

RULES AND REGULATIONS

FOR LICENSING

HOSPICE CARE

(R23-17-HPC)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

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INTRODUCTION

These *Rules and Regulations for Licensing Hospice Care (R23-17-HPC)* are promulgated pursuant to the authority conferred under section 23-17-10 of the General Laws of Rhode Island, as amended, and are established for the purpose of adopting minimum standards for the licensed hospice care in this state.

Pursuant to the provisions of section 42-35-3(C) of the General Laws of Rhode Island, as amended, the following were given consideration in arriving at the regulations: (1) alternative approaches to the regulations; (2) duplication or overlap with other state regulations; and (3) significant economic impact placed on facilities through these amended regulations. No alternative approach, duplication or overlap, nor significant economic impact was identified. Consequently, the regulations are adopted in the best interest of the public health, safety and welfare.

These amended regulations shall supercede all previous *Rules and Regulations for the Licensing of Hospice Care* promulgated by the Department of Health and filed with the Secretary of State.

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PART I *LICENSURE PROCEDURES AND DEFINITIONS*

Section 1.0 *Definitions*

Wherever used in these rules and regulations the following terms shall be construed as follows:

- 1.1 **"Bereavement"** refers to the extended period of grief preceding the death and following (usually for one year) the death of a loved one, during which individuals experience, respond and adjust emotionally, physically, socially and spiritually to the loss of a loved one.
- 1.2 **"Change in operator"** means a transfer by the governing body or operator of a hospice program to any other person (excluding delegations of authority to the medical or administrative staff of the facility) of the governing body's authority to:
- a) hire or fire the chief executive officer of the hospice program;
 - b) maintain and control the books and records of the hospice program;
 - c) dispose of assets and incur liabilities on behalf of the hospice program; or
 - d) adopt and enforce policies regarding operation of the hospice program.

This definition is not applicable to circumstances wherein the governing body of a hospice program retains the immediate authority and jurisdiction over the activities enumerated in subsection (a) through (d) herein.

- 1.3 **"Change in owner"** means:
- (1) in the case of a hospice program which is a partnership, the removal, addition or substitution of a partner which results in a new partner acquiring a controlling interest in such partnership;
 - (2) in the case of a hospice program which is an unincorporated solo proprietorship, the transfer of the title and property to another person;
 - (3) in the case of a hospice program which is a corporation:
 - a) a sale, lease, exchange or other disposition of all, or substantially all of the property and assets of the corporation; or
 - b) a merger of the corporation into another corporation; or
 - c) the consolidation of two or more corporations, resulting in the creation of a new corporation; or
 - d) in the case of a hospice program which is a business corporation, any transfer of corporate stock which results in a new person acquiring a controlling interest in such corporation; or

- e) in the case of a hospice program which is a non-business corporation, any change in membership which results in a new person acquiring a controlling vote in such corporation.
- 1.4 **"Clergy"** refers to individuals ordained for religious service.
- 1.5 **"Director"** means the Director of the Rhode Island Department of Health.
- 1.6 **"Equity"** means non-debt funds contributed towards the capital costs related to an initial licensure or change in owner or change in operator of a hospice facility which funds are free and clear of any repayment or liens against the assets of the proposed owner and/or licensee and that result in a like reduction in the portion of the capital cost that is required to be financed or mortgaged.
- 1.7 **"General inpatient care"** means short-term general care provided to terminally ill patients in an inpatient setting (either a licensed hospital or licensed skilled nursing facility) for the control of pain or management of acute or chronic symptoms.
- 1.8 **"Hospice care"** (hereinafter referred to as hospice program) means a distinct and identifiable program of care of a public or private organization, corporation or person, organized and staffed by an interdisciplinary team to provide both in the home and in an inpatient setting, palliative and supportive services to the terminally ill and their family, addressing their physical, psychological, social and spiritual needs through the stress experience of dying and bereavement.
- 1.9 **"Initial licensure"** means a review conducted pursuant to the provisions contained in section 6.0 herein.
- 1.10 **"Inpatient respite care"** means short-term care provided to terminally ill patients in an inpatient setting (either a skilled nursing or intermediate care 1 facility licensed in Rhode Island) to provide relief to family members or others caring for the patient.
- 1.11 **"Licensing agency"** means the Rhode Island Department of Health.
- 1.12 **"Nurse"** means an individual licensed to practice as a professional (registered) nurse in this state under the provisions of Chapter 5-34 of the General Laws of Rhode Island, as amended.
- 1.13 **"Palliative care"** means the reduction or abatement of pain and other troubling symptoms by appropriate coordination of care to help the terminally ill patient live as fully and comfortably as possible.
- 1.14 **"Person"** means an individual, trust or estate, partnership, corporation (including associations, joint stock companies), limited liability company, state or political subdivision or instrumentality of a state.
- 1.15 **"Physician"** means any individual licensed to practice medicine in this state under the provisions of Chapter 5-37 of the General Laws of Rhode Island, as amended.

- 1.15.1 **"Attending physician"** refers to a physician (who may or may not be on the hospice staff) identified by the terminally ill patient/family as having a significant role in the determination and delivery of the individual's medical care.
- 1.16 **"Terminally ill"** means that an individual has a medical prognosis of a life expectancy of six (6) months or less.

Section 2.0 ***General Requirements for Licensure***

- 2.1 No person acting alone or jointly with any other person, shall establish, conduct or maintain a hospice program in this state without a license in accordance with the requirements of section 23-17-4 of reference 1 and in accordance with the rules and regulations herein.
- 2.1.1 However, pursuant to section 23-17-2(a) of the Act, any provider of hospice care who provides hospice care without charge shall be exempt from the licensing provisions above, but shall meet the "Standards of a Hospice Program of Care" of the National Hospice Organization.
- 2.2 A certificate of need is required as a precondition to licensure of any inpatient hospice program, unless exempt, in accordance with reference 3.
- 2.3 Any initial licensure of an outpatient hospice program or any change in owner, operator, or lessee of a licensed hospice program shall require prior review by the Health Services Council and approval of the licensing agency as provided in sections 6.1 and 6.2 herein, or for expedited reviews conducted pursuant to sections 6.5 and 6.6 herein, as a condition precedent to the transfer, assignment or issuance of a new license.
- 2.4 No facility shall hold itself or represent itself as a hospice program or use the term "Hospice" or other similar term in its advertising, publicity or any other form of communication, unless licensed as Hospice Care in accordance with the provisions herein.
- 2.5 Any person and/or facility subject to the provisions of these rules and regulations shall have ninety (90) days from the date of filing of said rules and regulations within which to comply with the requirements thereof.

Section 3.0 ***Application for License***

- 3.1 Application for a license to conduct, maintain or operate a hospice program shall be made to the licensing agency upon forms provided by the licensing agency and shall contain such information as the licensing agency reasonably requires which may include affirmative evidence of ability to comply with the provisions of reference 1 and the rules and regulations herein.
- 3.1.1 Each application shall be accompanied by an application fee of three thousand dollars (\$3,000), made payable to the Rhode Island General Treasurer.

- 3.2 A notarized listing of names and addresses of direct and indirect owners whether individual, partnership or corporation with percentages of ownership designated shall be provided with the application for licensure and shall be updated annually. The list shall include each owner (in whole or in part) of any mortgage, deed or trust, note or other obligation secured (in whole or in part) by the hospice care program or any of the property or assets of the hospice program.
- 3.3 The list shall also include all officers, directors and other persons of any subsidiary corporation owning stock, if the hospice program is organized as a corporation and all partners if organized as a partnership.

Section 4.0 *Issuance and Renewal of License*

- 4.1 Upon receipt of an application for a license, the licensing agency shall issue a license for a period of no more than one (1) year, if the applicant meets the requirements of reference 1 and the rules and regulations herein. The license issued, unless sooner suspended or revoked, shall expire by limitation on the 31st day of December following its issuance and may be renewed from year to year subject to inspection and approval by the licensing agency.
 - 4.1.1 All renewal applications shall be accompanied by a renewal fee of three thousand dollars (\$3,000), made payable to the Rhode Island General Treasurer.
- 4.2 A license issued shall not be transferable or assignable except with the written approval of the licensing agency.

Section 5.0 *Application for Initial Licensure or Changes in Owner, Operator, or Lessee*

- 5.1 Application for review for initial licensure of an outpatient hospice program or changes in the owner, operator, or lessee of a hospice program shall be made on forms provided by the licensing agency and shall contain but not be limited to information pertinent to the statutory purpose expressed in section 23-17-3 of Chapter 23-17 or to the considerations enumerated in section 6.2 herein. Twenty-five (25) copies of such applications are required to be provided.
 - 5.1.1 Each application filed pursuant the provisions of this section shall be accompanied by a non-refundable, non-returnable application fee, made payable to the Rhode Island General Treasurer, as follows: applicants shall submit a fee equal to two tenths of one percent (0.2%) of the projected annual facility net operating revenue contained in the application; provided, however, that the minimum fee shall be fifteen hundred dollars (\$1,500) and the maximum fee shall not exceed twenty thousand dollars (\$20,000).

Section 6.0 *Initial Licensure and Change in Owner, Operator, or Lessee Review*

- 6.1 Except for expedited reviews conducted pursuant to sections 6.5 and 6.6, reviews of applications for initial licensure of an outpatient hospice program or for changes in the owner, operator, or lessee of a licensed hospice program shall be conducted according to the following procedures:

- a) Within ten (10) working days of receipt, in acceptable form, of an application for initial licensure of an outpatient hospice program or for a license in connection with a change in the owner, operator or lessee of an existing hospice program, the licensing agency will notify and afford the public thirty (30) days to comment on such application.
- b) The decision of the licensing agency will be rendered within ninety (90) days from acceptance of the application.
- c) The decision of the licensing agency shall be based upon the findings and recommendations of the Health Services Council unless the licensing agency shall afford written justification for variance therefrom.
- d) All applications reviewed by the licensing agency and all written materials pertinent to licensing agency review, including minutes of all Health Services Council meetings, shall be accessible to the public upon request

6.2 Except as otherwise provided in Chapter 23-17 of the General Laws of Rhode Island, as amended, a review by the Health Services Council of an application for an initial license of an outpatient hospice program or for a license in the case of a proposed change in the owner, operator, or lessee of a licensed hospice care may not be made subject to any criterion, unless the criterion directly relates to the statutory purpose expressed in section 23-17.3 of the General Laws of Rhode Island, as amended. In conducting reviews of such applications the Health Services Council shall specifically consider and it shall be the applicant's burden of proof to demonstrate:

6.2.1 The character, commitment, competence, and standing in the community of the proposed owners, operators or directors of the hospice program as evidenced by:

(A) In cases where the proposed owners, operators, or directors of the health care facility currently own, operate, or direct a health care facility, or in the past five years owned, operated or directed a health care facility, whether within or outside Rhode Island, the demonstrated commitment and record of that (those) person(s):

- (i) in providing safe and adequate treatment to the individuals receiving the health care facility's services;
- (ii) in encouraging, promoting and effecting quality improvement in all aspects of health care facility services; and
- (iii) in providing appropriate access to health care facility services;

(B) A complete disclosure of all individuals and entities comprising the applicant; and

(C) The applicant's proposed and demonstrated financial commitment to the health care facility.

6.2.2 The extent to which the facility will provide or will continue, without material effect on its viability at the time of change of owner, operator, or lessee, to provide safe and adequate treatment for individuals receiving the Hospice services as evidenced by:

- (A) The immediate and long term financial feasibility of the proposed financing plan;
 - (i) The proposed amount and sources of owner's equity to be provided by the applicant;
 - (ii) The proposed financial plan for operating and capital expenses and income for the period immediately prior to, during and after the implementation of the change in owner, operator or lessee of the health care facility;
 - (iii) The relative availability of funds for capital and operating needs;
 - (iv) The applicant's demonstrated financial capability;
 - (v) Such other financial indicators as may be requested by the state agency;
- 6.2.3 The extent to which the program will provide or will continue to provide safe and adequate treatment for individuals receiving the Hospice services and the extent to which the facility will encourage quality improvement in all aspects of the operation of the health care facility as evidenced by:
 - (A) The applicant's demonstrated record in providing safe and adequate treatment to individuals receiving services at facilities owned, operated, or directed by the applicant; and
 - (B) The credibility and demonstrated or potential effectiveness of the applicant's proposed quality assurance programs;
- 6.2.4 the extent to which the program will provide or will continue to provide appropriate access with respect to traditionally under served populations as evidenced by:
 - (A) In cases where the proposed owners, operators, or directors of the health care facility currently own, operate, or direct a health care facility, or in the past five years owned, operated or directed a health care facility, both within and outside of Rhode Island, the demonstrated record of that person(s) with respect to access of traditionally underserved populations to its health care facilities; and
 - (B) The proposed immediate and long term plans of the applicant to ensure adequate and appropriate access to the programs and health care services to be provided by the health care facility.
- 6.2.5 In consideration of the proposed continuation or termination of health care services by the hospice program:
 - (A) The effect(s) of such continuation or termination on access to safe and adequate treatment of individuals, including but not limited to traditionally under served populations.

- 6.2.6 And, in cases where the application involves a merger, consolidation or otherwise legal affiliation of two or more health care facilities, the proposed immediate and long term plans of such health care facilities with respect to the health care programs to be offered and health care services to be provided by such health care facilities as a result of the merger, consolidation or otherwise legal affiliation.
- 6.3 Subsequent to reviews conducted under sections 6.1, 6.2, 6.5, and 6.6 of these regulations, the issuance of a license by the licensing agency may be made subject to any consideration, provided that no condition may be made unless it directly relates to the statutory purpose expressed in section 23-17-3 of the General Laws of Rhode Island, as amended, or to the review criteria set forth in section 6.2 herein. This shall not limit the authority of the licensing agency to require correction of conditions or defects which existed prior to the proposed change of owner, operator, or lessee and of which notice has been given to the hospice program by the licensing agency.
- 6.4 A license issued hereunder shall be the property of the state and loaned to such licensee, and it shall be kept posted in a conspicuous place.
- 6.5 Applicants for initial licensure may, at the sole discretion of the licensing agency, be reviewed under expedited review procedures established in section 6.6 if the licensing agency determines (a) that the legal entity seeking licensure is the licensee for one or more health care facilities licensed in Rhode Island pursuant to the provisions of Chapter 23-17 whose records of compliance with licensure standards and requirements are deemed by the licensing agency to demonstrate the legal entity's ability and commitment to provide quality health services; and (b) that the licensure application demonstrates complete and satisfactory compliance with the review criteria set forth in set forth in section 6.2 herein.
- 6.6 Expedited reviews of applications for initial licensure of outpatient hospice programs shall be conducted according to the following procedures:
- a) Within ten (10) working days of receipt, in acceptable form, of an application for initial licensure the licensing agency will determine if such application will be granted expedited review and the licensing agency will notify the public of the licensing agency's initial assessment of the application materials with respect to the review criteria in section 6.2 as well as the licensing agency's intent to afford the application expedited review. At the same time the licensing agency will afford the public a twenty (20) day period during which the public may review and comment on the application and the licensing agency's initial assessment of the application materials and the proposal to afford the application expedited review.
 - b) Written objections from affected parties directed to the processing under the expedited procedures and/or the satisfaction of the review criteria shall be accepted during the twenty (20) day comment period. Objections must provide clear, substantial and unequivocal rationale as to why the application does not satisfy the review criteria and/or why the application ought not to be processed under the expedited review mechanism. The licensing agency may propose a preliminary report on such application provided such proposed report incorporates findings relative to the review criteria set forth in section 6.2. The Health Services Council may consider such proposed report

and may provide its advisory to the Director of Health by adopting such report in amended or unamended form. The Health Services Council, however, is not bound to recommend to the Director that the application be process under the provisions for expedited review as delineated in sections 6.5 and 6.6. The Health Services Council shall take under advisement all objections both to the merits of the application and to the proposed expedited processing of the proposed application and shall make a recommendation to the Director regarding each. Should the Health Services Council not recommend to the Director that the application be processed under expedited review procedures as initially proposed, such application may continue to be processed consistent with the time frames and procedures for applications not recommended for expedited review. If expedited review is not granted, then the comment period may be forthwith extended consistent with the time frames in section 6.1 for applications not proposed for expedited review. The Director, with the advice of the Health Services Council, shall make the final decision either to grant or to deny expedited review and shall make the final decision to grant or to deny the application on the merits within the expedited review mechanism and time frames.

Section 7.0 *Change of Ownership, Operation and/or Location*

- 7.1 When a change of ownership or operation or location of a hospice program or when discontinuation or addition of a service(s) is contemplated, the licensing agency shall be notified in writing.
- 7.2 A license shall immediately become void and shall be returned to the licensing agency when operation of a hospice program is discontinued or when any changes in ownership occur in accordance with the rules and regulations herein and section 23-17-6 of reference 1.
 - a) When there is a change in ownership or in the operation or control of the program, the licensing agency reserves the right to extend the expiration date of such license, allowing the program to operate under the same license which applied to the prior license for such time as shall be required for the processing of a new application or reassignment of patients, not to exceed six (6) weeks.

Section 8.0 *Inspections*

- 8.1 The licensing agency shall make, or cause to be made, such inspections and investigations, including medical records, as deemed necessary in accordance with section 23-17-10 of reference 1 and the rules and regulations herein.
 - 8.1.1 Such inspections and investigations may include on-site visits to patients, either in their homes or in the inpatient care facilities, provided however, that a signed statement of approval for such visitation has been obtained by the licensing agency from the patient/family.
- 8.2 Refusal to permit inspections, other than on-site visits referred to in section 8.1.1 above, shall constitute a valid ground for license denial, suspension or revocation.

- 8.3 Every hospice program shall be given notice by the licensing agency of all deficiencies reported as a result of an inspection or investigation.

Section 9.0 *Denial, Suspension, Revocation of License or Curtailment of Activities*

- 9.1 The licensing agency is authorized to deny, suspend or revoke the license or curtail activities of any hospice program which: (1) has failed to comply with the rules and regulations pertaining to the licensing of hospice care programs; or (2) has failed to comply with the provisions of reference 1.
- 9.1.1 Reports of deficiencies shall be maintained on file in the licensing agency and shall be considered by the licensing agency in rendering determinations to deny, suspend or revoke the license or to curtail activities of a hospice program.
- 9.2 Whenever an action shall be proposed to deny, suspend or revoke a license for a Hospice Care or curtail its activities, the licensing agency shall notify the hospice program by certified mail, setting forth reasons for the proposed action, and the applicant or licensee shall be given an opportunity for a prompt and fair hearing in accordance with section 23-17-8 of reference 1 and section 42-35-9 of reference 2, General Laws of Rhode Island, as amended, and in accordance with the provisions of section 30.0 herein.
- 9.2.1 However, if the licensing agency finds that public health, safety or welfare of patients requires emergency action and incorporates a finding to that effect in its order, the licensing agency may order summary suspension of license or curtailment of activities pending proceedings for revocation or other action in accordance with section 42-35-14(c) and 23-1-21 of the General Laws of Rhode Island, as amended.
- 9.3 The appropriate state and federal agencies shall be notified of any action taken by the licensing agency pertaining to either denial, suspension, or revocation of license, or curtailment of activities.

PART II ***ORGANIZATION AND MANAGEMENT***

Section 10.0 ***Governing Body***

- 10.1 There shall be an organized governing body or equivalent legal authority ultimately responsible for: (1) the management, fiscal affairs, and operation of the hospice program; (2) the assurance of quality care and services; and (3) compliance with all federal, state and local laws and regulations pertaining to hospice program and the rules and regulations herein.
- 10.2 The governing body or other legal authority shall furthermore be responsible to:
- a) make services available on a twenty-four (24) hour basis to meet the needs of patients/family as required under the provisions of section 11.5 herein;
 - b) to provide a sufficient number of appropriate personnel, physical resources and equipment to facilitate the delivery of prescribed services.
- 10.3 The governing body or other legal authority shall designate: (a) an administrator who shall be responsible for the management and operation of the hospice program; and (b) a medical director who assumes overall responsibility for the medical component of patient care and to ensure achievement and maintenance of quality standards of professional practice.
- 10.4 The governing body or equivalent legal authority shall adopt and maintain bylaws or acceptable equivalent which defines responsibilities for the operation and performance of the organization, identifies purposes and means of fulfilling such. In addition, the governing body or equivalent legal authority shall establish administrative policies pertaining to no less than the following:
- a) responsibilities of the administrator and the medical director;
 - b) conflict of interest on the part of the governing body, professional staff and employees;
 - c) the services to be provided;
 - d) criteria for the selection, admission and transfer of terminally ill patient/families;
 - e) patient/family consent and involvement in the development of patient care plan;
 - f) developing support network when relatives are not available and patient needs and wants that support;
 - g) linkages and referrals with community and other health care facilities or agencies which shall include a mechanism for recording, transmitting and receiving information essential to the continuity of patient/family care.

Such information must contain no less than the following:

- i. patient identification data; such as name, address, age, gender, name of next of kin, health insurance coverage, etc.

- ii. diagnosis and prognosis, medical status of patient, brief description of current illness, medical and nursing plans of care including such information as medications, treatments, dietary needs, baseline laboratory data;
 - iii. functional status;
 - iv. special services such as physical therapy, occupational therapy, speech therapy and such other;
 - v. psychosocial needs; and
 - vi. such other information pertinent to ensure continuity of patient care.
- h) professional management responsibilities for contracted services;
 - i) reports of patient's condition and transmission thereof to patients' physician; and
 - j) such other matters, as may be relevant to the organization and operation of hospice care.

Section 11.0 ***Minimum Services Required/Availability and Accessibility of Services***

- 11.1 Any service available through a hospice program shall be provided to patients/families, only if acceptable to the terminally ill patient and family.
- 11.2 Services which are to be provided directly through staff personnel of a hospice program shall include the following core services:
 - a) physician services (which may include attending physicians' services in accordance with section 23.1.1 herein);
 - b) nursing services;
 - c) social services;
 - d) bereavement counseling services;
 - e) spiritual counseling services; and
 - f) services of volunteers.
- 11.2.1 In those agencies where designated hospice care staff personnel are also assigned to other patients in addition to hospice care patients, the governing body or other legal authority shall ensure that only hospice care staff be assigned and render services to hospice care patients/families.
- 11.2.2 A hospice program may use contracted staff if necessary to supplement hospice staff personnel in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances. If contracting is used, the hospice shall maintain professional

management responsibility for the services and shall assure that the qualifications of staff and services provided meet the requirements herein.

11.3 In addition to the core services listed in 11.2 above, a hospice program must ensure that the following services are provided to patients/families directly by hospice staff personnel or under written arrangement as specified in section 17.0 herein.

- a) home health aide and homemaker services;
- b) short-term inpatient care which includes inpatient respite care and general inpatient care;
- c) therapeutic services (physical, occupational, and speech & hearing);
- d) medical supplies and appliances, including drugs and biologicals; and
- e) counseling services such as dietary, mental health, etc.

11.4 Additional health services or related services may be provided as may be deemed appropriate to meet patient/family needs and such services must be rendered in a manner consistent with acceptable standards of practice.

11.5 ***Availability of Services:***

A hospice program shall make:

- a) nursing services, physicians services, drugs and biologicals routinely available on a twenty-four (24) hour basis, seven (7) days a week, as may be required in accordance with the plan of care;
- b) all other services available on a twenty-four (24) hour basis to the extent necessary to meet the needs of individuals for care that is reasonable and necessary for the palliation and management of terminal illness and related conditions in accordance with the plan of care; and
- c) patient visiting and assessment capability available on a twenty-four (24) hour basis, seven (7) days a week to respond to acute and urgent patient/family needs.

11.6 ***Accessibility to Hospice Care:***

Each hospice program shall establish a mechanism to enable patients/families to make telephone contact with responsible staff personnel on a twenty-four (24) hour basis, seven (7) days a week. Mechanical answering devices shall not be acceptable.

11.7 ***Accessibility to Pharmacy Services:***

Each hospice program shall provide on a twenty-four (24) hour basis, seven (7) days a week, accessibility to pharmacy services to enable patient/family to obtain prescription drugs and biologicals, for the palliative care and management of the terminally ill patient.

Section 12.0 ***Organization of Services***

12.1 The governing body or other legal authority shall organize hospice program services to provide an integrated continuum of care for terminally ill patients/families and to ensure that such care is rendered under the professional management responsibility of the hospice program.

12.1.1 An organizational chart with written description of the organization, authorities, responsibilities, accountabilities and relationships shall be maintained, which shall include but not be limited to:

- a) a description of each level of care and services;
- b) policies and procedures pertaining to each level of care and services;
- c) a description of the system for the maintenance of patient records; and
- d) such other related provision as deemed appropriate.

Section 13.0 ***Administrator***

13.1 The governing body or other legal authority shall appoint an individual who possesses appropriate education and experience to serve as administrator of the hospice program, and who shall be responsible for: (1) the management and operation of the program; (2) the enforcement of policies, rules and regulations and statutory provisions pertaining to the program; (3) serving as liaison between the governing body and staff; and (4) the planning, organizing and directing of such other activities as may be delegated by the governing body.

Section 14.0 ***Medical Director***

14.1 The overall responsibility for the medical component of patient care shall be under the direction of a physician, qualified by training and experience in hospice care, who shall also be responsible for no less than the following:

- a) ensuring and maintaining quality standards of professional practice;
- b) the achievement and maintenance of quality assurance of professional practices through a mechanism for the assessment of patient/family care outcomes;
- c) the certification of terminally ill patients admitted to the hospice program;
- d) participation as a member of the interdisciplinary team, in the development, implementation and assessment of patient/family plan of care; and
- e) consulting with attending physician regarding patient care plans.

Section 15.0 ***Personnel***

- 15.1 A nurse with training and experience in hospice care shall be designated to coordinate the overall plan of care for each patient/family.
- 15.2 Each hospice program shall designate a sufficient number of staff personnel (including volunteers) with training and experience in hospice care and whose qualifications are commensurate with their duties and responsibilities to provide care services to patients/families.
 - 15.2.1 Staff personnel shall provide evidence of current registration, certification or licensure as may be required by law.
- 15.3 A job description for each classification of position shall be established, clearly delineating qualifications, duties, authority and responsibilities inherent in each position.
- 15.4 An ongoing program for the training of all personnel shall be conducted by the hospice program, which shall include: (1) an orientation program for new staff personnel (including volunteers); and (2) a continuing program for the development and improvement of skills of staff to ensure the delivery of quality hospice care services.
- 15.5 A health care facility shall require all persons, including students, who examine, observe, or treat a patient or resident of such facility to wear a photo identification badge which states, in a reasonably legible manner, the first name, licensure/registration status, if any, and staff position of such person.

Health Screening

- 15.6 Upon hire and prior to delivering services, a pre-employment health screening shall be required for each individual who has or may have direct contact with a patient in the hospice. Such health screening shall be conducted in accordance with the *Rules and Regulations Pertaining to Immunization, Testing, and Health Screening for Health Care Workers (R23-17-HCW)* promulgated by the Department of Health.

Section 16.0 ***Interdisciplinary Team***

- 16.1 The governing body or other legal authority shall designate an interdisciplinary team composed of staff personnel which includes:
 - a) patient/family;
 - b) physician; (may include the Medical Director or physician designee and the attending, see section 23.1.1 herein);
 - c) professional (registered) nurse;
 - d) social worker;

- e) volunteer;
 - f) clergy; and
 - g) such other staff and non-staff personnel as may be deemed appropriate.
- 16.2 The interdisciplinary team shall be responsible to develop, implement and assess patient/family plans of care, and in addition:
- a) the supervision of care, personnel and services provided;
 - b) the provision of direct patient care as may be required and appropriate;
 - c) the review on an ongoing regularly scheduled basis of patient/family plans of care, and the revision of such plans of care as may be required;
 - d) the development of policies and procedures governing patient/family care and services; and
 - e) such other duties as may be deemed appropriate.

Section 17.0 ***Written Agreements***

- 17.1 There shall be written agreements for the provision of those services required in section 11.3 herein, which are not provided directly by the hospice program. The agreement shall clearly delineate the responsibilities of the parties involved and shall include no less than the following provisions:
- a) a stipulation that services may be provided only with the express authorization of the hospice;
 - b) the responsibility of the licensed hospice program for the admission of patients/families to service;
 - c) identification of services to be provided which must be within the scope and limitations set forth in the 'plan of care' and which must not be altered in type, amount, frequency or duration (except in case of adverse reaction) by the individual, agency, or institution;
 - d) the manner in which the contracted services are coordinated, supervised and evaluated by the hospice program;
 - e) assurance of compliance with the patient care policies of the licensed hospice program;
 - f) establishment of procedures for and frequency of patient/family care assessment;
 - g) furnishing the hospice plan of care to inpatient care facilities upon transfer of patient;

- h) assurance that personnel and services contracted for meet the requirements specified herein pertaining to personnel and services, including licensure, personnel qualifications, functions, supervision, orientation, inservice training and attendance at case conferences;
- i) reimbursement mechanism, charges, and terms for the renewal or termination of the agreement; and
- j) such other provisions as may be mutually agreed upon.

Section 18.0 ***Uniform Reporting System***

- 18.1 Each hospice program shall establish and maintain records and data in such a manner as to make uniform a system of periodic reporting. The manner in which the requirements of this regulation may be met shall be prescribed from time to time in directives promulgated by the Director.
- 18.2 Each hospice program shall report to the licensing agency detailed statistical data pertaining to its operation and services. Such reports and data shall be made at such intervals and by such dates as determined by the Director.
- 18.3 The licensing agency is authorized to make the reported data available to any state or federal agency concerned with or exercising jurisdiction over the hospice program.
- 18.4 The directives promulgated by the Director pursuant to these regulations shall be sent to each hospice program to which they apply. Such directives shall prescribe the form and manner in which the statistical data required shall be furnished to the licensing agency.

Section 19.0 ***Rights of Patients***

- 19.1 Each hospice program shall adopt applicable "rights of patients" pursuant to the provisions of section 23-17-19.1 of reference 1 and shall make such available to patients/families.

PART III *PATIENT CARE MANAGEMENT*

Section 20.0 *Professional Management Responsibilities*

- 20.1 The hospice program shall retain professional management responsibility for all hospice care services including those services specified in section 11.3 herein, which may be provided under arrangements. Furthermore, the hospice program shall ensure that all services, including arranged services, are rendered in a safe and effective manner consistent with acceptable standards of practice and the requirements herein.
- 20.2 ***Continuity of Care:*** The hospice program shall assure the continuity of patient/family care in the home and inpatient settings through written policies, procedures and criteria pertaining to no less than the following:
- a) admission criteria and initial assessment of the patient/family need and decision for care;
 - b) signed informed consent;
 - c) ongoing assessment of patient/family needs;
 - d) development and review of the plan of care by the interdisciplinary team;
 - e) transfer of patients to inpatient care facilities for inpatient respite care and general inpatient care;
 - f) the provision of appropriate patient/family information at the point of transfer between levels of care settings;
 - g) community or other resources to insure continuity of care and meet patient/family needs;
 - h) management of symptom control through palliative care and utilization of therapeutic services (see section 11.3 herein);
 - i) constraints imposed by limitations of services, family conditions; and
 - j) such other criteria as may be deemed appropriate.

Section 21.0 *Plan of Care*

- 21.1 After an initial assessment of patient/family needs, a written plan of care shall be established by the Medical Director or physician designee, the attending physician and the Interdisciplinary Team for each patient/family admitted to the hospice program. Such plan of care shall be developed with the participation of the patient and family, and shall include only those services which are acceptable to the patient and family. Furthermore, the family shall be involved whenever possible in the implementation and continuous assessment of the plan of care. Such plan shall include provisions pertaining to:

- a) pertinent diagnosis and prognosis;
- b) identification of patient/family needs addressing the physical, psychological, social, and spiritual needs of the patient/family; the scope of services required; the frequency of visits; the need for inpatient care (respite and/or general inpatients); nutritional needs; medications; management of discomfort and symptom control; management of grief; and
- c) consent of patient/family; and
- d) such other relevant modalities of care and services as may be appropriate to meet patient/family care needs.

21.2 The plan of care shall be reviewed and updated at periodic intervals as specified in the plan of care by the interdisciplinary team. This provision also applies to hospice care patients in inpatient care facilities.

Section 22.0 *Levels of Care*

22.1 **Home Care:** Home care services shall be provided to hospice patients/families either as routine home care or continuous home care during periods of crisis, in order to maintain the terminally ill patient at home.

22.2 **General Inpatient Care:** Short-term general inpatient care for the control of pain or management of acute and severe clinical problems which cannot be managed in a home setting shall be provided only in licensed hospitals or licensed skilled nursing facilities, and which meet the requirements of section 26.0 herein and with whom the hospice care has entered into a binding written agreement. Such agreement includes, in addition to the provisions of section 17.0 herein, the following mutually agreed upon terms:

- a) that the inpatient provider has established policies consistent with those of the hospice program and that the inpatient care facility agrees to abide by the patient care plan and protocol established by the hospice program;
- b) the medical record to include a record of all inpatient services and events, and a copy of the discharge summary and, if requested, a copy of the medical record to be provided to the hospice program;
- c) hospice program to be responsible for the appropriate hospice care training of personnel who provided the care under the agreement;
- d) the party responsible for the implementation of the provisions of the agreement; and
- e) such other provisions as may be relevant and deemed necessary.

22.3 **Inpatient Respite Care:** inpatient respite care may be provided for short periods of time to relieve family members or others caring for the terminally ill patient. Such care shall be

provided only in a licensed skilled nursing or intermediate care I facility which meets the requirements of section 26.0 herein, and with whom hospice program has entered into a binding agreement as provided in section 17.0 herein.

22.3.1 This provision does not preclude hospice program from providing respite care in the home in accordance with section 11.4 herein.

Section 23.0 *Services*

23.1 ***Physician Services:*** shall be provided by a physician to meet the general medical needs of patients for the management of the terminal illness and related conditions, through palliative and supportive care and in accordance with hospice policies.

23.1.1 Such policies shall include provisions governing the relationship of the attending physician to the Medical Director, and the interdisciplinary team.

23.1.2 In addition to palliation and management of terminal illness and related conditions, staff physician(s) of the hospice program including the physician member(s) of the interdisciplinary group shall also meet the general medical needs of the patients to the extent that these needs are not met by the attending physician.

23.2 ***Nursing Services:*** shall be provided under a licensed professional (registered) nurse to meet the nursing care needs of patients/families as prescribed in the plan of care and in accordance with acceptable standards of practice and hospice policies.

23.3 ***Social Services:*** Social services shall be provided by a person with at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education. Such service shall be provided as prescribed in the plan of care and in accordance with acceptable standards of practice and hospice care policies.

23.4 ***Bereavement Services:*** An organized program for the provision of bereavement services shall be established to meet the needs of the members of families both before and after the death of the patient. Such services shall be provided by a professional person qualified by training and experience for the development, implementation and assessment of a plan of care to meet the needs of the bereaved.

23.5 ***Counseling Services:***

- a) Spiritual counseling by a member of the clergy and other members of religious organization shall be available. Patients/families shall be notified of the availability of such services;
- b) Dietary and any other counseling service for the patient/family shall also be available as may be required, while the individual is enrolled in hospice care.

23.6 ***Home-Health Aide Services:***

- a) Each hospice program shall provide home-health aide services pursuant to section 11.3 herein and as prescribed by the patient/family plan of care and consistent with policies of the hospice program.
 - b) The home-health aide shall provide personal care and other related support services under the supervision of a registered nurse from the licensed hospice program and/or a therapist when the aide carries out simple procedures as an extension of physical, speech or occupational therapy or social services. Duties of home-health aides shall include:
 - i. the performance of simple procedures as an extension of therapy services;
 - ii. personal care;
 - iii. ambulation and exercise;
 - iv. assistance with medications that are ordinarily self-administered;
 - v. preparing meals and assisting patients with eating;
 - vi. household services which are essential to the patient's health care at home;
 - vii. report change in patient's condition and needs; and
 - viii. completing appropriate records.
- 23.7 ***Volunteer Services:*** the development and utilization of specially trained lay and professional volunteers is integral and vital to a hospice program. Direct patient care rendered by volunteers shall be provided under the supervision of a qualified and experienced staff member of the hospice program and shall be consistent with the established patient/family plan of care. Furthermore, direct patient care volunteers shall:
- a) have the necessary qualifications and skills to provide the prescribed service;
 - b) have participated in an appropriate orientation and training program of hospice care; and
 - c) be responsible to record patient care services rendered.
- 23.8 ***Other Services:*** such as physical, occupational, speech and hearing therapy services must be available and when provided, such services must be rendered in accordance with the plan of care and in a manner consistent with accepted standards of practice.
- 23.9 ***Medical Supplies*** and appliances, including drugs and biologicals as may be needed shall be provided (either directly or by arrangement) for the palliation and management of the terminal illness and related conditions in accordance with section 11.3 herein.

23.10 ***Administration of Drugs and Biologicals:***

Drugs and biologicals as prescribed by the physician in the plan of care may be administered by the following individuals:

- a) A licensed nurse or physician.
- b) Selected non-licensed personnel with demonstrated competence who have satisfactorily completed a State-Approved Program on Drug Administration may administer oral or topical drugs, if adequate medical and nursing supervision is provided in accordance with reference 4 and agency policies.
- c) The patient, a member of the family or other care giver may also administer drugs, upon written approval by the attending physician.

23.11 Accessibility to a pharmacy as required in section 11.7 herein shall insure availability of necessary drugs and biologicals as may be required.

23.12 ***Controlled Substances:***

Hospice programs shall have policies pertaining to the disposal of controlled substances which are consistent with the *Rules and Regulations Governing the Disposal of Legend Drugs (R21-31-LEG)* of reference 5.

24.0 ***Clinical Records***

24.1 A clinical record shall be established for every individual receiving care and services. The record shall be completed promptly and accurately documented, readily accessible and systematically organized to facilitate retrieval.

24.2 Each clinical record shall include a comprehensive compilation of information. Entries shall be made for all services provided, signed by the staff providing the services. The record shall include entries on all services rendered whether furnished directly or under arrangements with the hospice. Each individual's record shall contain no less than:

- a) the initial and subsequent assessment;
- b) the plan of care;
- c) identification data;
- d) consent form;
- e) pertinent medical history; and
- f) complete documentation of all services and events (including evaluations, treatment, progress notes, etc.).

- 24.3 Records shall be maintained by the agency for a period of at least five (5) years following the date of discharge and shall be safeguarded against loss or unauthorized use.
- 24.4 Each program shall establish policies and procedures to govern the use and removal of records and determine the conditions for release of information in accordance with statutory provisions pertaining to confidentiality.

Section 25.0 *Quality Assurance*

- 25.1 Each hospice program shall conduct an ongoing comprehensive, integrated self-assessment of the quality and appropriateness of home care services, general inpatient and respite care services through a mechanism which shall ensure:
- a) patient care monitoring;
 - b) audits of patient/family care and services;
 - c) assessment of patient/family care outcomes;
 - d) identification of problems and measures taken to improve care;
 - e) evaluation of program; and
 - f) such other measures as may be deemed appropriate.

PART IV ***HOSPICE INPATIENT CARE UNITS***

Section 26.0 ***General Provisions***

26.1 A licensed hospital, a licensed skilled nursing facility or a licensed intermediate care I facility with whom a hospice program enters into a written agreement for the provision of inpatient care (general inpatient or respite care) for hospice patients shall be required to meet the following provisions pertaining to: (1) staffing; and (2) patient areas.

26.1.1 ***Twenty-four Hour Nursing Service:***

- a) The facility provides twenty-four (24) hour nursing services which are sufficient to meet total nursing needs and which are in accordance with the patient plan of care. Each patient receives treatments, medications, and diet as prescribed, and is kept comfortable, clean, well-groomed, and protected from accident, injury and infection.
- b) Each shift includes a registered nurse who provides direct patient care.

26.1.2 ***Patient Areas:***

The Patient Areas must be designed and equipped for the comfort and privacy of each patient/family which includes:

- a) physical space for private patient/family visiting;
- b) accommodations for family members, including children, if they wish to remain with patient overnight;
- c) accommodation for family privacy after a patient's death; and
- d) home-like interior decor.

Patients shall be permitted to receive visitors, including small children, at any hour.

PART V **WASTE DISPOSAL**

27.1 **Medical waste:**

Medical waste as defined in the *Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management & Disposal of Regulated Medical Waste in Rhode Island (DEM-DAH-MW-01-92)*, Rhode Island Department of Environmental Management (June 1994), shall be managed in accordance with the provisions of the aforementioned regulations.

27.2 **Other Waste:**

Wastes which are not classified as infectious waste, hazardous wastes or which are not otherwise regulated by law or rule may be disposed in dumpsters or load packers provided the following precautions are maintained:

- a) Dumpsters shall be tightly covered, leak proof, inaccessible to rodents and animals, and placed on concrete slabs preferably graded to a drain. Water supply shall be available within easy accessibility for washing down of the area. In addition, the pick-up schedule shall be maintained with more frequent pick-ups when required. The dumping site of waste materials must be in sanitary landfills approved by the Department of Environmental Management.
- b) Load packers must conform to the same restrictions required for dumpsters and, in addition, load packers shall be:
 - a) high enough off the ground to facilitate the cleaning of the underneath areas of the stationary equipment; and
 - b) the loading section shall be constructed and maintained to prevent rubbish from blowing from said area site.

PART VI *PRACTICES AND PROCEDURES, CONFIDENTIALITY AND SEVERABILITY*

Section 28.0 *Variance Procedure*

- 28.1 The licensing agency may grant a variance either upon its own motion or upon request of the applicant from the provisions of any rule or regulation in a specific case if it finds that a literal enforcement of such provision will result in unnecessary hardship to the applicant and that such variance will not be contrary to the public interest.
- 28.2 A request for a variance shall be filed by an applicant in writing setting forth in detail the basis upon which the request is made.
 - 28.2.1 Upon the filing of each request for variance with the licensing agency and within thirty (30) days thereafter, the licensing agency shall notify the applicant by certified mail of its approval or in the case of a denial, a hearing date, time and place may be scheduled if the hospice program appeals the denial.

Section 29.0 *Deficiencies and Plans of Correction*

- 29.1 The licensing agency shall notify the governing body or other legal authority of a facility of violations of individual standards through a notice of deficiencies which shall be forwarded to the facility within fifteen (15) days of inspection of the facility unless the director determines that immediate action is necessary to protect the health, welfare, or safety of the public or any member thereof through the issuance of an immediate compliance order in accordance with section 23-1-21 of the General Laws of Rhode Island, as amended.
- 29.2 A facility which received a notice of deficiencies must submit a plan of correction to the licensing agency within fifteen (15) days of the date of the notice of deficiencies. The plan of correction shall detail any requests for variances as well as document the reasons therefore.
- 29.3 The licensing agency will be required to approve or reject the plan of correction submitted by a facility in accordance with section 29.2 above within fifteen (15) days of receipt of the plan of correction.
- 29.4 If the licensing agency rejects the plan of correction, or if the facility does not provide a plan of correction within the fifteen (15) day period stipulated in section 29.2 above, or if a facility whose plan of correction has been approved by the licensing agency fails to execute its plan within a reasonable time, the licensing agency may invoke the sanctions enumerated in section 9.0 herein. If the facility is aggrieved by the action of the licensing agency, the facility may appeal the decision and request a hearing in accordance with Chapter 42-35 of the General Laws.
- 29.5 The notice of the hearing to be given by the Department of Health shall comply in all respects with the provisions of Chapter 42-35 of the General Laws. The hearing shall in all respects comply with the provisions therein.

Section 30.0 *Rules Governing Practices and Procedures*

- 30.1 All hearings and reviews required under the provisions of Chapter 23-17 of the General Laws of Rhode Island, as amended, shall be held in accordance with the provisions of the rules and regulations promulgated by the Rhode Island Department of Health entitled *Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health (R42-35-PP)*.

Section 31.0 ***Confidentiality***

- 31.1 Disclosure of any health care information relating to individuals shall be subject to the provisions of the "Confidentiality of Health Care Information" Chapter 5-37.3 of the General Laws of Rhode Island, as amended, and other relevant statutory and federal requirements.

Section 32.0 ***Severability***

- 32.1 If any provision of these regulations or the application thereof to any facility or circumstances shall be held invalid, such invalidity shall not affect the provisions or application or the regulations which can be given effect, and to this end the provisions of the regulations are declared to be severable.

PART VII ***REFERENCES***

1. "Licensing of Hospice Care", Chapter 23-17 of the General Laws of Rhode Island, as amended.
2. "Administrative Procedures Act", Chapter 42-35 of the General Laws of Rhode Island, as amended.
3. *Rules and Regulations for Determination of Need for New Health Care Equipment and New Institutional Health Services (R23-15-CON)*, Rhode Island Department of Health, January 2000 and subsequent amendments thereto.
4. "Nurses", Section 5-34-31 of the General Laws of Rhode Island, as amended.
5. *Rules and Regulations Governing the Disposal of Legend Drugs (R21-31-LEG)*, Rhode Island Department of Health, March 1998 and subsequent amendments thereto.
6. *Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management & Disposal of Regulated Medical Waste in Rhode Island (DEM-DAH-MW-01-92)*, Rhode Island Department of Environmental Management, June 1994 and subsequent amendments thereto.
7. *Rules and Regulations Pertaining to Immunization, Testing, and Health Screening for Health Care Workers (R23-17-HCW)*, Rhode Island Department of Health.

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