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PURPOSE

The purpose of this course is to review some of the requirements / regulations and policies within the Hospice Care setting, to educate and reinforce the knowledge of nurses; ARNP, RN, LPN and CNA/ HHA who are working in the Hospice care environment, as well as other individuals who would like to work within the Hospice care setting. This course is great for nurses who are interested in RN Case management or supervisory and Administrative positions.

OBJECTIVE

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

1. Describe Hospice care service program requirements

2. Discuss criteria defining eligibility for hospice services

3. Discuss the responsibilities of the Registered Nurse (RN) and supervising RN

4. Describe responsibilities of the Hospice interdisciplinary team

5. Discuss policies for administering Medications

6. Describe the the requirements for the comprehensive emergency management plan

7. Describe the Background screening requirements

8. Discuss Quality Assurance and Utilization Review (QAUR)/Quality Assessment and Performance Improvement (QAPI) Committee and Plan requirements

HOSPICE CARE

Hospice care is a healthcare option for patients and families who are experiencing/ facing a terminal illness. Hospice focuses on caring, not curing and most frequently Hospice care is provided in the patient's home.

Hospice care may also be provided in:

- Hospice care centers,
- hospitals,
- nursing homes and
- Other long-term care facilities.

HOSPICE CARE SERVICES

Hospice services means items and services furnished to a patient and family by a hospice, or by others under arrangements with such a program, in a place of temporary or permanent residence used as the patient's home for the purpose of maintaining the patient at home; or, if the patient needs short-term institutionalization, the services shall be furnished in cooperation with those contracted institutions or in the hospice inpatient facility.

HOSPICE CARE TEAM

Hospice care team is defined as an interdisciplinary team of qualified professionals and volunteers who, in consultation with the patient, the patient's family, and the patient's primary / attending physician, collectively make assessments, coordinate, and provide the appropriate palliative and supportive care to the hospice patient and the family.

The multi-disciplinary team includes, but not limited to:

- Physicians/ patient' s personal physician,
- Hospice physician (or medical director),
- nurses,
- hospice aides/ Home health aides,
- social workers,
- bereavement counselors
- Clergy /Chaplain
- volunteers
- Physical, Speech, and occupational therapists, if needed.

Some of the responsibilities of the interdisciplinary hospice team include:

- Assist to manage the patient's pain and symptoms,
- Provide the patient with needed medications, medical supplies, and/or equipment,
- Assists the patient and family with the emotional, psychosocial and spiritual aspects of dying,
- Educate the family/ caregiver regarding how to care for the patient,
- Schedule Home Health Aide /certified Nursing Assistants to provide personal health care services to the patient,
- Provides short-term inpatient care available when pain and/or symptoms become too difficult to manage at home,
- Makes short-term inpatient care available when the caregiver needs some respite time,
- Develops a care plan that meets each patient's individual needs,
- Provides special services such as speech, physical and occupational therapy when needed
- Provides bereavement care / counseling to surviving family and friends.

The hospice interdisciplinary team provides care to patients in their own home or in a home-like environment regardless of the age of the patient and address issues that are most important to the patients need and want at the end of their life while focusing on maintaining the individual's quality of life. The hospice care staff makes regular visits to assess the patient, provide additional care and/or other services that the patient may require. Hospice staff is always on-call 24 hours a day, seven days a week.

Hospice care is covered by:

- Medicare,
- Medicaid,
- Most private insurance plans, and
- Other managed care organizations.

HISTORICAL PERSPECTIVE

Middle Ages	Religious orders establish Hospices at key crossroads on the way to religious shrines such as Santiago de Compostela, Chartres and Rome. The shelters helped pilgrims, many were traveling to the shrines to seek miraculous cure of chronic and fatal illnesses, and many died while on the pilgrimages.
16th-18th Centuries	Religious orders offered care to the sick and dying; in local or regional based institutions. Most people died at home, cared for by women in the family.
1800s	Madame Garnier of Lyon, France opened calvaire to care for the dying. In 1879

	Mother Mary Aikenhead of the Irish Sisters of Charity opened Our Lady's Hospice in Dublin, caring only for the dying. By the late 19th Century, the increase in municipal or charitably-financed infirmaries, almshouses, hospitals, and the expansion of medical knowledge. By the mid-20th Century, almost 80% of people in the U.S.A. died in a hospital or nursing home.
1905	The Irish Sisters of Charity opened St. Joseph's Hospice in East London, to care for the sick and the dying.
Early 1900s	In London, St. Luke's Hospice and the Hospice of God open to serve the destitute dying.
1935-1990s	Interest grows in the psychosocial aspects of dying / bereavement, spark by the work of Worcester, Bowlby, Lindemann, Hinton, Parkes, Kubler-Ross, Raphael, Worden and others.
1957-67	Cicely Saunders; young physician previously trained as a nurse and a social worker, worked at St. Joseph's Hospice, studying pain control in advanced cancer. Dr. Saunders pioneered in the regular use of opioid analgesics given by the clock- not waiting for the pain to return before giving medications.
1967	Dr. Saunders opened St. Christopher's Hospice in London, emphasizing the multi-disciplinary approach to care for the dying, regular use of opioids to control pain, and special attention to spiritual, social and psychological suffering in the patients and their families.
1968-75	Many hospice and palliative care programs opened in Great Britain, adapting the St. Christopher's model to local needs, offering in-patient as well as home care.
1974	New Haven Hospice (Connecticut Hospice) began hospice home care in the United States, caring for people with

	cancer, ALS as well as other fatal illnesses.
1974-78	Hospice and palliative care units opened across North America. Some include Hospice of Marin in California, the Palliative Care Unit at the Royal Victoria Hospital in Montreal, the Support Team at St. Luke's Hospital in New York City, and Church Hospital Hospice in Baltimore.
1980s	Hospice care, emphasizing home care, expands throughout the United States. Medicare adds hospice benefit in 1983. Hospices begin to care for individuals with advanced AIDS.
1990-2000	Over 3,000 hospices and palliative care programs serve the United States. Well-established hospice and palliative care in Australia, Canada, New Zealand, much of Asia and Western Europe. Hospice and palliative care is now available in over 40 countries worldwide, as well as many less-developed nations.
21st Century	The principles of good hospice and palliative care are understood and accepted, and patients with advanced illness, and their families, are assured of compassionate care as well as trained competent staff and volunteers in their homes, in nursing homes/long term care facilities and in hospitals.

HOSPICE PATIENT ADMISSION, ASSESSMENT, PLAN OF CARE, DISCHARGE, DEATH

According to Florida Statutes 400.6095; relating to hospice patient admission, assessment, plan of care, discharge, death,

Each hospice shall make its services available to all terminally ill persons and their families without regard to gender, age, national origin, sexual orientation, diagnosis, cost of therapy, disability, life circumstances or ability to pay.

A hospice shall not impose any value or belief system on its patients or their families and shall respect the values and belief systems of its patients and their families.

Admission to a hospice program

Admission to the hospice program shall be made upon a diagnosis and prognosis of terminal illness by a physician licensed pursuant to chapter 458 or chapter 459 and shall be dependent on the expressed request and informed consent of the patient.

At the time of admission, the hospice shall inquire whether advance directives have been executed pursuant to chapter 765, and if not, provide information to the patient concerning the provisions of that chapter. The hospice shall also provide the patient with information concerning patient rights and responsibilities pursuant to s. 381.026.

The admission process shall include a professional assessment of the physical, social, psychological, spiritual, and financial needs of the patient. This assessment shall serve as the basis for the development of a plan of care.

Each hospice, in collaboration with the patient and the patient's primary or attending physician, shall prepare and maintain a plan of care for each patient, and the care provided to a patient must be in accordance with the plan of care.

The plan of care shall be made a part of the patient's medical record and shall include, at a minimum:

- Identification of the primary caregiver, or an alternative plan of care in the absence of a primary caregiver, to ensure that the patient's needs will be met.
- The patient's diagnosis, prognosis, and preferences for care.
- Assessment of patient and family needs, identification of the services required to meet those needs, and plans for providing those services through the hospice care team, volunteers, contractual providers, and community resources.
- Plans for instructing the patient and family in patient care.

- Identification of the nurse designated to coordinate the overall plan of care for each patient and family.

- A description of how needed care and services will be provided in the event of an emergency.

ONGOING ASSESSMENT

The hospice shall provide:

- An ongoing assessment of the patient and family needs,
- update the plan of care to meet changing needs,
- coordinate the care provided with the patient's primary or attending physician,
- Document the services provided.

DISCHARGE OR TRANSFER

In the event a hospice patient chooses to be discharged or transferred to another hospice, the hospice shall arrange for continuing care and services and complete a comprehensive discharge summary for the receiving provider.

DO NOT RESUSCITATE (DNR)

The hospice care team may withhold or withdraw cardiopulmonary resuscitation (CPR) if presented with an order not to resuscitate executed pursuant to s. 401.45.
Hospice staff 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 an order and applicable rules.

The absence of an order to resuscitate executed pursuant to s. 401.45 does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation as otherwise permitted by law.

DEATH OF A PERSON ENROLLED AS A HOSPICE PATIENT

The death of a person enrolled as a hospice patient shall be considered an attended death for the purposes of s. 406.11(1) (a) 5. However, a hospice shall report the death to the medical examiner if any unusual or unexpected circumstances are present.

As mentioned earlier Hospice care may be provided in the:

- The patient's current primary place of residence, including a private residence,
- assisted living facility,
- nursing home,
- hospice residential unit, or
- other place of permanent or temporary residence.

FLORIDA ADMINISTRATIVE RULES

CHAPTER 58A-2 below:

58A-2.003 License Requirements

(1) In addition to the requirement specified in Section 400.602(1)(b), F.S., the face of the license must contain the following information:

(a) The name and address of the provider, including the principal office and all satellite offices;

(b) All freestanding hospice inpatient facilities and residential units;

(c) All counties served by the hospice;

(d) The name of the owner; and

(e) The effective and expiration dates of the license.

(2) The hospice must notify the department and the agency in writing at least sixty (60) days before making a change in name or address of the provider's principal or satellite offices.

(3) If a change of ownership as defined in Section 408.803(5), F.S., is contemplated, the new owner must submit a license application and must receive a license prior to commencement of operation of the hospice. The following materials must accompany the license application:

(a) A signed agreement to correct any existing licensure deficiencies;

(b) Documented evidence that the change of ownership has taken place or will take place upon approval of the license; and

(c) A statement that records pertaining to the administrative operation of the provider must be retained and made available for official inspection by the agency.

(4) If a merger of two or more hospice providers is contemplated, the legal and incorporated entity that will be responsible for the operational function of the hospice after the merger must notify the agency prior to the merger. Notification must include the anticipated date for the merger and the reason for the merger. The agency shall require the legal entity to submit a license application, including a revised plan for the delivery of hospice care to terminally ill patients and their families.

58A-2.005 Administration of the Hospice

Governing Body

The hospice must established written bylaws for a governing body with autonomous authority for the conduct of the hospice program. The governing body must satisfy the following requirements:

Members must reside or work in the hospice's service area as defined in paragraph 59C-1.0355(2)(k), F.A.C.

No person shall be denied membership on the governing body by reason of race, creed, color, age or sex.

Duties of the governing body must include:

Adoption in writing of the following documents which must be in compliance with provisions of Chapter 400, Part IV, F.S., and these rules,

with updates as necessary:

Criteria defining eligibility for hospice services;

A program for building and coordinating relationships with other community organizations in order to provide hospice patients assistance with meals, utility payments, legal services, home repair and equipment, and other needs as identified on an individual basis;

Standards of hospice care which will ensure compliance with these rules and Chapter 400, Part IV, F.S., and which will promote and maintain a quality of life for each patient

and family that reflects the patient's needs and values;

A comprehensive emergency management plan for all administrative, residential, free-standing inpatient facilities, and hospice services designed to protect the safety of patients and their families and hospice staff; and

An annual operating and strategic plan and budget.

Promulgation of rules and bylaws which include at least the following:

- The purpose of the hospice;
- Annual review of the rules and bylaws which shall be dated and signed by the chairman of the governing body;
- The powers and duties of the officers and committees of the governing body;
- The qualifications, method of selection and terms of office of members and chairpersons of the governing body and committees; and
- A mechanism for the administrator's appointment of the medical director and other professional and ancillary personnel.

Administrative Officer

The hospice must employ an administrator whose duties must be outlined in a written job description, including job qualifications. The administrator must be approved by the governing body. The job description must be kept in an administrative file.

The administrator shall be responsible for day-to-day operations and the quality of services delivered by the hospice.

The administrator must be responsible for maintaining an administrative office for the purpose of the operations of the hospice.

ADMINISTRATIVE POLICIES AND PRACTICES

The administrator must be responsible for developing, documenting and implementing administrative policies and practices which are consistent with these rules, the bylaws, and the plans and decisions adopted by the governing body. These policies and practices must ensure the most efficient operation of the hospice program and the safe and adequate care of the patient and family units. These policies and practices must include:

- Policies governing admission to the hospice program and discontinuation of care.
- Personnel policies applicable to all full-time and part-time paid employees and

volunteers, including job descriptions, job qualifications and duties, which shall be kept in an administrative file.

- A plan for orientation and training of all staff, including volunteers, which must ensure that staff receive training prior to the delivery of services. This plan must describe the method of assessing training needs and designing training to meet those needs, and must include a curriculum outline with specific objectives.

Financial policies and practices that include:

a. An annual budget for approval by the governing body;

b. An annual audited financial statement for approval by the governing body;

c. An ongoing bookkeeping and financial management system that is developed and implemented according to sound business practice;

d. An ongoing payroll system that is developed and implemented according to sound business practice;

e. Procedures for accepting and accounting for gifts and donations; and

f. A fee schedule for hospice care.

Policies for administering drugs and biologicals in the home which must include:

a. All orders for medications shall be dated and signed by a physician licensed in the State of Florida pursuant to Chapter 458 or 459, F.S.

b. All orders for medications shall contain the name of the drug, dosage, frequency and route.

c. All verbal orders for medication or treatments, or changes in medication or treatment must be taken by a licensed health professional and recorded in the patient's record. Verbal orders must be signed by the physician within thirty (30) calendar days from the date of the order.

d. Experimental drugs shall not be administered without the written consent of the patient or the patient's legal representative, surrogate or proxy. The program administering such drugs must fully inform the patient or the patient's legal representative, surrogate or proxy of any risks, and be prepared to invoke remedial action should an adverse reaction occur. A copy of the signed consent must be kept in the patient's record.

POLICIES AND PROCEDURES

Policies and procedures for the administration and provision of pharmaceutical services in inpatient and residential settings that are consistent with the drug therapy needs of the patient as determined by the medical director or the patient's attending physician(s).

The pharmaceutical services shall be directed by a pharmacist registered in the State of Florida.

Policies and procedures approved by the medical director and governing body pertaining to the drug control system in the hospice including specific policies and procedures for disposal of Class II drugs upon the death of a patient.

Procedures which ensure the hospice can provide patients with medications on a twenty-four (24) hours a day, seven (7) days a week basis.

Policies and procedures for maintenance, confidentiality, and retention of clinical records for a minimum five-year period following the patient's death.

Procedures for inpatient visitation by family and friends.

Procedures for maintaining a record of requests for services;

The record shall indicate the action taken regarding each request for hospice services and whether or not the patient has the ability to pay for the services. In no case shall a hospice refuse or discontinue hospice services based on the inability of the patient to pay for such services.

Notice to the public that the hospice provides services regardless of ability to pay.

Notice to the public of all services provided by the hospice program, the geographic area in which the services are available, and admission criteria.

Policies for educating the community to enhance public awareness of hospice services.

Policies and procedures for completion, retention, and submission of reports and records as required by the department, agency, and other authorized agencies.

Policies and procedures for implementing universal precautions as established by the Centers for Disease Control and Prevention.

Equipment and personnel, under medical supervision, must be provided for diagnostic procedures to meet the needs of the hospice inpatient, residential and home-care programs. This must include the services of a clinical laboratory and radiological

services, which must meet all standards of the State of Florida.

There must be written agreements or contracts for such services unless provided on the premises of the hospice.

The hospice program must ensure that services are available twenty-four (24) hours a day, seven (7) days a week, either through contractual agreement, written agreement, or direct service provision by the hospice.

INFECTION CONTROL PROGRAM

Each hospice shall develop an infection control program which specifies procedures and responsibilities for inpatient, residential care and home-care programs.

Procedures regulating the structure and function of this program shall be;

- Approved by the medical director and the governing body, and shall comply with federal and state laws regarding blood-borne pathogens, infection control and biohazardous waste.

OUTCOME MEASURES

Hospices must annually report the outcome measures outlined in this subsection on DOEA Form H-002, State of Florida Department of Elder Affairs Hospice Demographic and Outcome Measures Report.

The form is hereby incorporated by reference and may be obtained from the following address: Department of Elder Affairs, Planning and Evaluation Unit, 4040 Esplanade Way, Tallahassee, Florida 32399-7000.

The form may also be obtained from the department's Web site at: http://elderaffairs.state.fl.us/english/hospice/DOEAformH002.xls.

The reporting time frame is January 1 through December 3.

The report must be submitted to the following e-mail address no later than March 31 of the following year: hospicereport@elderaffairs.org. The report may alternately be submitted to the following address: Department of Elder Affairs, Planning and Evaluation Unit, 4040 Esplanade Way, Tallahassee, FL 32399-7000.

National Hospice and Palliative Care Organization (NHPCO)

In addition to the outcome measure regarding pain management pursuant to Section 400.60501, F.S., each hospice must conduct the National Hospice and Palliative Care Organization (NHPCO) Patient/Family Satisfaction Survey, or a similar survey, with its patients and families.

Each hospice must report results from survey questions that inquire about the following areas of concern:

- Did the patient receive the right amount of medicine for his or her pain?
- Based on the care the patient received, would the patient and/or family member/caregiver/legal representative/surrogate/proxy recommend hospice services to others?

The acceptable standard for this measure must be an affirmative response on at least fifty (50) percent of the survey responses received by the hospice.

NATIONAL INITIATIVES

In accordance with Section 400.60501, F.S., the department adopts the national initiative of utilizing patient/family surveys as a tool to set benchmarks for measuring quality of hospice care in the State of Florida.

Hospices are encouraged to utilize the recommended guidelines, along with the initiatives developed by the National Hospice and Palliative Care Organization available at http://www.nhpco.org, in developing their own comprehensive data collection and performance measurement process for these initiatives.

Hospices has to maintain documentary evidence of their compliance with these national initiatives and demonstrate their operations to the department or the agency during the survey process.

58A-2.009 COORDINATED CARE PROGRAM

The administrator shall be responsible for ensuring the development, documentation and implementation of a staffing pattern for all components of a hospice program (inpatient, residential and home-care), which shall be kept in an administrative file.

- A general staffing plan shall include the rationale for determining staffing requirements, which shall be based on the needs of the patients and their families and shall ensure appropriate care to meet those needs.

- The staffing patterns for contracted inpatient components shall meet or exceed the minimum staffing requirements under which the contracted facility is currently licensed.

- Minimum service provided for routine home care, consistent with the patient's status and the family's well-being, shall be a weekly telephone contact and a biweekly visit by a registered nurse.

The administrator shall be responsible for ensuring the development, documentation and implementation of a current plan that delineates cooperative planning, decision-making and documentation by the disciplines represented in the members of the hospice care team and which provides the staff with methods of meeting collective and individual responsibilities as outlined and assigned in the plan of care for each patient and family unit.

Such policies and procedures shall, at a minimum, include the following:

Identification of the patient and the patient's family as the unit of care;

Identification of the hospice care team as the unit that provides care to the patient and family unit and that is responsible for admission, assessment and the individual plan of care for the patient and the patient's family in accordance with the requirements of Section 400.6095, F.S;

Methods of controlling the symptoms of terminal illness together with methods of evaluating and studying such methods;

Methods of teaching the patient and the patient's family those skills necessary to promote the patient and family relationship and enhance the independence of the patient and family unit.

Methods to ensure that the patient and the patient's family shall, insofar as practical, define the needs to be addressed in the plan of care, provide significant information and assistance in developing and implementing an effective plan of care, and have access to the written plan of care upon request.

The administrator shall be responsible for ensuring that the hospice care team:

Provides a mechanism whereby the patient and the patient's family shall be able to communicate directly with a member of the hospice care team on a twenty-four (24) hours a day, seven (7) days a week basis.

Documents all such communication including requests for hospice care and the disposition of such requests.

Is staffed in such a manner as to be able to receive and respond to such requests and provide interdisciplinary hospice services on a twenty-four (24) hours a day, seven (7) days a week basis.

Provides continuity of services without interruption through all modes of care delivery in the hospice program. Admission to a hospice program means accessibility to all its hospice core services as described in Section 400.609(1), F.S.

Documents all services provided by the hospice care team in the interdisciplinary care record.

58A-2.010 Quality Assurance and Utilization Review (QAUR)/Quality Assessment and Performance Improvement (QAPI) Committee and Plan

Pursuant to Section 400.610(2), F.S., each hospice must appoint a committee which must develop, document and implement a comprehensive quality assurance and utilization review plan, also referred to as a quality assessment and performance improvement plan.

The QAUR/QAPI plan must be in accordance with quality assessment and performance improvement (QAPI) standards incorporated within the Medicare Conditions for Participation, 42 CFR, Part 418, and must include goals and objectives, provisions for identifying and resolving problems, methods for evaluating the quality and appropriateness of care, and the effectiveness of actions taken to resolve identified problems.

The QAUR/QAPI plan must establish a process for revising policies, procedures and practices when reviews have identified problems. The QAUR/QAPI committee must review the QAUR/QAPI plan and report findings and recommendations to the governing body annually. Dated and signed minutes of those meetings of the governing body at which QAUR/QAPI findings and recommendations are presented must be kept in an administrative file.

(1) The QAUR/QAPI committee must be composed of individuals who are trained, qualified, supervised and supported by review procedures and written criteria related to treatment outcomes. These review procedures and written criteria must be established with involvement from physicians, and shall be evaluated and updated annually by the QAUR/QAPI committee.

(2) An incident or accident report shall be required in every instance of error in treatment, adverse reaction to treatment or medication, or injury to the patient. All of these incident or accident reports shall be reviewed by the QAUR/QAPI committee.

(3) The QAUR/QAPI committee must audit patient records, including interdisciplinary care records, on a regular and periodic basis. All records must be stored in secured areas to protect patient confidentiality.

(a) Active patient records shall be kept at the main office, a satellite office, a hospice residential facility or a hospice inpatient facility.

(b) The master record may be moved to storage in a secure and accessible location after termination of bereavement services or a minimum of one year after the patient’s death.

(4) The QAUR/QAPI committee shall assist the administrator in developing, documenting and implementing a formal training and orientation program for individuals conducting utilization review activities.

(5) Activities undertaken by the QAUR/QAPI committee must demonstrate a systematic collection, review, and evaluation of information and must result in proposed actions to correct any identified problems. The information used by the QAUR/QAPI committee must include:

(a) Care provided in alternate settings and by contracted entities;

(b) Services provided by professional and volunteer staff;

(c) Evaluations by the patient and the patient's family of care provided by the hospice;

(d) Incident reports;

(e) Complaints received from patients and their families;

(f) High-risk, high-volume and problem-prone activities that would have a significant impact on patients, staff or the organization, even if adverse incidents occur infrequently. For example, high-risk activities may include review and evaluation of protocols for containment of communicable diseases, emergency evacuations and continuity of operations; high-volume activities might include collection of information regarding administration of medications; lastly, identifying problem-prone activities might include deterioration or malfunction of equipment, including security of information systems, disposal of contaminated materials or other bio-medical waste; and

(g) Appropriateness of team services and levels of care measured by whether:

1. The plan of care was directly related to the identified physical and psychosocial needs of the patient and the patient's family;

2. Services, medications and treatments prescribed were in accordance with the current hospice plan of care; and

3. The hospice care was primarily a home-care program that utilized inpatient hospice care on a short-term or respite basis only.

(6) The QAUR/QAPI committee shall periodically review the accessibility of hospice services and the quality of those services.

(7) The QAUR/QAPI committee shall make recommendations to the administrator and the governing body for resolving identified problems and for improving patient and family care.

58A-2.012 Program Reporting Requirements

(1) With the exception of the report referenced in subsection (3) of this rule, each hospice shall complete a report annually for the period January 1 through December 31 and shall submit the report to the department no later than March 31 of the following year.

(2) The report shall include the information outlined on DOEA Form H-002, State of Florida Department of Elder Affairs Hospice Demographic and Outcome Measures Report, August 11, 2008, incorporated by reference in Rule 58A-2.005, F.A.C.

(3) The 2008 report due by March 31, 2009 need only include the collection of data from the rule effective date through December 31, 2008.

(4) The report must be submitted in accordance with subparagraph 58A-2.005(4)(a)3., F.A.C.

(5) A copy of the annual report shall at all times be available to any member of the public.

58A-2.014 Medical Direction

(1) The hospice shall employ a medical director who shall be a hospice physician licensed in the State of Florida pursuant to Chapter 458 or 459, F.S., who has admission privileges at one or more hospitals commonly serving patients in that hospice's service area as defined in Rule 59C-1.0355, F.A.C. Duties shall be enumerated in a job description, including job qualifications, which shall be kept in an administrative file.

(2)(a) The medical director or his or her designee, a physician licensed under Chapter 458 or 459, F.S., must be a member of the hospice care team and must be responsible for the direction and quality of the medical component of the care rendered to the patient by the hospice care team. The patient's attending physician(s) may remain the primary physician(s) to the patient, depending upon the preferences of the patient and the patient's family.

The patient and the patient's family may elect to have the hospice medical director assume all or part of the primary medical care functions, or act as a consultant to the patient's attending physician(s).

In either case, the hospice care team must maintain a reporting relationship with the patient's attending physician(s).

(b) Duties of the medical director shall include:

1. Reviewing clinical material of the patient's attending physician(s) to document basic disease process, prescribed medicines, assessment of patient's health at time of entry and the drug regimen, or performing an admission history and physical for each patient.

2. Validating the attending physician(s)' prognosis and life expectancy for the patient.

3. Assisting in developing and medically validating the plan of care for each patient and family unit with the coordination of the patient's attending physician(s).

4. Attending and actively participating in patient and family care conferences.

5. Rendering or actively supervising medical care for hospice patients and maintaining a record of such care.

6. Maintaining a regular schedule of participation in all components of the hospice care program and maintaining twenty-four (24) hours a day, seven (7) days a week coverage of and ready availability to the hospice program through him or herself or his or her licensed hospice physician designee.

7. Acting as a consultant to attending, including personal, physicians and other members of the hospice care team; helping to develop and review policies and procedures for delivering care and services to the patient and family unit; serving on appropriate committees; and reporting regularly to the hospice administrator regarding medical care delivered to the hospice patients.

8. Maintaining liaison with the patient's attending physician(s), who is encouraged to provide primary care to his or her patient even though the patient also receives hospice care. The hospice physician will provide palliative care to his or her patient.

9. Establishing written protocols for symptom control, such as pain, nausea, vomiting, or other symptoms.

10. Assisting the administrator in developing, documenting and implementing a policy for discharge of patients from hospice care.

(3) In addition to the hospice medical director, the hospice may appoint additional hospice physician(s) who shall perform duties prescribed herein. Any appointed physician shall be subject to the same licensing qualifications as the hospice medical director.

(4) The medical director shall assist the administrator in developing, documenting and implementing policies and procedures for regulating the delivery of physicians' services, for orientation of new hospice physicians, and for continuing training and support of hospice physicians. These policies and procedures shall:

(a) Ensure that a hospice physician is on-call twenty-four (24) hours a day, seven (7) days a week;

(b) Provide for the review and evaluation of clinical practices within hospice inpatient, residential and home-care programs in coordination with the QAUR/QAPI committee.

58A-2.0141 NURSING SERVICES; REGISTERED NURSE

The hospice shall employ a registered nurse who shall monitor all services provided by hospice nurses and home health aides.

The supervising registered nurse shall be qualified by supervisory or hospice experience and shall have completed a hospice training program sponsored by the employing hospice.

Duties shall be enumerated in a job description, including job qualifications, which shall be kept in an administrative file.

The supervising registered nurse shall assist the administrator in:

- Developing, documenting and implementing policies and procedures for the delivery of clinical nursing services throughout the hospice program, including home-care, residential and inpatient programs;
- the orientation and training of newly employed or contractual hospice nurses and home health aides; and
- ongoing training and education of the hospice nurses and home health aides.

The hospice shall ensure, by employment or contractual arrangements, that there are sufficient nurses and home health aides to meet the health care needs of the patient population of the hospice.

58A-2.015 SPIRITUAL COUNSELING SERVICES

The hospice shall employ a clergy-person or pastoral counselor to provide spiritual counseling. The clergy-person or pastoral counselor shall have a degree in ministry from a college, university or divinity school; or shall have completed a clinical pastoral education program with an emphasis in health care ministry; or shall have completed formal training and is recognized as qualified to perform pastoral services in his or her religion or belief system.

The clergy-person or pastoral counselor shall also have completed a hospice training program sponsored by the employing hospice. Duties shall be enumerated in a job description, including job qualifications, which shall be kept in an administrative file.

The clergy-person or pastoral counselor shall assist the administrator in developing, documenting and implementing policies and procedures regulating the delivery of such services.

The hospice shall ensure, by employment or contractual arrangement, that there are sufficient clergy-persons or pastoral counselors to provide spiritual support to the patient population of the hospice and the patients' families.

The hospice and its agents shall not impose the dictates of any value or belief system on its patients and their families.

58A-2.016 COUNSELING AND SOCIAL SERVICES

The hospice shall employ a social worker who has a degree in social work or a degree in a related field with experience in social work, and who has completed a hospice training program sponsored by the employing hospice. Duties shall be enumerated in a job description, including job qualifications, which shall be kept in an administrative file.

Therapeutic counseling services, if provided, must be provided by a social worker, marriage and family therapist, mental health counselor, or other mental health professional who is licensed by or authorized under the laws of the state of Florida to provide such services.

The social worker shall assist the administrator in developing, documenting and implementing policies and procedures regulating the delivery of such services.

The hospice shall ensure, by employment or contractual arrangement, that there are sufficient social workers and other mental health professionals to meet the social, emotional and mental health needs of the patients and families being served by the hospice. Check with your state for requirements.

58A-2.017 VOLUNTEER SERVICES

The hospice shall employ a coordinator of volunteer services who shall assist the administrator in developing, documenting and implementing a volunteer services program which meets the operational needs of the program and provides services to the patient and family units in accordance with the individual plans of care. Duties shall be enumerated in a job description, including job qualifications, which shall be kept in an

administrative file.

The volunteer coordinator shall assist the administrator in developing, documenting and implementing policies and procedures regulating the delivery of such services, volunteer orientation, and ongoing training and support for volunteers.

The hospice shall make effort to recruit volunteers to provide support for the needs and comfort of the patient population of the hospice and the patients' families. Check with your state for requirements.

58A-2.018 BEREAVEMENT SERVICES

The hospice shall provide bereavement counseling and services to the families of hospice patients for a minimum of one (1) year following the patient's death. The formal and informal supportive services which comprise bereavement counseling shall be supervised or provided by professional staff as described in Rules 58A-2.015 and 58A-2.016, F.A.C.

The administrator shall ensure the development, documentation and implementation of policies and procedures regulating the delivery of bereavement counseling and services.

The bereavement program shall provide educational and spiritual materials and individual and group support services for the patient's family after the patient's death. For check with your state for requirements.

58A-2.019 NUTRITIONAL SERVICES

The administrator shall ensure that dietary services and nutritional counseling services are available to all patient and family units in all components of hospice care on an as-needed basis.

The administrator shall ensure the development, documentation and implementation of written policies and procedures for dietary services including nutritional counseling services.

In hospice residential care and hospice inpatient care settings, the hospice shall provide consultation by a licensed dietitian on practical freedom-of-choice diets for hospice patients and shall ensure that patients' favorite foods are included in their diets whenever possible. Check with your state for requirements.

58A-2.0232 Advance Directives and Do Not Resuscitate Orders (DNRO).

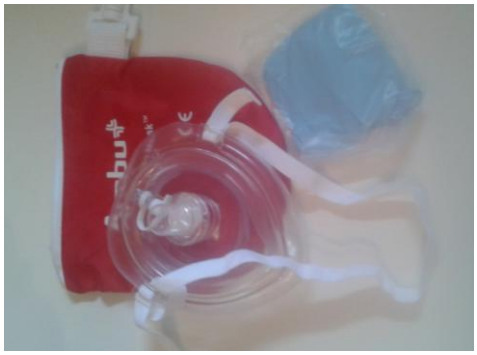
The administrator must ensure the development, documentation and implementation of policies and procedures which delineate the hospice's compliance with the state law and rules relative to advance directives. The hospice must not base or condition treatment or admission upon whether or not the patient has executed or waived an advance directive. In the event of a conflict between the hospice's policies and procedures and the patient's advance directive, resolution must be made in accordance with Chapter 765, F.S.

In the state of Florida, the hospice's policies and procedures must include:

- At the time of admission, providing each patient, or the patient's surrogate, proxy or other legal reprensentative, with a copy of Form SCHS-4-2006, "Health Care Advance Directives – The Patient's Right to Decide," effective April 2006, or with a copy of some other substantially similar document which incorporates information regarding advance directives included in Chapter 765, F.S.

- At the time of admission, providing each patient, or the patient's surrogate, proxy or other legal representative, with written information concerning the hospice's policies regarding resuscitation and advance directives, including information concerning DH Form 1896, Florida Do Not Resuscitate Order Form, incorporated by reference in Rule 64E-2.031, F.A.C.

- Requiring documentation of the existence of an advance directive in the patient's medical record. A hospice which is provided with a patient's advance directive shall make the advance directive or a copy thereof a part of the patient's interdisciplinary care record and the patient's medical record.



Hospice may withhold or withdraw cardiopulmonary resuscitation from a patient if a valid Do Not Resuscitate Order (DNRO) is presented and executed pursuant to Section 401.45, F.S.

An absence of an order not to resuscitate, executed pursuant to Section 401.45, F.S., does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation as otherwise permitted by law.

Hospice personnel 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 DNRO and rules adopted by the department, pursuant to Section 400.6095(8), F.S.

Any licensed professional hospice 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 or her performance regarding patient care.

Pursuant to Section 765.110, F.S., a hospice health care provider or facility shall be subject to discipline if the healthcare provider or facility requires an individual to execute or waive an advance directive as a condition of treatment or admission. Check with your state for requirements.

58A-2.0236 RESIDENTIAL UNITS

Residential units which are established by a licensed hospice provider will not be required to be separately licensed. Residential units shall comply with local codes and ordinances governing zoning, fire, safety, and health standards.

Residential units shall be maintained in a manner which provides for managing personal hygiene needs of the patients and implementation of infection control procedures.

Equipment and furnishings in residential units will provide for the health care needs of the resident while providing a home-like or non-institutional type of atmosphere.

The hospice provider shall insure that:

- Each patient residing in a residential unit has an identified individual who will serve as that patient’s principal advocate and contact person.
- The residential unit is staffed at sufficient skill level and number to meet the

needs of the patients and their families.

At all times the residential unit shall be staffed with a minimum of two (2) employees, one (1) of which shall be a licensed nurse.

Units for more than eight (8) patients shall be a staff-to-patient ratio of one to four (1:4) calculated on a twenty-four (24) hour period. At no time shall the unit have a staff-to-patient ratio of less than one to six (1:6).

All staff on duty shall assist with evacuation of patients in the event of an emergency.

Services provided in the residential unit are consistent with the plan of care prepared for that patient and are consistent with services provided by the hospice program in other settings.

Residential units shall be equipped to prepare meals that meet the dietary requirements of the patient.

Upon adoption of this rule, newly constructed or renovated residential units shall comply with the requirements of Section 400.6051, F.S.

Check with your state for requirements.

58A-2.026 Comprehensive Emergency Management Plan (CEMP)

Each hospice shall prepare and maintain a comprehensive emergency management plan.This document is available from:

The Agency for Health Care Administration, Licensed Home Health Programs Unit, 2727 Mahan Drive, Mail Stop 34, Tallahassee, Florida 32308 or the agency Web site at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Home_Care/definitions.shtml#hospices, and shall be included as part of the hospice's comprehensive emergency management plan.

The CEMP shall be submitted electronically for review to the local county health department in each county that the hospice is licensed to serve. Any method other than electronic submission of the form shall be expressly approved by the local county health department.

The hospice shall report changes in the after-hours emergency telephone number and address of those staff who are coordinating the hospice's emergency response to the local emergency management agency and county health department. The telephone numbers must include all numbers where the coordinating staff can be contacted outside the hospice's regular office hours. All hospices must report these changes, whether the plan has been previously reviewed or not.

Upon a change of ownership, the new owner shall submit a new plan identifying any substantive changes, including facility renovations and changes noted in subsection (3) above. Those hospices which previously have had the plan reviewed by the local county health department; shall report any substantive changes to the reviewing entity.

The CEMP shall describe:

Procedures to ensure preparation of hospice patients for potential or imminent emergencies and disasters.

Procedures for annual review of the plan and for the governing body to incorporate substantive changes to the plan.

In the event of an emergency or disaster, the hospice shall implement the hospice's CEMP Plan.

On admission, each hospice patient and, where applicable, home caregiver shall be informed of the hospice plan and of the special-needs registry maintained by the local emergency management agency.

The hospice shall document in the patient's file if:

- The patient plans to evacuate the home or the hospice facility,

- The caregiver can take responsibility for services normally provided by the hospice during the emergency or disaster or

- The hospice needs to arrange for alternative caregiver services for the patient.

Upon imminent threat of an emergency or disaster, the hospice shall confirm each patient's plan during and immediately following an emergency or disaster.

When the hospice is *unable to provide services during an emergency or disaster,* the hospice shall make all reasonable efforts to inform, where applicable, those facility and home patients whose services will be interrupted during the emergency or disaster, including patients sheltering in place; and shall inform when services are anticipated to be restored.

Each hospice shall contact each local emergency management agency in counties served by that hospice to determine procedures for registration of special-needs registrants.

Upon admission of a patient, each hospice shall collect registration information for special-needs registrants who will require continuing care or services during a disaster or emergency.

This registration information shall be submitted, when collected, to the local emergency management agency, or on a periodic basis as determined by the local emergency management agency.

The hospice shall educate patients registered with the special-needs registry that services provided by the hospice in special-needs shelters shall meet the requirements in Section 400.610(1)(b), F.S.

The hospice shall maintain a current list of patients who are special-needs registrants, and shall forward this list to the local emergency management agency upon imminent threat of disaster or emergency and in accordance with the local emergency management agency procedures.

Each hospice record for patients who are listed in the special-needs registry established, shall include a description of how care or services will be continued in the event of an emergency or disaster pursuant to Section 400.610(1)(b), F.S.

The hospice shall discuss the emergency provisions with the patient and the patient's caregiver, including where and how the patient is to evacuate, procedures for notifying the hospice in the event that the patient evacuates to a location other than the shelter identified in the patient record, and advance directives.

The hospice shall maintain for each special-needs patient a list of client-specific medications, supplies, and equipment required for continuing care and service, should the patient be evacuated.

If the hospice provides services to home patients, the hospice shall make arrangements to make the list of medications, supplies, and equipment available to each special-needs registrant in the event of an evacuation.

The hospice shall notify the patient that he or she is responsible for maintaining a supply of medications in the home. The list shall include the names of all medications, dose, frequency, times, any other special considerations for administration, any allergies, names of physicians and telephone numbers, and name and telephone number of the patient's pharmacy. If the patient gives consent, the list may also include the patient's diagnosis. Check with your state for requirements.

58A-2.027 HOSPICE EMPLOYEE TRAINING REQUIREMENTS

Each hospice licensed under Chapter 400, Part IV, F.S., shall provide that hospice employees receive the following training:

1. Understanding Alzheimer's Disease and Related Disorders;

2. Characteristics of Alzheimer's Disease and Related Disorders; and

3. Communicating with patients with Alzheimer's Disease or Related Disorders.

(See Chapter 400, Part IV, F.S for more details)

Completion of the required three hours of training after June 30, 2003, shall satisfy the requirement referenced in Section 400.6045(1)(c), F.S. The three hours of training must address the following subject areas as they apply to Alzheimer's Disease and Related Disorders:

1. Behavior management;

2. Assistance with activities of daily life to promote the patient's independence;

3. Activities for patients;

4. Stress management for the care giver;

5. Family issues;

6. Patient environment; and

7. Ethical issues.

Individuals who seek to provide Alzheimer's Disease or Related Disorders training shall provide the Department of Elder Affairs or its designee documentation that they hold a Bachelor's degree in a health-care, human service, or gerontology related field from an accredited college or university or hold a license as a registered nurse, and:

- Possess teaching or training experience as an educator of care givers for persons with Alzheimer's Disease or Related Disorders; or

- Have one year of practical experience in a program providing care to persons with Alzheimer's Disease or Related Disorders; or

- Have completed a specialized training program in Alzheimer's Disease or Related Disorders from a university or an accredited health care or human service or gerontology continuing education provider.

Check with your state for requirements.

400.6105 STAFFING AND PERSONNEL

Each hospice shall have a medical director who shall have responsibility for directing the medical care and treatment of hospice patients.

Each hospice shall employ a full-time registered nurse licensed who shall coordinate the implementation of the plan of care for each patient.

A hospice shall employ a hospice care team or teams who shall participate in the establishment and ongoing review of the patient's plan of care, and be responsible for and supervise the delivery of hospice care and services to the patient.

The team shall, at a minimum, consist of a physician, a nurse, a social worker, and a pastoral or other counselor. The composition of the team may vary for each patient and, over time, for the same patient to ensure that all the patient's needs and preferences are met.

A hospice must maintain a trained volunteer staff for the purpose of providing both administrative support and direct patient care. A hospice must use trained volunteers who work in defined roles and under the supervision of a designated hospice employee for an amount of time that equals at least 5 percent of the total patient care or administrative hours provided by all paid hospice employees and contract staff in the aggregate.

The hospice shall document and report the use of volunteers, including maintaining a record of the number of volunteers, the number of hours worked by each volunteer, and the tasks performed by each volunteer.

A hospice may contract with other persons or legal entities to provide additional services beyond those provided by the hospice care team or, to supplement the number of persons on the hospice care team, to ensure that the needs of patients and their families are met. Persons hired on contract shall have the same qualifications as are required of hospice personnel.

Each hospice shall provide ongoing training and support programs for hospice staff and volunteers.

400.611 Interdisciplinary records of care; confidentiality

An up-to-date, interdisciplinary record of care being given and patient and family status shall be kept. Records shall contain pertinent past and current medical, nursing, social, and other therapeutic information and such other information that is necessary for the safe and adequate care of the patient.

Notations regarding all aspects of care for the patient and family shall be made in the record. When services are terminated, the record shall show the date and reason for termination.

Patient records shall be retained for a period of 5 years after termination of hospice services, unless otherwise provided by law. In the case of a patient who is a minor, the 5-year period shall begin on the date the patient reaches or would have reached the age of majority.

Patient records of care are confidential. A hospice may not release a record or any portion thereof, unless:

(a) A patient or legal guardian has given express written informed consent;

(b) A court of competent jurisdiction has so ordered; or

(c) A state or federal agency, acting under its statutory authority, requires submission of aggregate statistical data.

Any information obtained from patient records by a state agency pursuant to its statutory authority is confidential and exempt from the provisions of s. 119.07(1).

400.609 HOSPICE SERVICES

Each hospice shall provide a continuum of hospice services which afford the patient and the family of the patient a range of service delivery which can be tailored to specific needs and preferences of the patient and family at any point in time throughout the length of care for the terminally ill patient and during the bereavement period.

These services must be available 24 hours a day, 7 days a week, and must include: Services. The hospice care team shall directly provide the following core services:

Nursing services, social work services, pastoral or counseling services, dietary counseling, and bereavement counseling services.

Physician services may be provided by the hospice directly or through contract.

A hospice may also use contracted staff if necessary to supplement hospice employees in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances.

Each hospice must also provide or arrange for such additional services as are needed to meet the palliative and support needs of the patient and family. These services may include, but are not limited to, physical therapy, occupational therapy, speech therapy, massage therapy, home health aide services, infusion therapy, provision of medical supplies and durable medical equipment, day care, homemaker and chore services, and funeral services.

HOSPICE HOME CARE

Hospice care and services provided in a private home shall be the primary form of care. The goal of hospice home care shall be to provide adequate training and support to encourage self-sufficiency and allow patients and families to maintain the patient comfortably at home for as long as possible. The services of the hospice home care program shall be of the highest quality and shall be provided by the hospice care team.

HOSPICE RESIDENTIAL CARE

Hospice care and services, to the extent practicable and compatible with the needs and preferences of the patient, may be provided by the hospice care team to a patient living in an assisted living facility, adult family-care home, nursing home, hospice residential unit or facility, or other nondomestic place of permanent or temporary residence.

A resident or patient living in an assisted living facility, adult family-care home, nursing home, or other facility subject to state licensing who has been admitted to a hospice program shall be considered a hospice patient, and the hospice program shall be responsible for coordinating and ensuring the delivery of hospice care and services to such person pursuant to the standards and requirements of this part and rules adopted under this part.

HOSPICE INPATIENT CARE

The inpatient component of care is a short-term adjunct to hospice home care and hospice residential care and shall be used only for pain control, symptom management, or respite care. The total number of inpatient days for all hospice patients in any 12 month period may not exceed 20 percent of the total number of hospice days for all the hospice patients of the licensed hospice. Hospice inpatient care shall be under the direct administration of the hospice, whether the inpatient facility is a freestanding hospice facility or part of a facility licensed pursuant to chapter 395 or part II of this chapter.

The facility or rooms within a facility used for the hospice inpatient component of care shall be arranged, administered, and managed in such a manner as to provide privacy, dignity, comfort, warmth, and safety for the terminally ill patient and the family. Every possible accommodation must be made to create as homelike an atmosphere as practicable.

To facilitate overnight family visitation within the facility, rooms must be limited to no more than double occupancy; and, whenever possible, both occupants must be hospice patients.

There must be a continuum of care and a continuity of caregivers between the hospice home program and the inpatient aspect of care to the extent practicable and compatible with the preferences of the patient and his or her family.

Fees charged for hospice inpatient care, whether provided directly by the hospice or through contract, must be made available upon request to the Agency for Health Care Administration.

The hours for daily operation and the location of the place where the services are provided must be determined, to the extent practicable, by the accessibility of such services to the patients and families served by the hospice.

BEREAVEMENT COUNSELING

The hospice bereavement program must be a comprehensive program, under professional supervision, that provides a continuum of formal and informal supportive services to the family for a minimum of 1 year after the patient's death.

Advance Directives

At the time of admission, providing each patient, or the patient's surrogate, proxy or other legal reprensentative, with a copy of Health Care Advance Directives – The Patient's Right to Decide, or with a copy of some other substantially similar document which incorporates information regarding advance directives.

At the time of admission, providing each patient, or the patient's surrogate, proxy or other legal representative, with written information concerning the hospice's policies regarding resuscitation and advance directives, including information concerning DH

Form 1896, Florida Do Not Resuscitate Order Form, incorporated by reference in Rule 64E-2.031, F.A.C.

Requiring documentation of the existence of an advance directive in the patient's medical record. A hospice which is provided with a patient's advance directive shall make the advance directive or a copy thereof a part of the patient's interdisciplinary care record and the patient's medical record.

Pursuant to Section 400.6095(8), F.S., a hospice may withhold or withdraw cardiopulmonary resuscitation from a patient if a valid Do Not Resuscitate Order (DNRO) is presented and executed pursuant to Section 401.45, F.S.

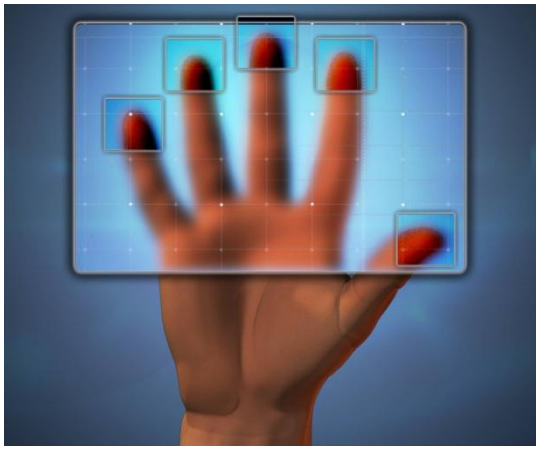
An absence of an order not to resuscitate, executed pursuant to Section 401.45, F.S., does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation as otherwise permitted by law.

Hospice personnel 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 DNRO and rules adopted by the department, pursuant to Section 400.6095(8), F.S.

Any licensed professional hospice 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 or her performance regarding patient care.

Pursuant to Section 765.110, F.S., a hospice health care provider or facility shall be subject to discipline if the healthcare provider or facility requires an individual to execute or waive an advance directive as a condition of treatment or admission.

BACKGROUND SCREENING



408.809 Background screening; prohibited offenses

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:

- The licensee, if an individual.
- The administrator or a similarly titled person who is responsible for the day-to-day operation of the provider.
- The financial officer or similarly titled individual who is responsible for the financial operation of the licensee or provider.
- 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.
- 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.

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. For any such rescreening, the agency shall request the Department of Law Enforcement to forward the person's fingerprints to the Federal Bureau of Investigation for a national criminal history record check.

If the fingerprints of such a person are not retained by the Department of Law Enforcement under s. 943.05(2)(g), the person must file a complete set of fingerprints with the agency and the agency shall forward the fingerprints to the Department of Law Enforcement for state processing, and the Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal history record check.

The fingerprints may be retained by the Department of Law Enforcement under s. 943.05(2)(g). The cost of the state and national criminal history records checks required by level 2 screening may be borne by the licensee or the person fingerprinted. Until the person's background screening results are retained in the clearinghouse created under s. 435.12, the agency may accept as satisfying the requirements of this section proof of compliance with level 2 screening standards submitted within the previous 5 years to meet any provider or professional licensure requirements of the agency, the Department of Health, the Department of Elderly Affairs, the Agency for Persons with Disabilities, the Department of Children and Family Services,

or the Department of Financial Services for an applicant for a certificate of authority or provisional certificate of authority to operate a continuing care retirement community under chapter 651, provided that:

- The screening standards and disqualifying offenses for the prior screening are equivalent to those specified in s. 435.04 and this section;

- The person subject to screening has not had a break in service from a position that requires level 2 screening for more than 90 days; and

- Such proof is accompanied, under penalty of perjury, by an affidavit of compliance with the provisions of chapter 435 and this section using forms provided by the agency.

All fingerprints must be provided in electronic format. Screening results shall be reviewed by the agency with respect to the offenses specified in s.435.04 and this section, and the qualifying or disqualifying status of the person named in the request shall be maintained in a database. The qualifying or disqualifying status of the person named in the request shall be posted on a secure website for retrieval by the licensee or designated agent on the licensee's behalf.

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: (may click on links for more information);

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

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

(h) Section 817.505, relating to patient brokering.

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

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

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

(l) Section 831.01, relating to forgery.

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

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

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

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

(q) 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.

An individual who serves as a controlling interest of, is employed by, or contracts with a licensee on July 31, 2010, who has been screened and qualified according to standards specified in s. 435.03 or s. 435.04 must be rescreened by July 31, 2015, in compliance with the following schedule.

If, upon rescreening, such person has a disqualifying offense that was not a disqualifying offense at the time of the last screening, but is a current disqualifying offense and was committed before the last screening, he or she may apply for an exemption from the appropriate licensing agency and, if agreed to by the employer, may continue to perform his or her duties until the licensing agency renders a decision on the application for exemption if the person is eligible to apply for an exemption and the exemption request is received by the agency within 30 days after receipt of the rescreening results by the person.

The rescreening schedule shall be:
(a) Individuals for whom the last screening was conducted on or before December 31, 2004, must be rescreened by July 31, 2013.
(b) Individuals for whom the last screening conducted was between January 1, 2005, and December 31, 2008, must be rescreened by July 31, 2014.
(c) Individuals for whom the last screening conducted was between January 1, 2009, through July 31, 2011, must be rescreened by July 31, 2015.

The costs associated with obtaining the required screening must be borne by the licensee or the person subject to screening. Licensees may reimburse persons for these costs. The Department of Law Enforcement shall charge the agency for screening pursuant to s. 943.053(3). The agency shall establish a schedule of fees to cover the costs of screening.

As provided in chapter 435, the agency may grant an exemption from disqualification to a person who is subject to this section and who:
1. Does not have an active professional license or certification from the Department of Health; or
2. Has an active professional license or certification from the Department of Health but is not providing a service within the scope of that license or certification.

As provided in chapter 435, the appropriate regulatory board within the Department of Health, or the department itself if there is no board, may grant an exemption from disqualification to a person who is subject to this section and who has received a professional license or certification from the Department of Health or a regulatory board within that department and that person is providing a service within the scope of his or her licensed or certified practice.

The agency and the Department of Health may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this section, chapter 435, and authorizing statutes requiring background screening and to implement and adopt criteria relating to retaining fingerprints pursuant to s. 943.05(2).

There is no reemployment assistance or other monetary liability on the part of, and no cause of action for damages arising against, an employer that, upon notice of a

disqualifying offense listed under chapter 435 or this section, terminates the person against whom the report was issued, whether or not that person has filed for an exemption with the Department of Health or the agency.

400.6085 CONTRACTUAL SERVICES

A hospice may contract out for some elements of its services. However, the core services, as set forth in s.400.609 (1), with the exception of physician services, shall be provided directly by the hospice.

Any contract entered into between a hospice and a health care facility or service provider must specify that the hospice retains the responsibility for planning, coordinating, and prescribing hospice care and services for the hospice patient and family.

A hospice that contracts for any hospice service is prohibited from charging fees for services provided directly by the hospice care team that duplicate contractual services provided to the patient and family.

A contract for hospice services, including inpatient services, must:

- Identify the nature and scope of services to be provided.
- Require that direct patient care shall be maintained, supervised, and coordinated by the hospice care team.
- Limit the services to be provided to only those expressly authorized by the hospice in writing.
- Delineate the roles of hospice staff and contract staff in the admission process and patient assessment.
- Identify methods for ensuring continuity of hospice care.

- Plan for joint quality assurance.

- Specify the written documentation, including patient records, required of contract staff.

- Specify qualifications of persons providing the contract services.

- Specify the effective dates for the contract.

With respect to contractual arrangements for inpatient hospice care:

- Licensed beds designated for inpatient hospice care through contract between an existing health care facility and a hospice shall not be required to be delicensed from one type of health care in order to enter into a contract with a hospice, nor shall the physical plant of any facility licensed pursuant to chapter 395 or part II of this chapter be required to be altered, except that a homelike atmosphere may be required.

- Hospices contracting for inpatient care beds shall not be required to obtain an additional certificate of need for the number of such designated beds. Such beds shall remain licensed to the health care facility and be subject to the appropriate inspections.

- Staffing standards for inpatient hospice care provided through a contract may not exceed the staffing standards required under the license held by the contractee.

- Under no circumstances may a hospice place a patient requiring inpatient care in a health care facility that is under a moratorium, has had its license revoked, or has a conditional license, accreditation, or rating. However, a hospice may continue to provide care or initiate care for a terminally ill person already residing in such a facility.

MEDICATION MANAGEMENT

CONDITION OF PARTICIPATION (§418.106)

Drugs and biologicals, medical supplies, and durable medical equipment.

Standard: Managing drugs and biologicals

The hospice must ensure that the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs.

Hospices must confer with an individual with education and training in drug management, and use acceptable standards of practice for hospice patients to select the most appropriate drugs to meet a particular patient’s need. Conferences may take place in person or through other means of communication for example teleconference, FAX, electronically etc.

The hospice should also be able to explain drug choices to those providing patient care, the patient or representative, the family, and any authority having jurisdiction, as necessary.

Individuals with education and training in drug management may include: licensed pharmacists; physicians who are board certified in palliative medicine; RNs who are certified in palliative care; and physicians, RNs and nurse practitioners who complete a specific hospice or palliative care drug management course, and other individuals as allowed by State law.

The hospice must be able to demonstrate that the individual has specific education and training in drug management.

A hospice that provides inpatient care directly in its own facility must provide pharmacy services under the direction of a qualified licensed pharmacist who is an employee of or under contract with the hospice.

The provided pharmacist services must include:

- Evaluation of a patient's response to medication therapy,
- Identification of potential adverse drug reactions, and
- Recommended appropriate corrective action.

Standard: Ordering of drugs

Only a physician as defined by Section 1861(r)(1) of the Act, or a nurse practitioner in accordance with the plan of care and State law, may order drugs for the patient.

If the drug order is verbal or given by or through electronic transmission:

(i) It must be given only to a licensed nurse, nurse practitioner (where appropriate), pharmacist, or physician; and

(ii) The individual receiving the order must record and sign it immediately and have the prescribing person sign it in accordance with State and Federal regulations.

Standard: Dispensing of drugs and biologicals

The hospice must:

(1) Obtain drugs and biologicals from community or institutional pharmacists or stock drugs and biologicals itself.

(2) The hospice that provides inpatient care directly in its own facility must:

(i) Have a written policy in place that promotes dispensing accuracy; and

(ii) Maintain current and accurate records of the receipt and disposition of all controlled drugs.

A biological is any medicinal preparation made from living organisms and their products including, but not limited to, serums, vaccines, antigens, and antitoxins.

Standard: Administration of drugs and biologicals

(1) The interdisciplinary group, as part of the review of the plan of care, must determine the ability of the patient and/or family to safely self-administer drugs and biologicals to the patient in his or her home.

(2) Patients receiving care in a hospice that provides inpatient care directly in its own facility may only be administered medications by the following individuals:

(i) A licensed nurse, physician, or other health care professional in accordance with their scope of practice and State law;

(ii) An employee who has completed a State-approved training program in medication administration; and

(iii) The patient, upon approval by the interdisciplinary group.

The patient's individualized written plan of care should identify if the patient and/or family are self-administering drugs and biologicals. If the patient and/or family are not capable of safely administering drugs and biologicals in the home, the hospice must address this issue in the patient's plan of care.

Standard: Labeling, disposing, and storing of drugs and biologicals

(1) Labeling

Drugs and biologicals must be labeled in accordance with currently accepted professional practice and must include appropriate usage and cautionary instructions, as well as an expiration date (if applicable).

(2) Disposing

(i) Safe use and disposal of controlled drugs in the patient's home. The hospice must have written policies and procedures for the management and disposal of controlled drugs in the patient's home. At the time when controlled drugs are first ordered the hospice must:

(A) Provide a copy of the hospice written policies and procedures on the management and disposal of controlled drugs to the patient or patient representative and family;

(B) Discuss the hospice policies and procedures for managing the safe use and disposal of controlled drugs with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe use and disposal of controlled drugs; and

(C) Document in the patient's clinical record that the written policies and procedures for managing controlled drugs was provided and discussed.

(ii) Disposal of controlled drugs in hospices that provide inpatient care directly. The hospice that provides inpatient care directly in its own facility must dispose of controlled drugs in compliance with the hospice policy and in accordance with State and Federal requirements. The hospice must maintain current and accurate records of the receipt and disposition of all controlled drugs.

Storing

The hospice that provides inpatient care directly in its own facility must comply with the following additional requirements;

(i) All drugs and biologicals must be stored in secure areas. All controlled drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1976 must be stored in locked compartments within such secure storage areas. Only personnel authorized to administer controlled drugs may have access to the locked compartments; and

(ii) Discrepancies in the acquisition, storage, dispensing, administration, disposal, or return of controlled drugs must be investigated immediately by the pharmacist and hospice administrator and where required reported to the appropriate State authority. A written account of the investigation must be made available to State and Federal officials if required by law or regulation.

Standard: Use and maintenance of equipment and supplies

(1) The hospice must ensure that manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment are followed. The equipment must be safe and work as intended for use in the patient's environment. Where a manufacturer recommendation for a piece of equipment does not exist, the hospice must ensure that repair and routine maintenance policies are developed. The hospice may use persons under contract to ensure the maintenance and repair of durable medical equipment.

(2) The hospice must ensure that the patient, where appropriate, as well as the family and/or other caregiver(s), receive instruction in the safe use of durable medical equipment and supplies. The hospice may use persons under contract to ensure patient and family instruction. The patient, family, and/or caregiver must be able to demonstrate the appropriate use of durable medical equipment to the satisfaction of the hospice staff.

(3) Hospices may only contract for durable medical equipment services with a durable medical equipment supplier that meets the Medicare DMEPOS Supplier Quality and Accreditation Standards at 42 CFR 424.57.

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:

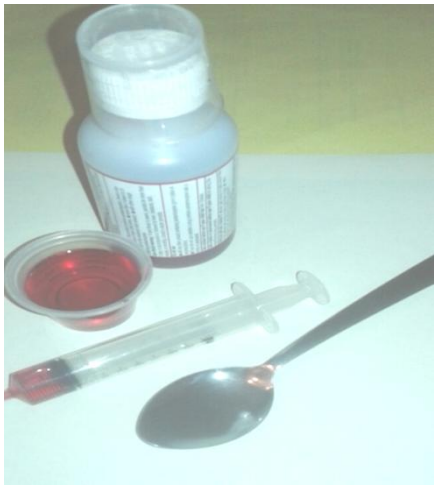
• oral route (by mouth)
• sublingual route (under tongue)
• buccal route (inside the cheek)
• otic (ear)
• ophthalmic (eye)
• topical (applied on the skin)
• nasal route (nose)
• vaginal route (vagina)
• rectal (by rectum)
• inhalation (by inhaling)
• nasogastric tube (tube in the nose to the stomach)
. 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:

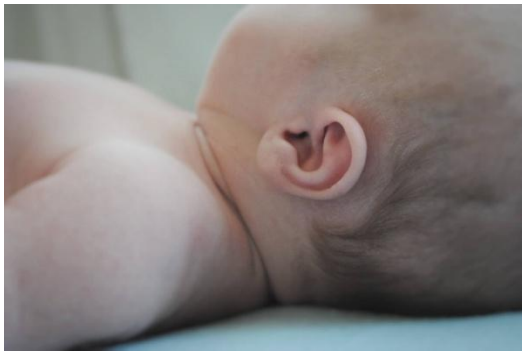
- capsule (regular and sustained release)
- tablet
- suppositories (rectal and vaginal)
- elixir
- syrup
- cream
- oral suspension
- tincture
- paste
- ointment
- drop (ears and eye)
- Intravenous /IV solutions and suspension
- metered dose inhaler



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.

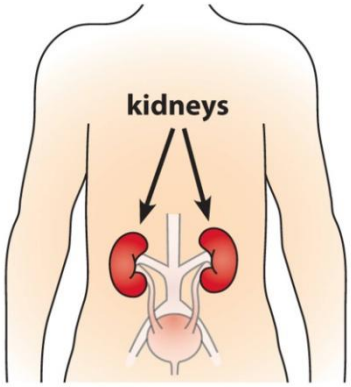
The aging process also is associated with a reduction in total body fluids (water), which can affect the volume of distribution of water-soluble drugs. Older individuals in general produce less albumin, which binds drugs in the bloodstream. Reduction in albumin; protein binding, may result in an increase 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 HOSPICE CARE DEFINITIONS (400.601):

Hospice care team means an interdisciplinary team of qualified professionals and volunteers who, in consultation with the patient, the patient's family, and the patient's primary or attending physician, collectively assess, coordinate, and provide the appropriate palliative and supportive care to hospice patients and their families.

Hospice residential unit means a homelike living facility, other than a facility licensed under other parts of this chapter, under chapter 395, or under chapter 429, that is operated by a hospice for the benefit of its patients and is considered by a patient who lives there to be his or her primary residence.

Hospice services means items and services furnished to a patient and family by a hospice, or by others under arrangements with such a program, in a place of temporary or permanent residence used as the patient's home for the purpose of maintaining the patient at home; or, if the patient needs short-term institutionalization, the services shall be furnished in cooperation with those contracted institutions or in the hospice inpatient facility.

Palliative care means services or interventions which are not curative but are provided for the reduction or abatement of pain and human suffering.

Plan of care means a written assessment by the hospice of each patient's and family's needs and preferences, and the services to be provided by the hospice to meet those needs.

Terminally ill means that the patient has a medical prognosis that his or her life expectancy is 1 year or less if the illness runs its normal course.

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