**Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

**Subtitle 07 HOSPITALS**

**Chapter 21 Hospice Care Programs**

**Authority: Health-General Article, §19-903, Annotated Code of Maryland**

*10.07.21.01*

**.01 Scope and Purpose.**

This chapter applies to any general or limited hospice care program as defined in Health-General Article, §19-901, Annotated Code of Maryland.

*10.07.21.02*

**.02 Definitions.**

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Attending physician" means the physician having the most significant role in the determination and delivery of the hospice patient's medical care.

(2) Bereavement Services.

(a) "Bereavement services" means counseling services provided to the patient's family after the patient's death.

(b) "Bereavement services" includes:

(i) Personal contacts with the family by hospice employees or volunteers;

(ii) Support groups; and

(iii) Referrals to other service providers.

(3) "Department" means the Department of Health and Mental Hygiene.

(4) "Family" means a group of two or more individuals related by legal status or affection who consider themselves a family.

(5) "General hospice care program" means a coordinated, interdisciplinary program of hospice care services designed to meet the special physical, psychological, spiritual, and social needs of dying individuals and their families, by providing palliative and supportive medical, nursing, and other health-related services during illness and bereavement through home or inpatient care.

(6) "Home-based hospice services" means hospice care services provided to a patient in the patient's permanent or temporary residence.

(7) Hospice Care Program.

(a) "Hospice care program" means a coordinated, interdisciplinary program of hospice care services.

(b) "Hospice care program" includes a general or limited hospice care program.

(8) "Inpatient care services" means services provided by a general hospice care program for the purpose of pain control, symptom management, or respite.

(9) "License" means a license issued by the Secretary to operate a general or limited hospice care program.

(10) "Limited hospice care program" means a coordinated, interdisciplinary program of hospice care services designed to meet the special physical, psychological, spiritual, and social needs of dying individuals and their families, by providing palliative and supportive nonskilled services during illness and bereavement through a home-based hospice care program.

(11) "Physician" means an individual who is licensed to practice medicine in this State under Health Occupations Article, Title 14, Annotated Code of Maryland.

(12) "Representative" means an individual with legal authority to make health care decisions on behalf of the patient as set forth in Regulation .20 of this chapter.

(13) "Secretary" means the Secretary of Health and Mental Hygiene.

(14) "Skilled services" means services that may be provided by an individual licensed under the Health Occupations Article, Annotated Code of Maryland.

(15) "Social worker" means an individual licensed to practice in this State under Health Occupations Article, Title 19, Annotated Code of Maryland.

*10.07.21.03*

**.03 License Required.**

A. A person may not operate or represent itself as operating a hospice care program in this State, without first obtaining a license from the Secretary.

B. Section A of this regulation applies to a home health agency, hospital, related institution, or other licensed facility that operates a hospice care program that is distinct from the other services that it is authorized to provide.

C. Types of Licenses. The Secretary shall require a hospice care program to be licensed as a:

(1) General hospice care program if the hospice care program provides, directly or by contract, home-based or inpatient care involving medical, nursing, or other skilled health services; or

(2) Limited hospice care program if the program provides, directly or by contract, nonskilled hospice services in a home-based setting.

D. A limited hospice care program shall refer patients in need of skilled services to a general hospice care program, or arrange for this care to be provided by an authorized health care provider.

E. Duration of License. A license expires on the third anniversary of its effective date unless it is:

(1) Renewed as provided in Regulation .04 of this chapter; or

(2) Revoked as provided in Regulation .27 of this chapter.

F. A license to operate a hospice care program is not transferable.

*10.07.21.04*

**.04 Application Procedure.**

A. Before a person may apply for a license to operate a general hospice care program, the person shall obtain a certificate of need from the Maryland Health Resources Planning Commission under Health-General Article, Title 19, Annotated Code of Maryland.

B. To apply for an initial license or renewal of a license, an applicant shall:

(1) Submit an application to the Secretary on a form provided by the Secretary; and

(2) Pay to the Secretary an application fee of $300.

C. The applicant shall provide the following information with the application as applicable:

(1) If the applicant is an individual and is sole owner of the hospice care program, the name and address of the applicant;

(2) If the applicant proposes to operate a facility providing inpatient hospice care services and someone other than the applicant owns the building or real property, or both, the name and address of the owner or owners;

(3) If the applicant is a partnership or limited partnership:

(a) The legal name of the partnership or limited partnership,

(b) Any trade name used by the partnership or limited partnership, and

(c) The name and address of each partner;

(4) If the applicant is a corporation:

(a) The name of the corporation,

(b) The date of incorporation,

(c) The state of incorporation,

(d) The name and address of each director,

(e) If the corporation is incorporated outside of the State, the name and address of the resident agent of the corporation,

(f) The name and address of each officer, and

(g) The name and address of any stockholder owning more than 5 percent of the stock of a corporate applicant;

(5) A statement that the applicant meets the requirements of Health-General Article, Title 19, Annotated Code of Maryland, and this chapter;

(6) The name of the individual who is to be the medical director of the hospice care program;

(7) The location and postal address of:

(a) The principal office of the proposed hospice care program,

(b) Any other office of the proposed hospice care program,

(c) Any facility providing inpatient hospice services to be operated by the hospice care program, and

(d) Any location where home-based hospice services are being provided in a residence owned or operated by the hospice; and

(8) A copy of the certificate of need determination from the Maryland Health Resources Planning Commission as required under §A of this regulation.

D. The Secretary:

(1) Shall deny or revoke a license if the applicant or licensee has been convicted of a felony involving Medicaid fraud or other activity involving a nursing home, or its residents; or

(2) May deny or revoke a license of the applicant or licensee who does not otherwise meet the requirements of this chapter.

E. A person aggrieved by the action of the Secretary under this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .28 of this chapter.

*10.07.21.05*

**.05 Inspection by the Department.**

A. A licensee, or a program seeking licensure under this chapter, shall be open at all times to inspection by the Department, and any agency designated by the Secretary, to conduct an inspection.

B. The Department may:

(1) Periodically inspect a hospice care program for compliance with this chapter; and

(2) Conduct complaint investigations involving alleged licensure violations.

C. Noncompliance.

(1) If the Secretary determines that a hospice care program fails to meet any provision of this chapter, the Secretary shall:

(a) Advise the hospice care program of the exact nature of the violation; and

(b) Require that the hospice care program specify what corrective action it is taking and monitor the hospice care program to ensure that it takes corrective action.

(2) This section does not preclude the Secretary from imposing any of the sanctions set forth in Regulation .27 of this chapter.

*10.07.21.06*

**.06 Administration.**

A. Responsibility of Licensee. A licensee shall ensure that the operation of the hospice care program complies with Health-General Article, Title 19, Subtitle 9, Annotated Code of Maryland, and this chapter.

B. Governing Body.

(1) A licensee shall have a governing body for the hospice care program. The governing body shall:

(a) Determine the hospice care program's mission and purpose;

(b) Conduct a periodic community needs assessment;

(c) Provide outreach programs appropriate to the needs of the communities it serves, including making information about hospice care services readily available and providing appropriate educational activities to the communities it serves;

(d) Make efforts to secure access to hospice care services for the underserved;

(e) Adopt administrative and clinical policies and procedures, and review them annually;

(f) Monitor the hospice's program and establish a process to evaluate the quality of services it is providing;

(g) Have fiscal and fiduciary responsibility for the hospice care program including the review and approval of its budget;

(h) Ensure compliance with all legal requirements;

(i) Adopt bylaws which:

(i) Specify the role and responsibility of the governing body, and

(ii) Define the hospice care program's relationship to any other governing body; and

(j) Develop and implement a written conflict of interest policy which includes guidelines for the resolution of any existing or apparent conflict of interest.

(2) All members of the governing body shall participate in an orientation program and continuing education to enable the members to fulfill their responsibilities to the hospice care program.

C. Administrator.

(1) The governing body or the licensee shall:

(a) Identify an administrator who has full responsibility for the day-to-day operations of the hospice care program; and

(b) Evaluate the administrator's performance on at least an annual basis.

(2) In the absence of the administrator, the program shall remain under the continuous supervision of a designated individual with appropriate experience and training.

*10.07.21.07*

**.07 Policies and Procedures.**

The hospice care program shall adopt and implement written policies and procedures for:

A. The use of advance directives;

B. Identifying, reviewing, and discussing ethical dilemmas which arise in the care of patients and family;

C. The use of specific treatment modalities in different hospice care settings, that is, palliative chemotherapy or radiation;

D. The administration of medications, including who is qualified to administer medications;

E. The management of treatment-related complications;

F. The use of investigational drugs and implementation of research protocols;

G. The initiation of resuscitation;

H. Attending to remains at the time of death;

I. The disposal of controlled drugs after death;

J. The provision of inpatient hospice care including:

(1) Privacy needs, including space for families to gather,

(2) 24-hour visitation and overnight stays, and

(3) Religious and spiritual worship;

K. Admission, transfer, and discharge, including criteria to be used for each; and

L. Obtaining informed consent.

*10.07.21.08*

**.08 Personnel.**

A. The hospice care program shall maintain sufficient health care professionals and volunteers to meet patient care needs.

B. The hospice care program shall identify an interdisciplinary care team with responsibility for ensuring continuous assessment of the patient's and family's needs and implementation of an integrated plan of care. The hospice care program shall ensure that:

(1) A qualified health care professional coordinates the activities of the interdisciplinary care team;

(2) The number of individuals who perform interdisciplinary team services is consistent with the needs of patients and their families and the type of services provided by the hospice care program; and

(3) Each interdisciplinary care team consists of at least:

(a) The patient's attending physician,

(b) A physician with training in palliative care,

(c) A registered nurse with demonstrated experience in pain and symptom management and the performance of physical assessments,

(d) A master's degree-prepared social worker with clinical experience in counseling and casework for the terminally ill,

(e) A volunteer, or volunteers, supervised by an individual with management experience in a hospice care program, and

(f) A spiritual care counselor or counselors with education and experience in pastoral counseling.

C. An interdisciplinary care team may include additional specialized team members needed to meet specific needs of patients as outlined in the patient's plan of care. Specialized team members may include allied therapists, art and music therapists, registered dietitians or licensed nutritionists, pharmacists, or nursing assistants.

D. Specialized team members may be employees, volunteers, or contractual staff.

E. Personnel Records. For all employees, volunteers, and contractual staff, the administrator shall ensure that there is:

(1) An accurate, complete, and current personnel record that includes:

(a) Verification of required licenses or certification,

(b) A signed conflict of interest statement,

(c) Written performance reviews,

(d) Documentation of all required training; and

(2) A job description for each position.

F. Outside Agreements. If a hospice care program utilizes the services of an outside entity to provide certain hospice services, the hospice care program shall enter into a written agreement with that entity which includes at a minimum:

(1) The service or services to be provided;

(2) The roles, rights, and responsibilities of the contracting entity;

(3) The roles, rights, and responsibilities of the hospice care program; and

(4) A plan to ensure that any individual providing services under this section shall have at least comparable training to that required by this regulation.

G. Orientation and Training.

(1) The hospice care program shall ensure that all licensed staff receive orientation and training, which includes at a minimum:

(a) The purpose and philosophy of hospice care;

(b) The skills necessary to provide for the physical care of the patient;

(c) The skills necessary to provide for the psychosocial and spiritual needs of the patient and family; and

(d) The need and importance of maintaining professional boundaries with the patient and the patient's family.

(2) The hospice care program shall have written criteria and a clear process for recruiting, selecting, and supervising volunteers, ensuring that:

(a) Any volunteer who provides direct patient care receives appropriate orientation and at least 16 hours of training which includes, at a minimum:

(i) The purpose and philosophy of hospice care,

(ii) The role of the volunteer in hospice,

(iii) Concepts of death and dying,

(iv) Communication skills,

(v) Care and comfort measures,

(vi) The physical, psychosocial, and spiritual issues related to death and dying,

(vii) The concept of the hospice family,

(viii) Patient rights,

(ix) Confidentiality,

(x) Bereavement,

(xi) Infection control,

(xii) Safety, and

(xiii) Stress management; and

(b) A volunteer, other than those specified in §G(2)(a) of this regulation, receives appropriate orientation regarding the volunteer's role in the hospice care program.

(3) Training shall be specifically tailored to ensure that staff is capable of providing care to meet the individual needs of patients.

(4) The hospice care program shall provide continuing inservice education for all employees and volunteers providing direct patient services at least:

(a) Once a year for volunteers; and

(b) Four times a year for employees.

*10.07.21.09*

**.09 Quality Assurance.**

A. The governing body shall ensure that the hospice care program conducts ongoing quality assurance and utilization review.

B. Quality Assurance Program. The governing body shall assure that the hospice care program develops and implements a quality assurance and improvement program to assess and improve the quality of services being provided by the program.

C. The quality assurance and improvement program shall:

(1) Focus on:

(a) The needs, expectations, and satisfaction of patients and their families, and

(b) All services provided by the hospice care program;

(2) Have outcomes and results that are measurable and which may be incorporated into systemic changes in the program's operation;

(3) Require the systematic collection, review, and evaluation of information and data and the analysis of trends identified through the quality assurance process;

(4) Require that regular reports are prepared and reviewed by the governing body and appropriate personnel;

(5) Provide for prompt and appropriate response to incidents when the patient's health and safety is at risk; and

(6) Include proactive strategies to improve the quality of services.

D. The hospice care program shall:

(1) Establish goals and standards to measure the quality of the services being delivered and define how these standards are measured;

(2) Maintain records to demonstrate the effectiveness of its quality assurance activities;

(3) Implement changes based upon results of the evaluated data; for example, when problems are identified in the provision of services, the hospice care program shall document corrective actions taken, including ongoing monitoring, revisions of policies and procedures, and educational interventions;

(4) Identify the individual responsible for performing the quality assurance functions as set forth in this regulation; and

(5) Review the quality assurance and improvement program at least annually and make revisions as necessary.

E. The hospice care program shall be held accountable by the governing body for accomplishing the goals and standards that are established as part of the quality assurance and improvement system.

F. Utilization Review.

(1) The hospice care program shall have a written plan for monitoring the allocation and utilization of patient and family services in order to identify and resolve concerns relating to the allocation and utilization of these services. The plan shall include:

(a) Goals and objectives for utilization review;

(b) Use of objective written criteria or treatment protocols to guide decisions about utilization of services;

(c) The analysis of the need for services;

(d) Time frames for review;

(e) Methods for identifying utilization review concerns and mechanisms for resolving problems; and

(f) A confidentiality policy consistent with legal and regulatory requirements.

(2) The hospice care program shall review the utilization review plan at least annually and make revisions as necessary.

(3) The plan shall include a monitoring protocol to address the following utilization concerns:

(a) The appropriateness of the services being provided, including the level of intensity;

(b) Patient admissions, including delays in the admission process; and

(c) Delays in the provision of services and specific treatment modalities.

(4) When the hospice care program identifies utilization problems, the hospice care program shall document corrective actions taken, including ongoing monitoring and educational interventions, as well as revisions to policies and procedures, and changes in the provision of services.

(5) Reports to the Secretary.

(a) Within 90 days after the close of a hospice care program's fiscal year, the hospice care program shall submit to the Department a report of the services it provided during the last fiscal year.

(b) The report shall include the:

(i) Types of services the hospice care program provided;

(ii) Number of patients provided each type of service;

(iii) Number of family members provided each type of service; and

(iv) Changes in the number of patients or family members provided services from the previous year.

*10.07.21.10*

**.10 The Interdisciplinary Plan of Care.**

A. The interdisciplinary team shall develop a written plan of care for each patient and family. The plan of care shall reflect current standards of practice. The hospice care program shall document the attending physician's participation in the development, revision, and overall approval of the plan of care.

B. The interdisciplinary plan of care shall reflect continuing communication between the attending physician and other members of the interdisciplinary care team. The interdisciplinary plan of care shall be reviewed, and revised if necessary, at least:

(1) Every 14 days after admission for home-based hospice services; and

(2) Every 7 days after admission for inpatient hospice services.

C. The interdisciplinary plan of care shall recognize the patient's and family's psychological, social, religious, and cultural values.

D. The interdisciplinary plan of care shall reflect efforts that the hospice care program staff and volunteers have made to:

(1) Maximize patient independence;

(2) Deliver services at the convenience of the patient, family, and caregiver;

(3) Arrange respite services for caregivers;

(4) Bridge gaps in the patient's care giving network; and

(5) Adapt the home environment to meet the patient's physical needs.

E. The interdisciplinary plan of care shall be based on the initial assessments conducted by interdisciplinary care team members.

F. The hospice care program shall encourage the patient and family to participate in developing and implementing the interdisciplinary plan of care.

G. Contents. The interdisciplinary plan of care shall include, at a minimum:

(1) Identification of patient and family problems and needs;

(2) Identification of realistic and achievable goals, objectives, and outcomes;

(3) The frequency and mix of services, including bereavement needs;

(4) The level of care to be provided;

(5) Prescribed medication and treatments; and

(6) Required medical equipment.

H. Bereavement Plan.

(1) The hospice care program shall initiate a written plan of bereavement intervention at the time of admission to the hospice which shall be incorporated into the patient's plan of care.

(2) The bereavement plan shall be based on an assessment of the needs of the family and shall recognize the family's social, religious, and cultural values.

(3) At a minimum, the bereavement plan shall include the:

(a) Scope and frequency of bereavement services; and

(b) Family's acceptance of bereavement services.

*10.07.21.11*

**.11 Continuity of Care.**

A. The hospice care program shall coordinate care to ensure continuity of care for the patient and family.

B. Any changes in service delivery are to be based on an assessment of the patient's and family's needs and desires for hospice services and a hospice care program's transfer and discharge criteria.

C. The hospice care program shall:

(1) Provide case management for the patient and family;

(2) Maintain an accurate, complete, and documented record of services and activities provided to the patient and family;

(3) Collaborate with other organizations and individuals providing care to the patient and family to ensure coordination of services;

(4) Provide on-call medical and nursing services in response to patient and family needs;

(5) Ensure the safety of staff and inform the patient and family of any personnel, service, or access limitations; and

(6) Have reporting mechanisms to keep all staff informed and updated about patient care changes to ensure continuity and coordination of care among interdisciplinary team members.

*10.07.21.12*

**.12 Transfer or Discharge.**

A. If the hospice care program does not provide inpatient hospice services directly, the hospice care program shall have a written transfer agreement with a hospice care program which provides those services.

B. The hospice care program shall provide adequate and appropriate information about the patient and family at the time of transfer or discharge.

C. When a patient and family transfers from one hospice care program to another or from home-based service to inpatient service, or vice versa, the current care provider shall provide a written summary of:

(1) The services being provided;

(2) The specific medical, psychosocial, spiritual, or other problems that require intervention or follow-up; and

(3) Any scheduled follow-up by a current interdisciplinary care team member.

D. The hospice care program shall document the specific reasons for transferring or discharging a patient from its program. These reasons may include:

(1) The patient moves from the service area;

(2) There is a change in terminal status;

(3) The patient and family are unwilling to comply with the interdisciplinary plan of care or consistently act in a way which compromises the standards of care;

(4) Issues of patient safety cannot be resolved;

(5) Issues of staff safety cannot be resolved; or

(6) Patient and family desire for discharge.

E. The hospice care program shall prepare a written discharge summary which shall be provided to the patient or the patient's family before the patient's discharge.

F. Before discharge, the hospice care program shall assess the patient's and family's continuing care needs and make referrals to appropriate services.

*10.07.21.13*

**.13 Physician Services.**

A. Medical Director. The hospice care program shall have a medical director who shall be:

(1) A physician licensed to practice medicine in this State; and

(2) Knowledgeable about the psychosocial and medical aspects of hospice care.

B. Medical Director Duties. The medical director is responsible for:

(1) Reviewing, coordinating, and managing the clinical and medical care for all patients in the hospice care program;

(2) Consulting with attending physicians regarding pain and symptom control;

(3) Reviewing patient eligibility for hospice services;

(4) Acting as the medical resource for the interdisciplinary team;

(5) Acting as the liaison to physicians in the community; and

(6) Designating a physician to contact in case the medical director is unavailable.

C. Attending Physician. An attending physician shall provide initial and ongoing medical services to the patient and participate in the development of the interdisciplinary plan of care.

D. Attending Physician Duties. At a minimum, the attending physician shall provide the following information before the patient is admitted to the hospice care program:

(1) Admitting diagnosis and prognosis;

(2) Current medical findings;

(3) Dietary restrictions;

(4) Medication and treatment orders, including instructions for symptom management; and

(5) Information concerning the medical management of patient conditions unrelated to the terminal illness.

E. The hospice care program shall ensure that the attending physician designates another physician to contact in case the attending physician is unavailable.

*10.07.21.14*

**.14 Nursing Services.**

A. Nursing services shall be provided by licensed or certified personnel, trained or experienced in hospice care and supervised by a registered nurse with training or experience in hospice nursing. All nursing services shall be provided in accordance with the requirements of Health Occupations Article, Title 8, Annotated Code of Maryland.

B. The hospice care program shall provide nurse staffing levels based on:

(1) An assessment of patient and family care needs;

(2) The experience level of the nursing staff available to provide services; and

(3) Available assistance from support service staff.

C. The hospice care program shall provide nursing services in accordance with each patient's interdisciplinary plan of care.

D. Registered Nurse. A registered nurse shall:

(1) Conduct the initial assessment of the patient;

(2) Regularly reevaluate the patient's nursing needs;

(3) Initiate the plan of care and necessary revisions;

(4) Prepare clinical and progress notes, coordinate services, and inform the physician and other personnel of changes in the patient's condition and needs;

(5) Inform the patient and family in regard to the patient's nursing needs; and

(6) Supervise other nursing personnel.

E. The initial assessment or any reevaluation of the patient's care needs may not be conducted by a licensed practical nurse or nursing assistant. Licensed practical nurses and nursing assistants shall provide all services in accordance with the patient's interdisciplinary plan of care.

*10.07.21.15*

**.15 Ancillary Services.**

A. The hospice care program shall have a written plan for the provision of pharmacy, laboratory, radiology, chemotherapy, and other ancillary services. When the service is provided by an organization other than the hospice care program, the hospice care program shall enter into a written agreement with the provider of ancillary services which specifies the services being provided and the procedures for accessing those services.

B. The hospice care program shall ensure that ancillary services are provided in accordance with federal and State laws and regulations.

C. Pharmacy Services.

(1) The hospice care program shall employ or contract with a licensed pharmacist to:

(a) Supervise all pharmacy services;

(b) Serve as a consultant to the interdisciplinary care team; and

(c) Ensure that all drugs and biologicals are prescribed, dispensed, administered, stored, and disposed of in accordance with applicable laws and regulations.

(2) The hospice care program shall have a system to obtain and provide drugs on an emergency basis, 24 hours per day, 7 days a week.

(3) The hospice care program shall maintain a drug profile for each patient and conduct periodic drug reviews and monitoring of each patient.

(4) The hospice care program shall ensure that the interdisciplinary care team and the patient and the patient's family are made aware of each medication prescribed for the patient and are given any instructions concerning the administration of prescribed medications.

*10.07.21.16*

**.16 Counseling Services.**

A. Counseling Services. The hospice care program shall provide counseling services which address the needs of patients and families. The hospice care program shall provide counseling services as set forth in B-----E of this regulation.

B. Social Work Services. Social work services are to be based on an initial and continuing assessment of patient and family psychosocial needs. Each assessment shall be conducted by a social worker. Services shall be provided in accordance with each patient's interdisciplinary plan of care with the goal of assisting the patient and family in adjusting to the psychosocial aspects of terminal illness.

C. Spiritual Services. The hospice care program shall provide spiritual services that are based on an initial, ongoing assessment of the spiritual needs of the patient and family. Spiritual services are to be consistent with patient and family beliefs and desires. These services shall be provided by a member of the interdisciplinary care team or by local clergy or spiritual counselors.

D. Nutritional Counseling. The hospice care program shall provide nutritional counseling to the patient and family. This counseling shall be provided by either a registered nurse, registered dietitian, or licensed nutritionist as specified in the interdisciplinary plan of care.

E. Bereavement services shall be provided as set forth in Regulation .10H of this chapter.

*10.07.21.17*

**.17 Emergency Services.**

A. The hospice care program shall ensure that emergency services are available 24 hours per day, 7 days a week.

B. Emergency services are to include, at a minimum:

(1) Registered nurse and physician services;

(2) Palliative medications; and

(3) Other services, equipment, and supplies necessary to meet the patient's immediate needs as directed by the patient's plan of care.

*10.07.21.18*

**.18 Volunteer Services.**

A. The hospice care program's volunteer services shall play a vital role in enhancing the quality of care delivered to the patient and family by encouraging community participation in the overall hospice care program.

B. Volunteers may assist with patient care and administrative services consistent with the hospice care program's policies and in accordance with the requirements of this regulation.

C. Volunteers shall document their activities in the clinical record.

D. Volunteers shall comply with personnel policies and procedures.

*10.07.21.19*

**.19 Medical Records.**

A. The hospice care program shall establish and maintain a clinical record for each patient in accordance with accepted principles of practice for maintaining medical records. The record is to be complete, accurately documented, readily accessible, and systematically organized to facilitate retrieval of information.

B. The hospice care program shall:

(1) Document clinical and progress notes in a patient's medical record within 14 days of a visit or provision of services;

(2) Obtain the attending physician's signature on an order within 30 days of receiving a verbal order; and

(3) Close a medical record within 30 days of a patient's discharge.

C. Access to or release of a patient's medical record by the hospice care program is permitted only with the consent of the patient or the patient's representative, or as required by law.

D. If services are not provided directly by the hospice care program, the hospice care program shall obtain a copy of the applicable medical record or written summary of services provided and maintain it in the hospice care program's medical record.

*10.07.21.20*

**.20 Patient's Representative.**

A. A hospice care program shall recognize the authority of:

(1) A guardian of the person under Estates and Trusts Article, §13-705, Annotated Code of Maryland;

(2) A guardian of the property under Estates and Trusts Article, §13-201, Annotated Code of Maryland;

(3) An advance directive established in compliance with Health-General Article, §5-602, Annotated Code of Maryland;

(4) A surrogate decision maker with authority under Health-General Article, §5-605, Annotated Code of Maryland;

(5) A power of attorney that meets the requirements of Estates and Trusts Article, §13-601, Annotated Code of Maryland;

(6) A representative payee or other similar fiduciary; or

(7) Any other person, if that person was designated by a patient who was competent at the time of designation, and the patient or representative has provided the hospice care program with documentation of the designation.

B. The hospice care program may not recognize the authority of the patient's representative if the representative attempts to exceed the authority:

(1) Stated in the instrument that grants the representative authority; or

(2) Established by State law.

C. The hospice care program shall document in the patient's record the name of the representative, including a copy, when applicable, of the designation.

*10.07.21.21*

**.21 Patient's Rights.**

A. The hospice care program shall provide the patient or representative with a written notice of the patient's rights in advance of furnishing care. Documentation verifying receipt of and understanding of this information shall be included as part of the patient's record.

B. The patient has the right to:

(1) Be treated with consideration and respect for individual dignity;

(2) Confidentiality in all aspects of service or treatment;

(3) Privacy;

(4) Be free from physical or mental abuse;

(5) Participate in the planning of the patient's hospice care;

(6) Formulate advance directives as provided under State law;

(7) Have all personal property treated with respect;

(8) Refuse care and services, including continued participation in the hospice care program;

(9) Be informed of short-term inpatient care options available for pain control, management, and respite;

(10) Be informed of the hospice care program's discharge policy;

(11) Make complaints or grievances to the hospice care program, government agencies, or other persons without threat or fear of retaliation; and

(12) Be informed orally and in writing, before care is initiated, of the extent to which payment may be expected from the patient, third-party payers, and any other source of funding known to the hospice care program.

C. The hospice care program shall ensure that all employees and volunteers respect the rights of a patient.

*10.07.21.22*

**.22 Complaint Procedure.**

A. A hospice care program shall establish a procedure under which a patient or family member may make a complaint to a representative of the hospice care program.

B. The hospice care program shall investigate and seek to resolve the complaint.

C. The hospice care program shall maintain documentation which reflects findings of the investigation and efforts to resolve the complaint.

D. The hospice care program shall inform each patient and family of:

(1) Its complaint procedure; and

(2) The address and telephone number of the Department's Licensing and Certification Administration.

E. The Department may conduct investigations of complaints involving alleged violations of this chapter.

*10.07.21.23*

**.23 Infection Control.**

A. The hospice care program shall have an infection control program in all care settings.

B. There is to be a written plan for identifying, preventing, and controlling the spread of infection, which includes:

(1) Identifying an individual responsible for implementing and monitoring the infection control program;

(2) Establishing a system for periodic review and update of infection control policies and procedures governing at a minimum:

(a) Personal hygiene,

(b) Aseptic and isolation techniques,

(c) Supplies, medication, and food storage, and

(d) Waste disposal;

(3) Reviewing patient and family caregiver practices to identify potential exposure to infection; and

(4) Ensuring that the infection control program is monitored, reviewed, and evaluated regularly at specified intervals.

*10.07.21.24*

**.24 Safety and Emergency Preparedness.**

A. The hospice care program shall have a safety and emergency preparedness program that includes, at a minimum:

(1) A plan for reporting, monitoring, and following up on all accidents, injuries, and safety hazards;

(2) Education for patient and family caregivers, employees, and volunteers in the safe use of medical equipment;

(3) Evidence that equipment maintenance and safety requirements have been met; and

(4) A safe and sanitary system for identifying, handling, and disposing of special medical wastes that meets the requirements of COMAR 10.06.06.

B. The hospice care program shall ensure that the emergency preparedness program provides appropriate continuous support and care to patients and families and other caregivers during natural or man-made disasters.

C. The hospice care program shall monitor, review, and evaluate the safety and emergency preparedness program at regularly specified intervals.

*10.07.21.25*

**.25 Home-Based Hospice Care Provided in a Licensed Health Care Facility.**

A. Professional Management.

(1) When a hospice care program delivers hospice care to a resident of a licensed health care facility, the hospice care program shall assume full responsibility for professional management of the patient's hospice care in accordance with the requirements of this chapter.

(2) When a hospice care program delivers hospice care to a resident of a licensed health care facility, the hospice and the facility shall have a written agreement which defines their respective roles and responsibilities in regard to the care of the patient.

(3) The hospice care program shall designate a qualified health care professional from the hospice care program who shall coordinate the activities of the interdisciplinary care team and the health care facility staff to assure continuous assessments of the patient's and family's needs, and to ensure implementation of an integrated plan of care.

(4) All core hospice services, specifically, physician, nursing, social work, and counseling services identified in the plan of care, shall be provided directly by hospice care program employees or volunteers and may not be delegated to the health care facility.

B. Plan of Care.

(1) The interdisciplinary plan of care shall be jointly developed by the patient, the patient's family, the hospice care program, and the licensed health care facility, and shall identify the services to be provided by each entity.

(2) Both providers shall review the interdisciplinary plan of care at intervals specified in the plan, and shall jointly update the plan as necessary to reflect the patient's current status.

(3) Both the hospice care program and the health care provider shall maintain the interdisciplinary plan of care in their respective medical records.

*10.07.21.26*

**.26 Inpatient Hospice Care.**

A. In addition to the other requirements of this chapter, when a hospice care program delivers inpatient care, the hospice care program shall provide nursing services 24 hours a day in a manner sufficient to meet the total nursing needs identified in the patient's plan of care. A registered nurse shall be on duty during each shift.

B. The hospice care program shall design and equip all areas for the comfort and privacy of patients and family members. Specifically, the hospice care program shall:

(1) Provide accommodation for family members to remain with the patient throughout the night;

(2) Provide an adequate supply of hot water at all times for patient use;

(3) Have available at all times a quantity of linen sufficient for proper care and comfort of patients;

(4) Make provisions for isolating patients with infectious diseases; and

(5) Provide privacy for patient/family visitation and accommodations for the family's privacy immediately after a patient's death.

C. The hospice care program shall provide food services designed to meet the nutritional needs of the patients, in accordance with physician orders and the following guidelines:

(1) At least three meals shall be served each day with not more than 14 hours between the evening meal and breakfast, unless otherwise prescribed by the patient's physician;

(2) All foods shall be stored, prepared, and served as required by COMAR 10.15.03; and

(3) Medically prescribed special diets shall be planned by a registered dietitian or licensed nutritionist.

D. In addition to all other State and federal requirements, all medications shall be labeled, stored, and administered in accordance with the following:

(1) All medications shall be ordered by a physician;

(2) All medications shall be administered by a licensed nurse or physician;

(3) All medications shall be labeled in accordance with Health-General Article, §21-221(a), Annotated Code of Maryland, 21 U.S.C. 301 et seq. and 801 et seq.;

(4) All medications shall be stored in locked compartments under proper temperature control and all schedule II drugs shall be maintained separately from other medications and secured by use of two different locks; and

(5) All medications no longer needed by the patient shall be destroyed in the presence of two witnesses authorized by the hospice care program.

*10.07.21.27*

**.27 Penalties.**

A. Administrative Penalty.

(1) The Secretary may, for noncompliance with any regulation under this chapter, impose an administrative penalty of up to:

(a) $500 for a first violation; and

(b) $1,000 for a subsequent repeated violation.

(2) When considering whether to impose an administrative penalty and the amount of the penalty, the Secretary shall consider the following factors:

(a) The number, nature, and seriousness of the violations;

(b) The extent to which the violation or violations are part of an ongoing pattern during the preceding 24 months;

(c) The degree of risk, caused by the violation or violations, to the health, life, or safety of the patients;

(d) The efforts made by, and the ability of, the licensee to correct the violation or violations in a timely manner; and

(e) Other factors as justice may require.

B. Emergency Suspension.

(1) The Secretary may immediately suspend a license on finding that the public health, safety, or welfare imperatively requires emergency action.

(2) The Department shall deliver a written notice to the hospice care program:

(a) Informing it of the emergency suspension;

(b) Giving the reasons for the action, and the regulation or regulations with which the licensee has failed to comply that forms the basis for the emergency suspension; and

(c) Notifying the hospice care program of its right to request a hearing and to be represented by counsel.

(3) The filing of a hearing request does not stay the emergency action.

(4) When a license is suspended by emergency action:

(a) The hospice care program shall immediately return the license to the Department;

(b) The hospice care program shall stop providing hospice services immediately; and

(c) The licensee shall notify the patients or their representatives of the suspension and make every reasonable effort to assist them in making other hospice service arrangements.

(5) In the event of an emergency suspension, the Department may assist in the relocation of patients.

(6) A person aggrieved by the action of the Secretary under this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .28 of this chapter.

(7) The Office on Administrative Hearings shall conduct a hearing as set forth in Regulation .28 of this chapter and issue a proposed decision within 10 business days of the close of the hearing record. Exceptions may be filed by an aggrieved person pursuant to COMAR 10.01.03. The Secretary shall make a final decision pursuant to COMAR 10.01.03.

(8) If the Secretary's final decision does not uphold the emergency suspension, the hospice care program may resume operation.

C. Suspension or Revocation of License.

(1) The Secretary, for cause shown, may suspend or revoke the hospice care program's license.

(2) The Department shall notify the hospice care program in writing of the following:

(a) The effective date of the suspension or revocation;

(b) The reason for the suspension or revocation;

(c) The regulations with which the licensee has failed to comply that form the basis for the suspension or revocation;

(d) That the hospice care program is entitled to a hearing if requested, and to be represented by counsel;

(e) That the hospice care program shall stop providing services on the effective date of the suspension or revocation if the hospice care program does not request a hearing;

(f) That the suspension or revocation shall be stayed if a hearing is requested; and

(g) That the hospice care program is required to surrender its license to the Department if the suspension or revocation is upheld.

(3) The licensee shall notify the patients or their representatives of any final suspension or revocation and make every reasonable effort to assist them in making other hospice care arrangements. The Department may assist in the relocation of residents.

(4) A person aggrieved by the action of the Secretary under this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .28 of this chapter.

*10.07.21.28*

**.28 Hearings.**

A. A request for a hearing shall be filed with the Office of Administrative Hearings, with a copy to the Licensing and Certification Administration of the Department, not later than 30 days after receipt of notice of the Secretary's action. The request shall include a copy of the Secretary's action.

B. A hearing requested under this chapter shall be conducted in accordance with State Government Article, §10-210 et seq., Annotated Code of Maryland, and COMAR 28.02.01 and 10.01.03.

C. The burden of proof is as set forth in COMAR 10.01.03.28.

D. Unless otherwise stated in this chapter, the Office of Administrative Hearings shall issue a proposed decision within the time frames set forth in COMAR 28.02.01.

E. The aggrieved person may file exceptions as set forth in COMAR 10.01.03.35.

F. A final decision by the Secretary shall be issued in accordance with COMAR 10.01.03.35.