause the medication that the patient is taking, to be less effective, or cause unexpected side effects, or cause an increase action of a particular medication. Some drugs interaction

can be very harmful to the patient. Always read the medication label for every prescription and nonprescription medications.

Take the time to learn about the medication interactions. You will reduce the risk of potentially harmful medication interactions and / or side effects.

Medication interactions fall into three categories:

Drug to drug interactions
Drug to drug interaction occur whenever two or more medications react with each other. This drug-drug interaction may cause the patient to experience an undesired side effect / reaction, for example, patient who takes a blood thinner e.g. Coumadin and then takes aspirin for a headache will increase the risk of bleeding.

Drug to food/beverage interactions
Drug to food / beverage interactions result from medications reacting with the food or drink. For example, having alcohol with some medications may cause the patient to feel sleepy or slow his/ her reaction.

Drug to condition interactions
Drug to condition interactions may occur when the patient has an existing medical condition / disease that makes some medications potentially harmful. For example, patients with high blood pressure may experience an undesired reaction if he/she takes a cough or decongestant medication.

ADVERSE REACTIONS / SIDE EFFECTS

Side effects

A side effect is also known as an adverse effect, adverse event, or undesirable secondary effect when a medication or treatment goes beyond the desired effect and causes or leads to a problem (an undesirable secondary effect). Some side effects are not life threatening but others can be life threatening.

Side effects vary for each patient, and depend on different factors such as;

- the patient's general health,
- age,
- the stage of their disease,
- weight and
- Gender.

Adverse drug reactions

Adverse drug reactions are serious and they can also lead to death. Some medications also have toxic effects. Learn about the possible adverse drug reactions, side effects and the toxic effects of all the medications that your patient is taking so that you can report them.

DOSAGES/ DOSES

All medications have prescribed amount or dosage ranges for the adults and for children. Older patients are at greater risk for adverse drug events because of the metabolic changes and decreased medication clearance that is associated with the aging process. Some adult dosages may be lowered for the older patient because they are more susceptible to adverse medication reactions, side effects, over dose and even toxicity. Adolescents can take the adult dosages. Children are given medications with a dose that is based on their body weight.

Toxicity

Toxicity is the degree to which a substance /a toxin can cause harm to humans or animals.

- Acute toxicity involves the harmful effects in an individual or organism through short-term exposure.

- Subchronic toxicity is the ability of a toxic substance to cause effects for more than one year but less than the lifetime of the exposed organism.

- Chronic toxicity is the ability of a mixture of substances or a substance to cause harmful effects over an extended time period, usually upon continuous or repeated exposure, that can sometimes last for the entire lifetime of the exposed organism/ individual.

Toxicology is the study of adverse and/or toxic effects of drugs/medications and other chemical agents. It involves both drugs used in the treatment of diseases as well as chemicals that may cause environmental, household or industrial hazards.

Medication Routes and Forms

Route of medication administration refers to the path by which the medication is taken into the body. Medications are made in various forms and for administration by different routes. Some routes may be unsafe or ineffective. This can be due to the patient's health conditions, such as unable to swallow, dehydration or other factors. Some medications can be administered by more than one route, for example Tylenol is available in tablet form, suppository and also in liquid etc. The tablet may be taken by mouth in tablet or liquid form; however, a child might not be able to take the tablet and able to take the liquid and/ or a suppository may need to be given by a nurse per rectum if the patient is unable to take the medication by mouth. The medication order has to state the form and the route that the physician wants the patient to take.

Route of administration will vary depending on:

- The property of the medication,
- Its action of the medication,
- The desired effect,
- The patient's physical wellbeing,
- The patient's mental status,
- The patient's age.

Routes of medication administration include:

• oral route (by mouth)
• sublingual route (under tongue)
• buccal route (inside the cheek)
• otic (ear)
• ophthalmic (eye)
• topical (applied on the skin)
• nasal route (nose)
• vaginal route (vagina)
• rectal (by rectum)
• inhalation (by inhaling)
• nasogastric tube (tube in the nose to the stomach)
. gastrostomy tube (tube in the stomach)
• intramuscular (into the muscle)
• subcutaneous (under skin)
• intradermal (in the skin)
• intravenous (into the vein via an I.V)
• transdermal (through the skin e.g. a patch on the skin)

Forms of medications

Medications are made in various forms meaning that they are available in more than one form. Therefore a tablet cannot be given if the order says liquid.

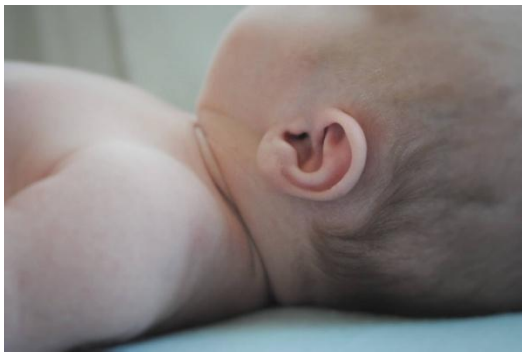
Different forms of medications include:

- capsule (regular and sustained release)
- tablet
- suppositories (rectal and vaginal)
- elixir
- syrup
- cream
- oral suspension
- tincture
- paste
- ointment
- drop (ears and eye)
- Intravenous /IV solutions and suspension
- metered dose inhaler

Some Route and Form considerations

When a patient is very ill or has a problem such as difficulty with swallowing, the following things can be done:

- Crush the pill and put it into applesauce or open the capsule and put it into applesauce. Some medications **cannot be crushed**. Some of these medications include time release capsules, sublingual medications, some coated tablets and other medications that may upset the stomach. Check with the Pharmacist or supervisor to find out if a medication can be crushed or what that medication can be mixed with.
- Use the liquid form of the medication. Using a liquid form can also help patients who have trouble swallowing or using the tablets and/or the capsules. At other times the nurse may have to administer the medication by I.V.



MEDICATION DELIVERY CONSIDERATIONS

Age is one factor that you must consider when giving medications;

- For an infant you may use a dropper, syringe or nipple for liquid oral medication.
- For the toddler you may use a cup or spoon for oral liquid medication.
- For the preschool and School Age children, they may be able to take tablets and capsules.
- For adolescents, they are allowed to take adult dosages, forms and routes of Medications.

ELDERLY POPULATION

The gastrointestinal (GI) tract

The gastrointestinal tract may change as the individual get older and this may affect how some medications are absorbed. The aging process can reduce gastrointestinal motility and gastrointestinal blood flow.

Gastric acid secretion is reduced in older adults and this can result in an elevation in gastric pH. Increased gastric pH and reduced gastric blood flow may cause reduced drug absorption, whereas reduced gastrointestinal motility may result in more of the medications being absorbed.

DISTRIBUTION OF THE DRUG

As the individual gets older, the aging process can have a significant effect on how the medication is distributed in the body. As the body ages, there are several age related changes; muscle mass declines and proportion of body fat increases.

The aging process also is associated with a reduction in total body fluids (water), which can affect the volume of distribution of water-soluble drugs. Older individuals in general produce less albumin, which binds drugs in the bloodstream. Reduction in albumin; protein binding, may result in an increase in free drug concentration.

Healthcare providers / physicians need to take these changes into consideration when prescribing medications to the older adults. If these changes are not taken into consideration, this can result in drug toxicity, among other anomalies.

DRUG METABOLISM

The aging process can also affect drug metabolism. Several physiological changes occurs in the elderly that can influence metabolic capacity such as; hepatic blood flow is decreased / reduced in the elderly adult, this can affect metabolism because the medication is introduced to the liver at a much lower rate. During the aging process, liver mass and the intrinsic metabolic activity (CYP450 enzyme system) is also reduced.

EXCRETION

Aging changes in the kidneys
As mentioned earlier, the kidneys have multiple functions including:

- Filtering the blood and help to remove waste and excess fluid from the body.
- The kidneys also assist in controlling the body's chemical balance.

The urinary system includes:

- The kidneys, ureters, bladder, and the urethra.

Aging Changes and the effects on the Kidneys

- As the individuals get older, the kidneys and the bladder change. This can definitely affect their function.
- Muscular changes and changes in the reproductive system also affect bladder control.

Within a healthy aging individual, kidney function remains normal. However with illness, medications, and other conditions may cause changes in the kidney function.

Changes in the kidneys:

As the individual gets older the amount of kidney tissue also decreases. The nephrons, (filtering units in the kidneys) also decreases. The nephrons are responsible for filtering waste material from the blood; therefore, what will happen when this function is not taking place effectively? Filter function is not doing the work it should be doing. The blood vessels that supply the kidneys can also become hardened. This will affect the rate at which the kidneys will filter blood (slower rate). The reduction in glomerular filtration rate will influence dosing / dosage of medications; knowing which medications are excreted renally and knowing how to adjust the dosage of those medications in patients with renal impairment is vital to ensure safe and effective drug dosing in all patients

Due to the physiological changes in the elderly individuals, they may also be at high risk for certain drug adverse effects. Many older individuals are prone to the effects that certain medications have on the central nervous system; such as confusion, sedation, dizziness and seizures. These effects cause problems for the elderly persons, who may be extremely sensitive to any drug-induced actions on the central nervous system.

PEDIATRIC

The absorption, distribution, excretion and metabolism of medication can vary throughout infancy, early childhood and puberty.

Drug Absorption
Drug absorption in infants and children can be altered from adult values by 2 factors:

- Gastrointestinal (GI) function and
- Blood flow at the site of administration (rectal, intramuscular or percutaneous).

Most medications that are administered orally are absorbed in the small intestine.

Since infants have proportionately larger small intestinal surface areas, this may result in unpredictable absorption compared with adults. Infants have increased intestinal motility, which can alter the absorption of medications with limited water solubility. (PA and NP 2016).

Neonates have reduced lipase secretion, which decreases the ability for the neonate to absorb lipid formulations. Gastric pH is higher in the neonate (pH >5) and infant (pH 2-4). Gastric pH reaches adult levels (pH 2-3) at age 20 months to 30 months.

Young infants (<12 months) have increased percutaneous absorption of topical medications due to well-hydrated, thinner stratum corneum. Systemic toxicity may occur with small amounts of topical application of medications.

Distribution

Within the 1st few months of life, there are changes within body composition that alters the physiologic spaces in which medications are distributed.

Infants and newborns have a higher percentage of body water; 70% - 80% (infants) and in adults; 60%. The percentage of total body water is related to the amount of body fat; at maturity, men have slightly higher total body water than women, mainly due to the differences in body composition.

The % of body water in infants, neonates and during puberty can affect the dosing of some medications drugs.

Infants, who are younger than 6 months old, have less plasma proteins available for drug binding. This will cause increase levels of unbound medications, resulting in drug toxicity, this may occur with normal or low plasma concentration of total drug.

The blood-brain barrier is incomplete and permeable in the newborn, leading to increased central nervous system (CNS) effects of some medications. Phenobarbital levels in the brains of neonates are higher than phenobarbital levels in older children and adults.

Elimination

Renal elimination rates are affected by the lower glomerular filtration rate in newborns, which is only 30% to 40% of adult values. The glomerular filtration rate rises in the first 2 weeks of life in the preterm and term neonate; birthweight >1,500 g.

By age 6 to 12 months, the glomerular filtration rate reaches adult values. Any medication that depends on renal excretion are cleared slowly in neonates.

- Drug dosages and dosing intervals in newborns needs to be adjusted accordingly when prescribing certain medications.

Renal blood flow is also reduced in neonates and reaches adult levels at approximately 9 months old.

Metabolism

As mentioned earlier, most of the research has been conducted in the adult population.

In the very young neonate and infant, the delayed maturity of drug-metabolizing enzymes may account for drug toxicity. The pathways of drug clearance develop variably over the1st year of life and may be influenced by medications that induce drug-metabolizing enzymes.

There has been an increase in knowledge about the role of phase I cytochrome P450 and phase II enzymes in drug metabolism during the past few years, however a lot is still not known.

Pediatric formulations

Pediatric formulations for several medications are lacking. Many medications are effective in adults but not used in children because of the lack of pediatric formulations.

There is also not enough funding available for the development of liquid stable forms of medications.

The *Food and Drug Administration Modernization Act* (FDAMA) incentive encourages pediatric formulations of new medications, but there is not enough financial incentive for older medications.

One of the obstacles is that data about the stability of medications in liquid form is scarce.

Stability of medications can be affected by several factors, such as:

- Storage temperature,
- Type of container and vehicle; sugar can affect the stability of some medications.

The National Institute of Child Health and Human Development (NICHD) has established pediatric pharmacology research units (PPRUs) to facilitate the study of pediatric pharmacology. The mission of the pediatric pharmacology research unit network is to facilitate and promote pediatric labeling of new medications or drugs that are already on the market.

The pediatric pharmacology research units study the pharmacokinetics and pharmacodynamics of medications in a collaboration which involves pediatric academic researchers, pediatric clinical pharmacologists and industry.

SOME MAJOR CATEGORY OF MEDICATIONS

ALLERGY MEDICATIONS

Epinephrine injection

Epinephrine injection is used along with emergency medical treatment to treat life-threatening allergic reactions caused by medications, foods, insect stings or insect bites, latex, and other causes.

Epinephrine is in the class of medications called Alpha- and Beta-adrenergic agonists (sympathomimetic agents).

Epinephrine works by relaxing the muscles in the airways while it tightens /constricts blood vessels.

Epinephrine is a chemical that narrows blood vessels and opens airways in the lungs. These effects can reverse severe wheezing, hypotension (low blood pressure), severe itching of the skin, hives, and other symptoms of an allergic reaction.

Epinephrine injection is used to treat anaphylaxis (severe allergic reactions) to insect bites or stings, medications, foods and other allergens.

Epinephrine is also used to treat exercise-induced anaphylaxis.

Epinephrine auto-injectors such as EpiPen and EpiPen Jr. are available and should be kept on hand for self-injection by individuals with a history of an severe allergic reaction.

DESCRIPTION

Adrenalin® (epinephrine injection, USP) is a clear, colorless, sterile solution containing 1 mg/mL (1:1000) epinephrine, packaged as 1 mL of solution in a single-use clear glass vial or 30 mL of solution in a multiple-dose amber glass vial.

Epinephrine is a sympathomimetic catecholamine.
The chemical name of epinephrine is: 1,2-Benzenediol, 4-[(1R)-1-hydroxy-2-(methylamino)ethyl]-, or (-)-3,4-Dihydroxy-α-[2(methylamino)ethyl]benzyl alcohol.

Epinephrine solution deteriorates rapidly on exposure to air or light, turning pink from oxidation to adrenochrome and brown from the formation of melanin.

Pharmacokinetic properties
Epinephrine is rapid in onset and of short duration and is rapidly distributed to the heart, spleen, several glandular tissues and adrenergic nerves.

Epinephrine crosses the placenta and is excreted in breast milk.
Epinephrine is approximately 50% bound to plasma proteins. The onset of action is rapid and after i.v. infusion the half-life is approximately 5-10 minutes.

Epinephrine is rapidly metabolized in the liver and tissues.

PATIENT TEACHING

Possible side effects of epinephrine injection

Serious side effect may include:

- Increased breathing difficulty,
- Elevated BP (High blood pressure)
- severe headache,
- blurred vision,
- buzzing in the ears,
- anxiety,
- confusion,
- chest pain,
- shortness of breath,

- uneven heartbeats,
- seizure.

Less serious side effects may include:

- sweating
- nausea / vomiting
- pale skin
- feeling short of breath
- dizziness
- weakness
- tremors
- Headache
- feeling nervous
- anxious.

To report SUSPECTED ADVERSE REACTIONS, contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Adrenalin® is available as a single-use 1 mL vial and a multiple-use 30 mL vial.

- The 1 mL vial is for use intramuscular, subcutaneous, and intraocular use.
- The 30 mL vial is for intramuscular and subcutaneous use only, and is NOT FOR OPHTHALMIC USE.

Anaphylaxis (Adrenalin® 1 mL Single-Use and 30 mL Multiple-Dose Vials)

Emergency treatment of allergic reactions (Type I), including anaphylaxis, which may result from allergic reactions to insect stings, biting insects, foods, drugs, sera, diagnostic testing substances and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.

The signs and symptoms associated with anaphylaxis include:

- flushing,
- apprehension,
- syncope,
- tachycardia,
- thready or unobtainable pulse associated with hypotension,
- convulsions,
- vomiting,
- diarrhea and abdominal cramps,

- involuntary voiding,
- airway swelling,
- laryngospasm,
- bronchospasm,
- Pruritus
- Urticaria or angioedema
- swelling of the eyelids, lips, and tongue.

Induction and Maintenance of Mydriasis during Intraocular Surgery (Adrenalin® 1 mL single-use vial only)

Induction and maintenance of mydriasis during intraocular surgery.

Overdosage

Overdosage of epinephrine may produce elevated arterial pressure, which may result in cerebrovascular hemorrhage, especially in the elderly patient. Overdosage can also result in pulmonary edema due to peripheral vascular constriction together with cardiac stimulation.

- Treatment consists of a rapidly acting α-adrenergic blocking drug and respiratory support.

Epinephrine is rapidly inactivated in the body and treatment following overdose with epinephrine is primarily supportive. If necessary, pressor effects may be counteracted by rapidly acting vasodilators or α-adrenergic blocking medications.

Overdosage may results in extreme pallor and coldness of the skin, metabolic acidosis due to increased blood lactic acid level, and kidney failure. Appropriate corrective measures must be taken in such situations.

Warn patients with the diagnosis of diabetes that they may develop increased blood glucose levels after epinephrine administration.

Diphenhydramine (Benadryl)

Brand Names: *Aler-Tab, Allergy, Allermax, Altaryl, Benadryl Allergy, Benadryl DF, Benadryl Dye Free Allergy, Benadryl Ultratab, Children's Allergy, Diphen Cough, Diphenhist, Dytuss, PediaCare Children's Allergy, Q-Dryl, Q-Dryl A/F, Siladryl, Siladryl Allergy, Silphen Cough, Simply Sleep, Sleep-ettes, Sleep-ettes D, Sominex Maximum Strength Caplet, Theraflu Thin Strips Multi Symptom, Triaminic Thin Strips Cough & Runny Nose, Unisom Sleepgels Maximum Strength, Valu-Dryl*

Generic Name: Diphenhydramine
Diphenhydramine is an antihistamine.

Diphenhydramine blocks the effects of the naturally occurring chemical histamine in the body.

Diphenhydramine is used to treat sneezing; runny nose; itching, watery eyes; hives; rashes; itching; and other symptoms of allergies and the common cold.

Diphenhydramine is also used to suppress coughs, to treat motion sickness, to induce sleep, and to treat mild forms of Parkinson's disease and other purposes not listed.

DOSAGE

A typical dose of Benadryl is 25-50 mg every 4-6 hours.

Benadryl adds to the sedating effects of alcohol and other sedating medications.

Benadryl can intensify the drying effects of drugs with anticholinergic properties.

Benadryl has not been adequately evaluated in pregnant women. Benadryl is secreted in breast milk.

Because of the risk of stimulation and seizures in newborns and premature infants, antihistamines should not be used by nursing mothers.

INSTRUCT PATIENTS – CAUTION !!!

Use caution when driving, operating machinery, or performing other hazardous activities. Diphenhydramine may cause dizziness or drowsiness. Instruct patients that If they experience dizziness or drowsiness, avoid these activities.

Alcohol may increase drowsiness and dizziness while taking diphenhydramine.

Instruct patients not to take diphenhydramine if they have taken a monoamine oxidase inhibitor (MAOI). A very dangerous medication interaction could occur and lead to serious side effects.

PATIENT TEACHING (continue)

Before taking Benadryl, tell the physician/ healthcare provider if have

- glaucoma or increased pressure in the eye
- a stomach ulcer
- an enlarged prostate,
- bladder problems
- difficulty urinating
- hyperthyroidism
- hypertension
- any type of heart problems
- asthma.

Diphenhydramine is in the FDA pregnancy category B. This means that it is not expected to be harmful to an unborn baby.

Infants are especially sensitive to the effects of antihistamines, and side effects could occur in a breast feeding baby.

Instruct patients:

Do not take diphenhydramine without first talking to the healthcare provider if they are nursing a baby.

If patients are over 60 years of age, they may be more likely to experience side effects from diphenhydramine. They may require a lower dose of this medication.

Talk to the pharmacist or physician before taking other over-the-counter cold, cough, allergy, or other insomnia drugs. These products may contain medications that are similar to diphenhydramine, which may lead to an antihistamine overdose.

SIDE EFFECTS

Stop taking diphenhydramine and seek emergency medical attention if experience an allergic reaction such as: difficulty breathing; closing of the throat; swelling of the lips, tongue or face or develops hives.

Other, less serious side effects may be more likely to occur such as:

- sleepiness,
- fatigue,
- dizziness
- headache;
- dry mouth; or
- Difficulty urinating
- an enlarged prostate.

Common side effects of Benadryl include:

- Sedation,
- tiredness,
- sleepiness,
- dizziness,
- disturbed coordination,
- constipation,
- dry mouth
- dry nose
- dry throat,
- difficulty urinating,
- upset stomach.

Benadryl may also cause double vision, blurred vision, tremor, nausea loss of appetite, and other side effects may occur.

Side effects may be reported to FDA at 1-800-FDA-1088.

PHARMACOKINETICS

Absorption: Benadryl is well absorbed after PO (oral) or intramuscular (IM) administration and 40–60% of an oral dose reaches systemic circulation due to first-pass metabolism.

Distribution: Widely distributed; crosses the placenta- enters the breast milk.

Metabolism and Excretion: 95% metabolized by the liver.

Half-life: 2.4–7 hr.

Time / Action Profile (antihistaminic effects)

ROUTE	ONSET	PEAK	DURATION
PO	15-60 Min	2-4 hr	4-8 hr
IM	20- 30 min	2-4 hr	4-8 hr
IV	Rapid	unknown	4-8 hr

ANALGESICS (PAIN RELIEVERS)

TYLENOL

Tylenol (acetaminophen) is a pain reliever and a fever reducer.

Tylenol is used to treat many conditions such as headache, muscle aches, arthritis, backache, toothaches, colds, and fevers.

INDICATIONS

Temporary relieves minor aches and pains due to:

minor pain of arthritis
backache
the common cold
muscular aches
premenstural and menstrual cramps
headache
toothache
temporarily reduces fever

PATIENT TEACHING

Side effects of acetaminophen

Get emergency medical help if experience any of these signs of allergic reactions such as:

- Hives,
- difficulty breathing
- swelling of face,
- swelling of lips,
- swelling of tongue,
- swelling of throat.

Instruct patients to STOP taking the medication and call the physician immediately if they have serious side effects such as:

- nausea,
- upper stomach pain,
- itching,
- loss of appetite,
- dark urine,
- clay-colored stools,
- jaundice (yellow color to eyes or skin).

and other side effects may occur.

Overdose Management

In 1985, the United States Food and Drug Administration (FDA) approved acetylcysteine (N-acetyl cysteine (NAC) as an antidote for the treatment of acetaminophen overdose.

N-acetyl cysteine treats acetaminophen (Tylenol) poisoning by binding the poisonous forms of acetaminophen that are formed in the liver.

OVERDOSE

If overdose is suspected, contact a poison control center or emergency room immediately. US residents can call the local poison control center at 1-800-222-1222.

Symptoms of overdose may include:

- nausea,
- vomiting,
- loss of appetite,
- sweating,
- abdominal pain,
- stomach pain,
- extreme tiredness,
- yellowing eyes,
- yellowing of the skin,
- dark urine.

ASPIRIN

Aspirin is a salicylate. It works by reducing substances in the body that cause fever, pain and inflammation.

Aspirin is used to treat pain, and reduce fever or inflammation. It is sometimes used to treat or prevent heart attacks, strokes, and chest pain (angina).

Pharmacokinetics

Absorption:

Well absorbed from the upper small intestine

Absorption from enteric coated drugs may not be reliable

Rectal absorption is slow and variable.

Distribution:

Quickly and widely distributed

Crosses the placenta

Enters breast milk.

Metabolism and Excretion:

Metabolized by the liver – extensively

Inactive metabolites are excreted by the kidneys.

Half-life: 2–3 hr for low doses; up to 15–30 hr with larger doses because of saturation of liver metabolism.

TIME/ACTION PROFILE

ROUTE ONSET PEAK DURATION

PO 5–30 min 1–3 hr 3–6 hr

Contraindications/Precautions

Contraindicated in:

Hypersensitivity to aspirin or other salicylates;
Cross-sensitivity with other Nonsteroidal anti-inflammatory drugs (NSAIDs) may exist.

Bleeding disorders or thrombocytopenia;

Pediatric

May increase the risk of Reye's syndrome in children or adolescents with viral infections.

Use with caution in:

History of GI bleeding

History of ulcer disease

Chronic alcohol use

Alcohol abuse

Severe hepatic

Renal disease

OBSTETRIC:

Salicylates may have adverse effects on the fetus and the woman and should be avoided during pregnancy, especially during the 3rd trimester.

Lactation:

Safety is not established.

Geriatric: Increase risk of adverse reactions such as gastrointestinal bleeding

The elderly patients are more sensitive to toxic levels.

Lab Test

Hepatic function

Monitor hepatic function;

- Before antirheumatic therapy
- If symptoms of hepatotoxicity occur;
- Especially in patients; children with rheumatic fever, juvenile arthritis, systemic lupus erythematosus, or with pre-existing hepatic disorder /disease.

Serum ALT, AST and alkaline phosphatase

May cause increase serum ALT**,** AST and alkaline phosphatase, especially when plasma concentrations exceed 25 mg/100 mL.

Serum salicylate levels

Monitor serum salicylate levels periodically with prolonged high-dose therapy to determine safety, dose, and efficacy.

Prothrombin time; Bleeding time, Hematocrit

May prolong bleeding time for 4–7 days.

In large dosage, may cause prolonged prothrombin time.

Monitor hematocrit to assess for gastrointestinal blood loss, in prolonged high dose therapy.

Toxicity / Overdose

Monitor for the onset of:

- Tinnitus,
- Headache,
- Hyperventilation,
- Agitation,

- Mental confusion,
- lethargy, diarrhea,
- sweating.

If the above symptoms occur, withhold the medication and contact the physician or other health care provider immediately.

SIDE EFFECTS

Aspirin may cause side effects:

- Nausea
- Vomiting
- Stomach pain
- Heartburn

Some side effects can be serious:

Hives

Rash

Swelling of the eyes,

Swelling of the face,

Swelling of the lips,

Swelling of the tongue,

Swelling of the throat

wheezing

Difficulty breathing

Hoarseness

Rapid heartbeat

Rapid breathing

Clammy, cold skin

Ringing in the ears

loss of hearing

blood in vomit

Vomit (coffee grounds)

Blood in stools- bright red

Tarry or black stools

Aspirin may also cause other side effects.

If there is serious side effect it may be reported to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (http://www.fda.gov/Safety/MedWatch) or by phone (1-800-332-1088).

In case of overdose, call the poison control center at 1-800-222-1222.

Some symptoms of overdose may include:

Burning pain in the throat

Burning pain in the stomach

Fever

Vomiting

Decreased urination

Restlessness

Irritability

Fear

Nervousness

Dizziness

Double vision

Confusion

Hallucination (hearing voices or seeing things that are not there)

Seizures

Drowsiness

Loss of consciousness for a period of time

Shaking uncontrollable; (a part of the body).

Treatment

Treatment depends on the amount of aspirin, the time it was swallowed and the overall condition of the patient.

Treatment may include:

Activated charcoal

Airway support (oxygen, breathing tube/ ventilator).

Intravenous (IV) fluids

Laxative

Blood tests

Urine tests

Chest x-ray

Electrocardiogram (EKG)

Medications to treat symptoms

Other medications may be administered IV, including potassium and sodium bicarbonate, which will help the body remove aspirin that has already been digested.

If these treatments do not work or the overdose is extremely severe, hemodialysis (kidney machine) may be needed to remove aspirin from the blood.

ANTIBIOTICS

Antibiotics are medications that are used to fight bacterial infections. The first antibiotic was penicillin, discovered accidentally from a mold culture.

Although antibiotics are useful in a wide variety of infections, it is important to realize that antibiotics only treat bacterial infections.

PENICILLIN VK

Penicillin V potassium is an antibiotic used to treat certain infections caused by bacteria such as scarlet fever, pneumonia, and throat, skin, ear infections.

PENICILLIN V POTASSIUM
(penicillin v potassium) Tablet

PENICILLIN V POTASSIUM
(penicillin v potassium) Powder for Solution

Indications

Treatment of a wide variety of infections including:

- Pneumococcal pneumonia,
- Streptococcal pharyngitis,
- Syphilis,
- Gonorrhea strains.

Action

Bind to the bacterial cell wall, leading to cell death.

Pharmacokinetics

Absorption:

Variably absorbed from the gastrointestinal tract.
Resists acid degradation in the gastrointestinal tract.

Distribution:

Widely distributed although central nervous system (CNS) penetration is poor in the presence of normal meninges.
Crosses the placenta
Enters breast milk.
Protein Binding: 60%.

Metabolism and Excretion:

Minimal; metabolized by the liver, excreted mainly by the kidneys (unchanged).

Half-life: 30–60 min.

Time / Action Blood levels

ROUTE	ONSET	PEAK	DURATION
PO	rapid	0.5–1 hr	4–6 hr

Use Cautiously in:

Severe renal insufficiency - dose reduction is recommended.

OBSTETRIC: safety not established.

Lactation: Safety not established

GERIATRIC:

Consider decreased body mass, age related decrease in renal age related decrease in hepatic, age related decrease in cardiac function, concurrent diseases and drug therapy.

SIDE EFFECTS

- Seizures
- Diarrhea,
- Anaphylaxis,
- Epigastric distress,
- nausea,
- vomiting,
- pseudomembranous colitis
- Rash,
- urticaria
- Eosinophilia,
- leukopenia

Laboratory Test Considerations

May cause neutropenia and leucopenia (especially with hepatic impairment or prolonged therapy.

May cause elevated ALT, AST, LDH, and serum alkaline phosphatase concentrations.

May cause positive direct Coombs' test results.

CIPROFLOXACIN

Indications

Ciprofloxacin is an antibiotic in a group of drugs called fluoroquinolones

Ciprofloxacin fights bacteria in the body; is used to treat different types of bacterial infections.

Action

Inhibits bacterial DNA synthesis by inhibiting DNA gyrase enzyme.

Pharmacokinetics

Absorption:

70% absorbed following oral administration

Intravenous administration results in complete bioavailability.

Distribution:

Widely distributed.

High tissue levels are achieved.

High urinary levels are achieved

Crosses the placenta

Enters breast milk.

Metabolism

15% metabolized by the liver,

Excretion: 40–50% excreted by the kidneys (unchanged).

Half-life: 4 hr.

Time / Action profile - blood levels

ROUTE	ONSET	PEAK	DURATION
PO	rapid	1–2 hr	12 hr
PO-ER	rapid	1–4 hr	24 hr
IV	rapid	end of infusion	12 hr

Use Cautiously in:
Patients with known or suspected central nervous system disorder.
Renal impairment; dose reduction if Creatinine Clearance Rate (ccr) ≤50 mL/min.

Lactation: Safety not established (except for treatment of anthrax)

Geriatric: Increase risk of side effects/ adverse reactions.

Side Effects

Some side effects may include but not limited to:

- Severe dizziness,
- fainting,
- fast heartbeat,
- pounding heartbeat,
- Sudden pain,
- bruising,
- swelling,
- stiffness,
- tenderness,
- loss of movement in any of the joints,
- Diarrhea (that is bloody or watery),
- Confusion,
- hallucinations,
- Depression.

Patient needs emergency medical help for signs of an allergic reaction such as:

- Hives
- Difficult breathing
- Swelling of the face,
- Swelling of the lips,
- Swelling of the tongue,
- Swelling of the throat.

INSTRUCT PATIENTS TO:

Stop using ciprofloxacin and call the physician immediately if they experience serious side effects.

ANTICOAGULANTS

WARFARIN

COUMADIN (warfarin sodium) tablets and COUMADIN (warfarin sodium) for injection contain warfarin sodium, an anticoagulant that acts by inhibiting vitamin K-dependent coagulation factors.

Action

Interferes with hepatic synthesis of vitamin K-dependent clotting factors (II, VII, IX, and X).

Therapeutic Effects: Prevention of thromboembolic events.

Pharmacokinetics

Absorption: Well absorbed from the gastrointestinal after oral administration.

Distribution: Cross the placenta BUT does not enter the breast milk.

Protein Binding: 99%.

Metabolism and Excretion: Metabolized by the liver.

Half-life: 42 hrs

Time /Action

ROUTE	ONSET	PEAK	DURATION
PO, IV	36–72 hr	5–7 days	2–5 days

Indications

Prophylaxis and treatment of:

- Venous thrombosis,
- Pulmonary embolism (PE),
- Atrial fibrillation (a-fib) with embolization.

Management of myocardial infarction:

- Reduces risk of death,
- Reduces risk of subsequent Myocardial Infarct (MI),
- Reduces the risk of future thromboembolic occurrences.
- Prevention of thrombus forming and embolization after placement of prosthetic valve.

Contraindicated in:

- Uncontrolled bleed
- Open wound
- Ulcer disease
- Recent eye surgery or injury
- Recent brain surgery or injury
- spinal cord surgery or injury
- Severe liver disease
- Severe kidney disease
- Uncontrolled hypertension
- Obstetric: Crosses placenta; may cause fatal hemorrhage in fetus. May cause congenital anomaly/ malformation.

Use Cautiously in individuals with:

- Malignancy
- Patients with history of ulcer disease
- Patients with history of liver disease
- History of poor or non compliance

Pediatric:

Has been used safely (may require frequent PT/INR monitoring)

Geriatric:

Initiate / maintain at lower dosage.

Side Effects / adverse reactions:

Nausea, loss of appetite, or stomach/abdominal cramps /pain dermal necrosis, bleeding, fever may occur.

Lab Test Considerations:

Monitor PT/ INR and other clotting factors during therapy.

Therapeutic PT ranges 1.3–1.5 times greater than control.

Normal INR (not taking anticoagulants) is 0.8–1.2.

An INR of 2.5–3.5 is recommended for patients at very high risk of passage of an embolus within the bloodstream, for example, patients with mitral valve replacement patients with ventricular hypertrophy.

Lower levels are usually acceptable when the risk is lower.

Assess hepatic function and complete blood count (CBC) before therapy and periodically during therapy.

Assess stool and the urine for occult blood prior therapy and periodically throughout therapy.

Toxicity and Overdose:

Sometimes withholding one or more doses of warfarin is sufficient if the international normalized ratio (INR) is excessively elevated or if there is minor bleeding.

If anticoagulation needs to be immediately reversed or if overdose occurs, the antidote is **vitamin K (phytonadione, AquaMEPHYTON**).

Administration of whole blood or plasma also may be required in severe bleeding because of the delayed onset of the vitamin K.

OVERDOSE

INSTRUCT PATIENTS:

If overdose is suspected, contact the emergency room or poison control center immediately. US - local poison control center at 1-800-222-1222.

Signs and Symptoms may include:

Bleeding for example;

- appearance of blood in urine, hematuria,
- blood in stool,
- excessive menstrual bleeding,
- melena (black stools),
- petechiae,
- excessive bruising
- persistent oozing of blood from superficial injuries,
- unexplained reduction in hemoglobin (manifestation of excess anticoagulation).

High Alert

Medication errors involving anticoagulants have resulted in serious harm and /or death from internal or intracranial bleeding.

HEPARIN

Heparin Sodium
Injection, USP 2000 and 2500 USP Units/mL
Heparin Sodium ADD-Vantage™ Vial

Heparin sodium is indicated for:

- Atrial fibrillation (A-fib) with embolization
- Treatment of acute and chronic consumption coagulopathies (disseminated intravascular coagulation (DIC)
- Prevention of clotting in arterial and heart surgery
- Anticoagulant therapy in prophylaxis and treatment of venous thrombosis and its extension
- In a low-dose regimen- for prevention of postoperative deep venous thrombosis (DVT) and pulmonary embolism when undergoing major abdomino-thoracic surgery or patients who for other reasons are at risk of developing thromboembolic disease.
- Prophylaxis and treatment of pulmonary embolism
- Prophylaxis and treatment of peripheral arterial embolism.

PHARMACOLOGY

Heparin inhibits reactions that lead to clotting of blood and formation of fibrin clots both *in vitro* and in vivo. The drug acts at multiple sites in the normal coagulation system.

Small amounts of heparin in combination with antithrombin III ; heparin cofactor, can inhibit thrombosis by:

- inactivating activated Factor X and
- inhibiting the conversion of prothrombin to thrombin.

Once active thrombosis has developed, larger amounts of heparin can inhibit further coagulation by inactivating thrombin and preventing the conversion of fibrinogen to fibrin.

Heparin also prevents formation of stable fibrin clot in inhibiting the activation of the fibrin stabilizing factor.

Bleeding time is usually not affected by heparin.

Clotting time is prolonged by full therapeutic doses of heparin; most of the time, it is not measurably affected by low doses of heparin.

Peak plasma levels of heparin are achieved 2 to 4 hours after subcutaneous administration, however there are individual variations.

Heparin does not have fibrinolytic activity; therefore, it will not lyse existing clots.

COMPLICATIONS

Hemorrhage

Hemorrhage is a main complication that can result from taking the heparin therapy. A prolong clotting time or minor bleeding during therapy, may be controlled by withdrawing heparin therapy.

Hypersensitivity

Generalized hypersensitivity reactions have been reported with;

- Fever,
- chills,
- fever,
- urticaria
- asthma,
- rhinitis,
- lacrimation,
- headache,
- nausea
- vomiting

Also some anaphylactoid reactions may include:

- Shock (occur more rarely)
- Itching and burning (especially plantar site of feet may occur).

Thrombocytopenia (deficiency of platelets in the blood) has been reported to occur in patients who are receiving heparin.

LAB CONSIDERATIONS

Significant elevations of aminotransferase (SGOT [S-AST] and SGPT [S-ALT]) levels have occurred in a high percentage of patients received heparin.

OVERDOSE

Signs and Symptoms

- Bleeding is the chief sign of heparin overdosage
- Nosebleeds,
- blood in urine
- tarry stools
- Easy bruising
- petechial.

Treatment

Neutralization of heparin effect

When bleeding /clinical circumstances require reversal of heparinization;

- protamine sulfate (1% solution) by slow infusion will neutralize heparin sodium.

Administration of the protamine sulfate may cause severe hypotensive and severe anaphylactoid reactions.

ANTICONVULSANTS

ANTICONVULSANTS (ANTI-SEIZURE)

DILANTIN

Indications

For prevention / treatment of tonic-clonic; grand mal seizure and complex partial seizures, may also be used to treat certain types of irregular heartbeat.

Action

It works by reducing the spread of seizure activity in the brain. Limits seizure by altering ion transport. May also reduce synaptic transmission.

Therapeutic Effects:

Diminished seizure activity.

Pharmacokinetics

Absorption:

Absorbed slowly from the gastrointestinal tract.
Bioavailability may differ among products.

Distribution:

Distributes into the CSF and other body fluids and tissues.

Enters breast milk

Crosses the placenta

Preferentially distribute into the fatty tissue.

Protein Binding:

Adults 90–95%

Decreased protein binding in neonates (up to 20% free fraction available),

Infants (up to 15% free).

Metabolism

Mostly metabolized by the liver.

Excretion:

Minimal amounts excreted in urine.

Half-life: 22 hr (range 7–42 hr).

Time / action (anticonvulsant effect)

ROUTE	ONSET	PEAK	DURATION
PO	2–24 hr (1 wk)	1.5–3 hr	6–12 hr
PO-ER	2–24 hr (1 wk)	4–12 hr	12–36 hr
IV	0.5–1 hr (1 wk)	rapid	12–24 hr

(1 wk) is time required for onset of action without loading dose.

Use Cautiously in:

- Every patient - may increase the risk of suicidal behaviors or thoughts
- Renal or hepatic disease- due to increase risk of adverse reactions (reduce dose recommended for hepatic impairment)
- Patients with severe respiratory disease or cardiac or disease (use of intravenous (IV) phenytoin may result in an increased risk of serious adverse reactions).
- Obstetric: safety not established (may result in hemorrhage in the newborn)
- Lactation: Safety not established
- Pediatric: Suspension which contains sodium benzoate, a metabolite of benzyl alcohol that can cause potentially fatal gasping syndrome in neonates.

- Geriatric: Use of IV phenytoin may result in an increase risk of serious adverse reactions.

Side Effects /adverse Reactions

- Confusion,
- Agitation,
- Suicidal thoughts,
- Ataxia,
- Dizziness,
- drowsiness,
- dysarthria,
- dyskinesia,
- extrapyramidal syndrome,
- headache,
- insomnia,
- weakness
- Diplopia,
- Nystagmus
- hypotension (increase with IV phenytoin),
- tachycardia
- gingival hyperplasia,
- nausea,
- constipation,
- drug-induced hepatitis,

- vomiting,
- Rash,
- Fever
- Pruritus,
- Aplastic anemia,
- leukopenia,
- thrombocytopenia,
- osteoporosis
- And other allergic reactions (such as Stevens-Johnson syndrome).

ANTIFUNGAL MEDICATION

DIFLUCAN

Indications

Diflucan (fluconazole) is an antifungal medication.

PO and Intravenous:

- Fungal infections which is caused by susceptible organisms, including: esophageal or oropharyngeal or candidiasis,
- Serious systemic infections (candida)
- Urinary tract infections (UTI),
- Peritonitis,
- Cryptococcal meningitis.
- Prevention of candidiasis in patients who have bone marrow transplantation.

PO: Single-dose oral treatment of vaginal candidiasis.

Action

Inhibits synthesis of fungal sterols (necessary component of cell membrane).

Therapeutic Effects:

Fungistatic action (interfering with synthesis of the fungal cell membrane) against susceptible organisms.

May be fungicidal in higher concentrations. Spectrum: Cryptococcus neoformans. Candida spp.

Pharmacokinetics

Absorption:

Well absorbed after oral (PO) administration.

Distribution:

Widely distributed; good penetration into saliva, eye, CSF, sputum, skin, vaginal fluid, and peritoneum, (Excreted in breast milk).

Metabolism

<10% metabolized by the liver.

Excretion:

>80% excreted unchanged by the kidneys

Half-life: Premature neonate: 46–74 hr; Children: 19–25 hr (PO) and 15–17 hr (IV); Adults: 30 hr (increase in renal impairment).

Time /action (blood level)

ROUTE	ONSET	PEAK	DURATION
PO	unknown	2–4 hr	24 hr
IV	rapid	end of infusion	24 hr

Use Cautiously in:

Renal impairment (dose reduction required if CCr <50 mL/min)

Underlying liver disease

Obstetric: Safety not established

Lactation: Usually compatible with breastfeeding

Geriatric: Increased risk of adverse reactions such as diarrhea, vomiting, rash, seizures (consider age-related reduction in renal function in determining dose).

Side Effects/ Adverse Reactions

- Headache,
- Dizziness,
- Seizures
- Hepatotoxicity
- Abdominal discomfort,
- Diarrhea,
- Nausea,
- Vomiting,
- Skin disorders such as Stevens-Johnson syndrome,
- Hypokalemia,
- Allergic reactions may also include anaphylaxis.

Incidence of adverse reactions is increased in patients with HIV.

ANTIVIRAL

ACYCLOVIR

Indications

PO administration:

Genital herpes infections (recurrent infections).

Localized cutaneous herpes zoster infections; shingles and chickenpox; varicella.

Intravenous (IV):

Severe initial episodes of genital herpes (in nonimmunosuppressed patient).

Cutaneous or mucosal herpes simplex infections or herpes zoster infections;shingles in immunosuppressed patients.

Herpes simplex encephalitis.

Topical:

Cream; Cold sores; recurrent herpes labialis.

Ointment:

Treat limited non–life-threatening herpes simplex infections in immunocompromised patients (prefer systemic treatment).

Action

Interferes with viral DNA synthesis.

Therapeutic Effects:

Inhibition of viral replication, decreased viral shedding, and reduced time for healing of lesions.

Pharmacokinetics

Absorption:

Despite poor absorption (15–30%), therapeutic blood levels are achieved.

Distribution:

Widely distributed - CSF concentrations are 50% of plasma.

Crosses placenta, enters breast milk.

Protein Binding: <30%.

Metabolism

Metabolized by liver

Excretion: >90% eliminated unchanged by kidneys

Half-life: Neonates: 4 hr; Children 1–12 yr: 2–3 hr; Adults: 2–3.5 hr (↑ in renal failure).

Time /action (antiviral blood level)

ROUTE	ONSET	PEAK	DURATION
PO	unknown	1.5–2.5 hr	4 hr
IV	Rapid	end of infusion	8 hr

Use Cautiously in:

Pre-existing serious hepatic, neurologic, pulmonary, or fluid and electrolyte abnormalities.

Renal impairment (dose alteration recommended if CCr <50 mL/min).

Geriatric: Due to age related reduction in renal function.

Patients who are obese (dose should be based on ideal body weight)

Obstetric /Lactation: Safety not established.

Side Effects and adverse Reaction

- Dizziness,
- Seizure,
- headache,
- hallucinations,
- trembling,
- diarrhea,
- nausea,
- vomiting,
- elevated liver enzymes,
- hyperbilirubinemia,
- abdominal pain,
- anorexia,
- renal pain,
- Renal failure,
- crystalluria,
- hematuria,
- Stevens –Johnson syndrome,
- hives,
- ache,
- skin rashes,

- unusual sweating,
- change in menstrual cycle
- joint pain,
- phlebitis,
- polydipsia
- and others not mentioned.
-

Lab Test Considerations:

Monitor BUN, serum creatinine, and CCr before and during therapy.

increased BUN and serum creatinine levels or decreased CCr may indicate renal failure.

ASTHMA MEDICATIONS

Montelukast Sodium (Singulair)

Montelukast is a leukotriene inhibitor.

Leukotrienes are chemicals the body releases when you breathe in an allergen for example pollens. These chemicals cause swelling in the lungs and tightening of the muscles around the airways, which can result in asthma symptoms.

Montelukast is used;

- to prevent asthma attacks (in adults and children as young as 12 months old),
- to prevent exercise-induced bronchospasm (in adults and children who are at least 6 years old).
- to treat symptoms of year-round allergies (perennial) in adults and children who are at least 6 months old.
- to treat symptoms of seasonal allergies in adults and children (at least 2 years old).
- to prevent exercise-induced bronchoconstriction; narrowing of the air passages in the lungs, in adults / teenagers who are at least 15 years old and are not already taking this medication for other conditions.

Montelukast will not work quick enough to treat an asthma attack that has already begun; (use only a fast-acting inhalation medication to treat an asthma attack). Regularly used to prevent the wheezing and shortness of breath caused by asthma and decrease the number of asthma attacks. As mentioned earlier Montelukast is also used before exercise to prevent breathing problems (bronchospasm) during exercise.

Side effects of montelukast (Singulair)
Side effect may include but not limited to:

- skin rash,
- bruising,
- severe tingling,
- numbness,

- pain,
- muscle weakness
- mood changes
- behavior changes,
- anxiety,
- depression,
- thoughts about suicide
- tremors
- shaking
- easy bruising,
- unusual bleeding from mouth, nose, vagina, rectum,
- severe sinus pain, swelling, or irritation
- worsening asthma symptoms
- severe skin reaction
- fever,
- sore throat,
- swelling of the face or tongue
- headache
- stomach pain,
- heartburn,
- upset stomach,
- nausea,
- diarrhea
- tooth pain
- feeling tired
- fever,
- stuffy nose,
- sore throat,
- cough,
- hoarseness
- mild rash

INSTRUCT PATIENTS TO:

Get emergency medical help if have any signs of an allergic reaction including:

- Hives
- Difficulty breathing
- swelling of the face,
- swelling of the lips,
- swelling of the tongue,
- swelling of the throat.

ALBUTEROL

Indications

Used as a bronchodilator to control and prevent reversible airway obstruction caused by COPD or asthma.

Inhalation:

Used as a quick-relief agent for acute bronchospasm and for prevention of exercise-induced bronchospasm.

PO:

Used as a long-term control agent for patients with chronic persistent bronchospasm.

Action

Binds to beta2-adrenergic receptors in airway smooth muscle, leading to activation of adenyl cyclase and increased levels of cyclic-3′, 5′-adenosine monophosphate (cAMP).

Increases in cAMP activate kinases, which inhibit the phosphorylation of myosin and decrease intracellular calcium.

Decreased intracellular calcium relaxes smooth muscle airways.

Relaxation of airway smooth muscle; bronchodilation.

Selective for beta2; pulmonary receptors.

Therapeutic Effects:

Bronchodilation

Pharmacokinetics

Absorption:

Well absorbed after oral administration but quickly undergoes extensive metabolism.

Distribution:

Small amounts appear in the breast milk.

Metabolism and Excretion: metabolized by the liver and other tissues.

Half-life:

Oral 2.7–5 hr

Inhalation: 3.8 hr.

Time /action (bronchodilation)

ROUTE	ONSET	PEAK	DURATION
PO	15–30 min	2–3 hr	4–6 hr or more
PO–ER	30 min	2–3 hr	12 hr
Inhalation	5–15 min	60–90 min	3–6 hr

Contraindicated in:

Hypersensitivity to adrenergic amines.

Use Cautiously in:

- Cardiac disease
- Hypertension

- Hyperthyroidism
- Diabetes
- Glaucoma
- Seizure disorders

Obstetric ,Lactation and Pediatric:

Safety not established for pregnant women near term, breastfeeding women, and children <2 yr.

Geriatric: increase risk of adverse reactions (may require reduced dose).

Side Effects / Adverse Reactions

- Nervousness,
- restlessness,
- tremor,
- headache,
- insomnia
- Paradoxical bronchospasm (excessive use of inhalers)
- chest pain,
- palpitations,
- angina,
- arrhythmias,
- hypertension,
- nausea,
- vomiting,
- hyperglycemia
- hypokalemia,

- tremor.

Patient and Family Teaching

Instruct patients to take albuterol as prescribed.

Remind patients not to exceed the recommended dose; this may cause adverse effects, paradoxical bronchospasm or loss of effectiveness of medication.

Instruct patient to contact the physician/ health care provider immediately if shortness of breath is not relieved by medication or is accompanied by dizziness, diaphoresis, chest pains or palpitations.

Advise patient to consult physician/ health care provider before taking any over the counter medications, natural /herbal products, or alcohol while taking this medication.

Caution patient also to avoid smoking and other respiratory irritants.

Inform patient that albuterol may cause an unusual taste or bad taste.

Inhalation:

Instruct patient in the proper use of the metered-dose inhaler or nebulizer.

Advise patients to use albuterol first if using other inhalation medications and allow 5 minutes to elapse before using other inhalant medications unless otherwise directed.

Advise patient to use water to rinse mouth after each inhalation dose to minimize dry mouth.

Pediatric:

Caution adolescents and the parents about overuse of inhalers, which can cause heart damage and life-threatening arrhythmias.

CARDIOVASCULAR MEDICATIONS

DIGOXIN

Indications

- Heart failure
- Atrial fibrillation and
- Atrial flutter (slows ventricular rate)
- Paroxysmal atrial tachycardia.

Action

- Increases the force of myocardial contraction.
- Prolongs refractory period of AV node.
- Decrease conduction through SA and AV nodes.

Therapeutic Effects:

Increase cardiac output, positive inotropic effect and slowing of the heart rate (negative chronotropic effect).

Pharmacokinetics

Absorption:

60–80% absorbed after PO administration of tablets

70-85% absorbed following administration of elixir.

Absorption from liquid filled capsule is 90–100%

80% absorbed from IM sites (IM route not recommended due to pain/irritation).

Distribution:

Widely distributed

crosses placenta

Enters breast milk.

Metabolism / Excretion:

Excreted almost entirely unchanged by the kidneys.

Half-life: 36–48 hr (increased in renal impairment).

Time /action (antiarrhythmic or inotropic effects, provided that a loading dose has been administered).

ROUTE	ONSET	PEAK	DURATION
Digoxin PO	30–120 min	2–8 hr	2–4 days
Digoxin IM	30 min	4–6 hr	2–4 days
Digoxin IV	5–30 min	1–4 hr	2–4 days

(with impaired renal function duration will be longer)

Contraindicated in:

Hypersensitivity

Uncontrolled ventricular arrhythmias

AV block (in absence of pacemaker)

Constrictive pericarditis

Use Cautiously in:

- Patients with hypokalemia- will increase the risk of digoxin toxicity,
- Hypomagnesemia - may increase the risk of digoxin toxicity,
- Hypercalcemia – will increase the risk of toxicity; especially with mild hypokalemia,
- Diuretic use - may cause electrolyte imbalance such as hypokalemia and hypomagnesemia,
- Geriatric: sensitive to toxic effects (dose adjustments required for age related decrease in renal function / body weight,
- Myocardial infarction,
- Hypothyroidism,
- Renal impairment - dose reduction required,
- Obesity - dose should be based on ideal body weight,
- Obstetric: safety has not been established (has been used during pregnancy without adverse effects on fetus)
- Lactation - similar concentrations in serum and breast milk (use with caution).

Side Effects / adverse reactions

- Fatigue,
- headache,
- weakness
- blurred vision,
- Green or yellow vision
- Arrhythmias,

- bradycardia,
- ECG changes,
- AV block,
- SA block
- anorexia,
- nausea,
- vomiting,
- diarrhea
- thrombocytopenia
- electrolyte imbalances (with acute digoxin toxicity).

Assessment

Monitor apical pulse for 1 min before administering the medication.

Withhold dose and notify physician if pulse rate is <60 bpm in an adult . Also notify physician/ health care provider promptly of any significant changes in or quality of pulse, rate or rhythm of pulse.

Pediatric:

Heart rates vary in children depending on age, ask physician to specify at what heart rate digoxin should be withheld.

Geriatric:

Assess for falls risk. Digoxin has been associated with increased risk of falls in elderly. Implement prevention measures per facility policy.

Lab Test Considerations:

Evaluate serum electrolyte levels;

Monitor potassium, magnesium, and calcium levels

Monitor renal functions monitor hepatic functions during therapy.

Notify physician /health care provider before giving dose if patient has hypokalemia.

Hypomagnesemia, hypokalemia or hypercalcemia may cause the patient to be more susceptible to digitalis toxicity.

Pediatric:

Neonates may have falsely elevated serum digoxin concentrations.

Geriatric:

Older adults may be toxic even when serum concentrations are within normal range, therefore assess for clinical symptoms of toxicity even when the serum levels are normal.

Toxicity and Overdose:

Therapeutic serum digoxin levels range from 0.5–2 ng/mL. Serum levels may be drawn 6–8 hr after a dose is administered (may be drawn immediately before the next dose).

For the patient with congestive heart failure, the ideal range of levels of digoxin in the blood, (the therapeutic range) may be between 0.5 and 0.8 ng/mL. If the patient is taking digoxin because of an irregular heartbeat, the patient probably should have a blood level between 1.5 and 2.0 ng/mL. Most individuals find that the symptoms improve when the digoxin levels are within these ranges.

Geriatric:

Older adults are at increased risk for toxic effects of digoxin due to age related decreased renal clearance (can exist when serum creatinine levels are normal).

Digoxin requirements in the elderly patient may change (a formerly therapeutic dose can become toxic).

Observe for signs and symptoms of toxicity

In adults and older children, the first signs of toxicity usually include:

- Abdominal pain,
- Anorexia,
- nausea,

- vomiting,
- visual disturbances,
- Bradycardia,
- And other arrhythmias.

In infants and small children;

- the first symptoms of overdose- usually cardiac arrhythmias.

If cardiac arrhythmias appear, withhold the drug and notify pediatrician/ healthcare provider immediately.

Patient /Family Teaching

Instruct patients and family to take medication as directed, at the same time every day. Teach patients to take pulse and to contact healthcare provider before taking medication if pulse rate is <60 or >100 bpm.

Pediatric:

Teach parents that changes in heart rate; cardiac arrhythmias such as bradycardia, are among the 1st signs of digoxin toxicity in infants/ children.

Teach parents in apical heart rate assessment and instruct them to notify the physician/ healthcare provider if heart rate is outside of range set by pediatrician, before giving the next dose.

Review the signs and symptoms of digitalis toxicity with patient /family. Advice patients to notify physician immediately if these symptoms occur or if experience symptoms of congestive heart failure. Instruct patients that these symptoms may be resemble those of flu or cold.

Advise patient not to take any antacids or antidiarrheals within 2 hr of taking digoxin.

Patients who are taking digoxin should ALWAYS carry identification (ID) describing disease process and medication regimen.

Geriatric:

Review fall risk and prevention strategies with the elderly and the families.

Remind them of the importance of follow up examinations to determine the effectiveness of the therapy and to monitor for toxicity.

METOPROLOL

Indication

Hypertension (high blood pressure), angina pectoris, prevention of myocardial infarct (MI) and decreased mortality in patients with recent myocardial infarct. Management of stable, symptomatic; class II or III heart failure due to hypertensive, ischemic or cardiomyopathc origin.

Action

Blocks stimulation of beta1 (myocardial) adrenergic receptors; (does not usually affect beta2 - pulmonary, vascular, uterine) adrenergic receptor sites.

Therapeutic Effects:

- Reduce blood pressure and reduce heart rate.
- Decreased frequency of angina pectoris attacks.
- Reduced rate of cardiovascular mortality and decrease hospitalization in patients with heart failure.

Pharmacokinetics

Absorption:

Well absorbed after PO administration.

Distribution:

Crosses the blood-brain barrier,

Crosses Placenta

Small quantity enter breast milk

Metabolism and Excretion:

Metabolized by the liver.

Half-life: 3–7 hr.

Time / action (cardiovascular effects)

ROUTE	ONSET	PEAK	DURATION
PO	15 min	unknown	6–12 hr
PO–ER	unknown	6–12 hr	24 hr
IV	immediate	20 min	5–8 hr

Maximal effects on blood pressure (chronic therapy) may not occur for 1 wk.
Hypotensive effects may persist for up to four weeks after drug has been discontinued.

Contraindications

Contraindicated in uncompensated congestive heart failure, Cardiogenic shock, Bradycardia Pulmonary edema or heart block.

Use Cautiously in:

Patients with renal impairment, hepatic impairment.

Geriatric:

Increase sensitivity to beta blockers (initial dose reduction recommended), pulmonary disease such as asthma (beta1 selectivity may be lost at higher doses), diabetes mellitus (may mask signs/symptoms of hypoglycemia).

Patients who have history of severe allergic reactions- intensity of reactions may be increased.

Obstetric, lactation, pediatric:

Safety not established, all agents cross placenta and may cause fetal bradycardia, respiratory depression, hypotension or hypoglycemia.

Side Effects / adverse effects

- Fatigue,
- weakness,
- Anxiety,
- Depression,
- Dizziness,
- Drowsiness,
- Insomnia,
- memory loss,
- mental status changes,
- nervousness,
- nightmares,
- blurred vision,
- stuffy nose,
- bronchospasm,
- wheezing,
- Bradycardia,
- congestive heart failure,
- Pulmonary edema,
- hypotension,
- peripheral vasoconstriction,
- constipation,
- diarrhea,

- drug induced hepatitis,
- dry mouth,
- flatulence,
- gastric pain,
- heartburn,
- increased liver enzymes,
- nausea/ vomiting,
- erectile dysfunction,
- decrease libido,
- urinary frequency,
- rashes,
- hyperglycemia,
- hypoglycemia,
- Arthralgia,
- Joint pain,
- Drug-induced lupus syndrome.

Assessment

Monitor blood pressure (BP), pulse and ECG often during dose adjustments and during therapy.

Usually if heart rate <40 bpm, and cardiac output is also decreased, atropine IV is administered.

Monitor intake and output (I&O) and daily weights. Assess for signs and symptoms of congestive heart failure such as rales /crackles, dyspnea, weight gain, jugular venous distention peripheral edema.

Assess for angina during therapy.

Lab Test Considerations:

- May cause increased *blood urea nitrogen* (BUN),
- increased serum lipoprotein,
- increased potassium,
- increased triglyceride,
- increased uric acid levels,
- Increased antinuclear antibody ANA levels.
- increase in blood glucose levels,
- increased serum alkaline phosphatase,
- increased LDH,
- increased AST, and
- increased ALT levels.

CHOLESTEROL LOWERING MEDICATIONS

SIMVASTATIN

Indication

Simvastatin is used to help lower cholesterol and fats in the blood. It belongs to a group of drugs that is known as statins. Simvastatin works by reducing the amount of cholesterol that is made by the liver. Manages primary hypercholesterolemia and mixed dyslipidemia. Reduces the risk of myocardial infarct (MI), stroke, coronary revascularization and cardiovascular mortality in patients with coronary heart disease.

Action

Inhibit an enzyme, 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase, which is responsible for catalyzing an early step in the synthesis of cholesterol.

Therapeutic Effects:

Lowers the total cholesterol, LDL cholesterol and triglycerides, slightly increase HDL. Slows of the progression of coronary atherosclerosis ; therefore decrease in coronary heart disease related events.

Pharmacokinetics

Absorption:

85% absorbed and quickly metabolized.

Distribution:

Simvastatin; unknown.

Protein Binding:

Simvastatin >98%.

Metabolism and Excretion:

Extensively metabolized by; amount excreted unchanged in urine- simvastatin 13%.

Half-life: simvastatin unknown.

Time /action (cholesterol-lowering effect)

ROUTE	ONSET	PEAK	(DURATION after discontinuation)
PO	several days	2–4 wk	unknown

Contraindications

Contraindicated in:

Hypersensitivity,

Active liver disease or unexplained persistent elevations in ALT or AST,

severe renal impairment (CCr <30 mL/min),

Obstetric: Potential for fetal anomalies

Lactation: can disrupt lipid metabolism in infants.

Assessment

Obtain dietary history (fat consumption).

Lab Test Considerations:

Assess serum cholesterol and triglyceride levels prior to initiating, after 4 to 6 wk of therapy, and after, periodically.

Monitor liver function tests such as AST, before, also at 12 weeks after starting therapy or after dose elevation, and then every 6 months.

If patients develop muscle tenderness while taking the drug therapy, monitor creatine kinase (CK) levels. If CK levels are >10 times the upper limit of normal or myopathy develops, therapy should be discontinued.

CORTICOSTEROIDS

PREDNISONE

Prednisone is used to treat wide a variety of chronic diseases including: Inflammatory, arthritis, severe allergies, blood disorders, skin diseases, breathing problems, cancer, and immune system / autoimmune disorders.

Prednisone belongs to a class of drugs called corticosteroids. It decreases the immune system's response to various diseases to reduce symptoms such as allergic-type reactions, inflammation/ swelling.

Action

It suppresses inflammation and the normal immune response, with multiple intense metabolic effects. Suppress the adrenal function at chronic doses of 5 mg per day.

Therapeutic Effects:

Suppression of inflammation, modification of normal immune response.

Pharmacokinetics

Absorption:

Well absorbed after PO administration.

Distribution:

Widely distributed

Crosses placenta (probably enters breast milk).

Metabolism

Metabolized by the liver.

Excretion:

Urine (as conjugates).

Half-life: 3.4–3.8 hr (plasma),

18–36 hr (tissue)

Adrenal suppression lasts 1.25–1.5 days.

Time /action (anti-inflammatory activity)

ROUTE	ONSET	PEAK	DURATION
PO	hrs	unknown	1.25–1.5 days

Contraindications

Contraindicated in:

Some products contain alcohol and should be avoided in patients with known intolerance

Lactation: Avoid chronic use.

Use Cautiously in:

Chronic treatment may lead to adrenal suppression; use lowest possible dosage for short period of time.

Pediatric: Chronic use will result in reduced growth (use lowest dose for shortest time). Stress such as infections, surgery (supplemental doses may be needed). Potential infections may mask signs; inflammation, fever.

Obstetric: Safety not established.

Side Effects / Adverse Reactions

Side effects and adverse reactions are more common with high dose and /or long-term use of the drug. Side effects / adverse reactions may include:

- Depression,
- Euphoria,
- Headache,

- Increased intracranial pressure in children,
- personality changes,
- Restlessness,
- cataracts,
- Increased intraocular pressure,
- Hypertension,
- Peptic ulcers,
- anorexia,
- nausea/ vomiting,
- Acne,
- Decrease wound healing,
- ecchymoses,
- Hirsutism,
- Petechiae,
- Adrenal suppression,
- Hyperglycemia,
- Fluid retention,
- Hypokalemia,
- Thrombophlebitis,
- weight gain,
- weight loss
- muscle wasting,
- osteoporosis,
- Avascular necrosis of joints,

- muscle pain,
- Cushingoid appearance; buffalo hump, moon face,
- Increase risk of infection.

Assessment

Assess patient for signs of adrenal insufficiency before and during therapy. Signs of adrenal insufficiency such as:

- Hypotension,
- weight loss,
- weakness,
- nausea/ vomiting,
- anorexia,
- lethargy,
- confusion,
- restlessness.

Monitor intake and output (I&O) and daily weight.

Assess patients for peripheral edema, weight gain, crackles/rales, or dyspnea. Notify physician/ healthcare provider if occur.

Pediatric:

Children should have periodic growth evaluations.

Lab Test Considerations:

Monitor serum glucose and electrolytes. May cause elevations in glucose levels (hyperglycemia), especially in patients with diabetes. May also cause decreased potassium (hypokalemia).

Patients who are on prolonged therapy should routinely have;

- Hematologic levels, electrolytes, and urine and serum glucose assessed.

May cause decrease in white blood cell (WBC) counts.

May decrease serum potassium and calcium and increase serum sodium concentrations.

Guaiac-test stools; quickly report the presence of guaiac positive stools.

May increase serum lipid and cholesterol levels.

May suppress reactions to the allergy skin test.

Adrenal function tests; adrenal function tests may be ordered periodically to assess the degree of hypothalamic; pituitary; adrenal axis suppression in systemic/ chronic topical therapy .

Patient and Family Teaching

Teach patients and family the correct technique of medication administration. Instruct them to take the medication as prescribed.

Do not stop medication suddenly; may result in adrenal insufficiency such as: nausea, anorexia, fatigue, weakness, dyspnea, hypoglycemia hypotension. If these signs occur, notify the physician/ healthcare provider immediately (can be life threatening).

Teach patients and family about possible side effects. Instruct patient to inform physician/ healthcare provider immediately if experience severe abdominal pain or tarry stools, unusual weight gain, swelling, bruising, tiredness, visual disturbances, bone pain or behavior changes or nonhealing sores.

Instruct patients to notify healthcare providers of medication regimen before surgery or other treatments.

Instruct patients to always carry identification (ID) describing disease process and medication regimen (if experiences emergency and unable to relate medical history).

Instruct patients to avoid alcohol during therapy.

DIABETIC MEDICATIONS

METFORMIN

Indications

Used for management of type 2 diabetes mellitus (DM). May be used with insulin, diet or oral hypoglycemics.

Action

Decrease amount of glucose the liver produces. Reduces intestinal glucose absorption. Also increases sensitivity to insulin.

Therapeutic Effects:

Maintenance of blood glucose.

Pharmacokinetics

Absorption:

50–60% absorbed after PO administration.

Distribution:

Enters the breast milk in concentrations similar to plasma.

Metabolism

Not metabolized

Excretion:

Eliminated almost unchanged by the kidneys.

Half-life: 17.6 hr.

Time /action (blood level)

ROUTE	ONSET	PEAK	DURATION
PO	unknown	unknown	12 hr

XR	unknown	4–8 hr	24 hr

Contraindicated in:

Hypersensitivity,

Metabolic acidosis

Dehydration,

sepsis,

hypoxemia,

hepatic impairment,

excess alcohol use (acute or chronic)

Renal dysfunction (serum creatinine >1.5 mg/dL in men or >1.4 mg/dL in female);

Radiographic studies that requires IV iodine contrast media (withhold metformin)

Congestive heart failure

Side Effects/ adverse reactions

- Abdominal bloating,
- Diarrhea,
- Nausea/ vomiting,
- unpleasant metallic taste,
- hypoglycemia
- Lactic acidosis,
- Reduced vitamin B12 values.

Assessment

If combined with oral sulfonylureas, monitor for signs /symptoms of hypoglycemic reactions such as:

- Sweating,
- tachycardia,
- abdominal pain,
- weakness,
- hunger,
- dizziness,
- tremor,
- headache,
- anxiety.

Monitor patients who develop illness or have abnormal labs; assess for lactic acidosis or ketoacidosis.

Assess labs:

- serum electrolytes,
- ketones,
- glucose,
- blood pH,
- lactate,
- pyruvate
- metformin levels.

If acidosis is present, metformin should be discontinued immediately and initiate treatment for the acidosis.

Lab Test Considerations:

Monitor serum glucose and glycosylated hemoglobin during therapy to evaluate effectiveness of therapy. May cause false positive results for urine ketones.

Monitor blood glucose routinely by patient and every 3 months by the physician/ healthcare provider to determine the effectiveness of the medication.

Assess renal function before starting and at least yearly during the therapy. Metformin should be discontinued if renal impairment occurs.

Monitor the serum folic acid and vitamin B12 (every 1–2 yr with long term therapy). Metformin may interfere with absorption.

Patient and family teaching

Instruct patient to take metformin as directed.

Encourage patient to follow prescribed diet, medication, and exercise regimen to prevent hyperglycemic or hypoglycemic episodes.

Review signs of hypoglycemia and hyperglycemia with patient and how to treat if occurs.

Teach the patients and families (as applicable) the proper testing of blood glucose and also urine ketones. These tests need to be monitored closely during times of illness or stress.

Teach the patient and family the risk of lactic acidosis and to monitor for symptoms.

Symptoms of lactic acidosis may include:

- chills,
- diarrhea,
- dizziness,
- low blood pressure,

- muscle pain,
- sleepiness,
- slow heartbeat
- slow pulse,
- dyspnea,
- weakness

All should be reported to the physician/ healthcare provider immediately.

Instruct patients to report the occurrence of diarrhea, nausea, vomiting, and stomach pain or fullness to the physician / healthcare provider.

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