

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 **Delaware Code**, Section 122(3)(m) (16 **Del.C.** §122(3)(m))
16 **DE Admin. Code** 4468

PROPOSED

PUBLIC NOTICE

4468 Delivery of Hospice Services

The Office of Health Facilities Licensing and Certification, Health Systems Protection Section, Division of Public Health, Department of Health and Social Services, has proposed amendments to the State of Delaware 4468 Delivery of Hospice Services regulation.

Senate Bill 119, signed into law in June 2013, requires the Department of Health and Social Services to establish and implement uniform protocol for all hospice programs operating in Delaware for the safe disposal of unused medication upon the death or discharge of an in-home hospice patient. The proposed amendments add to the existing regulation a section 6.5.5 and an Appendix A: *Protocol Regarding the Safe Disposal of Unused Prescription Medication Following the Death of an In-Home Hospice Patient*.

On April 1, 2014, the Department plans to publish proposed amendments to the 4468 Delivery of Hospice Services regulation and hold them out for public comment per Delaware law.

Copies of the proposed regulation are available for review in the April 1, 2014 edition of the Delaware *Register of Regulations*, accessible online at: <http://regulations.delaware.gov> or by calling the Office of Health Facilities Licensing and Certification at (302) 283-7220.

Any person who wishes to make written suggestions, testimony, briefs or other written materials concerning the proposed regulations must submit same to Deborah Harvey by 4:30 p.m. on Wednesday, April 30, 2014 at:

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4468 Delivery of Hospice Services

1.0 Definitions

“A Coordinated Program” (including both services and personnel) implies the capacity to respond to patient/family needs whenever they arise. It also implies enough administrative and staff integration to ensure continuation of the same high quality care when the patient moves from home to inpatient care or vice versa.

“Bereavement” means that period of time, usually at least one year, during which survivors mourn the death and resolve their grief.

“Bereavement Service” means counseling and support services to be offered during the bereavement period.

“Family” means the hospice patient's kin. Other relations and individuals with significant personal ties to the hospice patient may be designated as members of the hospice patient's family.

“Governing Authority” means the policy-making body of a government agency, the Board of Directors or trustees of a not-for-profit corporation, or the proprietor or proprietors of an organization.

“Home Care Services” means services which are provided primarily in the patient's home. These services may include, but are not necessarily limited to, one or more of the following services: nursing services, physician services, home health aide services, homemaker services, physical therapy, social services, pastoral counseling and trained volunteer services.

“Hospice” means a coordinated program of home, outpatient and inpatient care under the direction of an identifiable hospice administration providing palliative and supportive medical and other health services to terminally ill patients and their families. Hospice is an option for care which utilizes a medically directed interdisciplinary team, which may also include services provided by trained volunteers. A hospice program provides care to meet the physical, psychological, social, spiritual and other special needs which are

experienced during the final stages of illness, and during dying and bereavement. Hospice care shall be available twenty-four hours a day, seven days a week.

"Identifiable Hospice Administration" means an administrative group, individual or legal entity. This administration shall be responsible for the management of all aspects of the program.

"Inpatient Services" means those services to patients/families who require either 24 hour supervision in a health care facility; i.e., acute care hospital, skilled or intermediate care facility or services which necessitate the admission of the patient for treatment in the health care facility.

"Institution" as it appears in these regulations is used to refer to acute care hospitals, skilled nursing care facilities and intermediate care facilities (Title 16, **Delaware Code**).

"Interdisciplinary Care Team" means a care group of qualified individuals consisting of at least a physician, registered nurse, and social worker who collectively have expertise in assessing the special needs of hospice patients/families and in providing palliative and supportive care to meet the special needs arising out of the physical, psychological, spiritual, social and economic stress which are experienced during the final stages of illness, dying, and bereavement.

"Optional Mode of Care" means the patient volunteers to become a hospice patient after meeting certain eligibility criteria and signs a consent agreement to participate in the program.

"Outpatient Services" means those services which are delivered in other than the home setting or as an inpatient in a hospital facility. They are delivered on an ambulatory basis either in a physician's office, clinic setting, emergency room or other area such as an x-ray department.

"Palliative Services" means those services, and/or treatments which produce the greatest degree of relief from the symptoms caused by disease for the longest period of time, minimizing side effects. The goal of hospice care is to provide symptom control through appropriate palliative therapies.

"Patient/family Unit" means the patient and family are considered as one, and are the primary unit of care.

"Symptom Control" means the relief of distressing physical, emotional, social and spiritual symptoms of both patient and family. It does not mean "cure of disease".

"Terminally Ill Patient" means an individual in the terminal stage of illness, with an anticipated life expectancy of six months or less, who, alone or in conjunction with a family member, or members, has voluntarily requested admission and been accepted into a hospice.

"Trained Volunteers" means individuals who are required to participate in a structured orientation and training program before they become participants in the hospice program.

9 DE Reg. 415 (9/1/05)

2.0 Licensing Requirements

- 2.1 The term hospice (or any like term such as hospice care, palliative care, etc.) shall not be used as a part of the name of any institution or description of services in the State unless it has been so classified by the Department of Health and Social Services.
- 2.2 Skilled care regulations, Intermediate care regulations, Hospital regulations shall apply when hospice inpatient care is to be provided.
- 2.3 All organizations whether or not they are currently licensed in the State of Delaware and/or are eligible to receive Medicare/Medicaid certification are required to apply for a hospice license if they plan to call themselves a hospice or to offer services described by them in terms such as hospice type care, palliative care, etc.
- 2.4 A license is not transferable from person to person nor from one location to another.
- 2.5 The license shall be conspicuously posted. All applications for renewal of licenses shall be filed with the Department of Health and Social Services at least thirty (30) days prior to expiration. Licenses will be issued for a period not to exceed one (1) year (twelve months), and may be issued for that period only if the hospice is in full compliance with these regulations. (Application fee is \$100.00 and annual licensure fee is \$50.00).
- 2.6 In addition to the annual license noted in 2.5 above provisional licensure may be granted by the Department of Health and Social Services for a period not exceeding three (3) months, when the hospice is in compliance with most but not all of these regulations and has demonstrated the ability and willingness to comply within the three (3) month period.

3.0 Hospice Care

- 3.1 Hospice is an option for care which utilizes an interdisciplinary team of the patient's choice. The team shall consist of at least a physician, nurse, social worker, trained volunteer, and the patient/family.
- 3.2 The interdisciplinary team shall have the following qualifications:

- 3.2.1 Licensed physician shall mean a physician who is licensed in the State of Delaware according to 24 **Del.C.** Ch. 17, Subchapter III.
- 3.2.2 Licensed nurse shall mean a registered nurse who is licensed in the State of Delaware according to 24 **Del.C.** §§1909-1912.
- 3.2.3 A social worker shall mean a person who is licensed in the State of Delaware according to 24 **Del.C.** Ch. 39.
- 3.2.4 A volunteer will be qualified to participate in the hospice program after completion of a structured orientation and training program.
- 3.2.5 Specialized services as deemed necessary by the interdisciplinary team shall be performed by persons qualified to perform such functions and licensed by the Delaware Code, if required.
- 3.2.6 Providers of special services such as homemaker/ home health aides, physical therapists, nutritional, pharmaceutical, psychiatric, psychological, radiological, pediatric, oncologic specialists or other therapists may also be included on the team as deemed necessary by the team.
- 3.2.7 One qualified health care professional member of the team shall be designated as the patient care coordinator.
- 3.3 The interdisciplinary team shall have the following responsibilities:
 - 3.3.1 Perform an admission history which includes medical, social, spiritual, emotional aspects of the patient/ family.
 - 3.3.2 Develop the care plan for each patient/family. The patient care coordinator will be responsible for assuring the implementation and ongoing review of the care plan.
 - 3.3.3 Hold an interdisciplinary care team meeting at least semimonthly or more often if needed to review and update the care plan.
 - 3.3.4 Emphasize prevention and control of pain and other distressing symptoms.
 - 3.3.5 Make provision for 24 hours per day, seven days a week coverage.

9 DE Reg. 415 (9/1/05)

4.0 Personnel/Administrative

- 4.1 No rules shall be adopted by the licensee or administrator of the hospice program which are in conflict with these regulations.
- 4.2 The Department of Health and Social Services shall be notified, in writing, of any changes in the hospice administration.
- 4.3 Hospice program shall comply with applicable local, state and federal laws and regulations governing the organization and delivery of health care to patients and families.
- 4.4 The hospice administration shall adopt by-laws identifying the purpose of hospice and the means of fulfilling them.
- 4.5 A hospice administrator will be identified and be responsible for the overall coordination and administration of the hospice program.
- 4.6 A governing authority must be established. Hospice established within existing licensed hospitals, nursing homes and home health agencies need not establish a separate governing authority specifically for hospice but must provide a hospice advisory committee.
- 4.7 Governing authority shall:
 - 4.7.1 Adopt by-laws which identify the purposes of hospice and the means of fulfilling them.
 - 4.7.2 The governing authority shall establish a procedure for and regularly conduct a systematic professional and administrative review and program evaluation of the services. Licensed hospitals, nursing homes and home health agencies may establish a committee specifically for this purpose or they may assign the responsibility to an existing committee.
 - 4.7.3 Governing authority shall prepare an annual review and program evaluation which should include, but not be limited to the following, and should be available upon request to the licensing agency:
 - Review and reevaluation of the program objectives.
 - Evaluation of the appropriateness of the scope of services offered.
 - Review of admission, discharge and patient care policies and procedures.
 - Annual review of a random sample of patient/family records and written evaluation on quality of services provided.
 - Annual review of staffing qualifications, responsibilities and needs.

5.0 Patient Care Policies

- 5.1 Every hospice shall develop written policies pertaining to the services they provide. Such policies shall include:
 - 5.1.1 The goal of hospice care.
 - 5.1.2 The scope of program services.
 - 5.1.3 Interdisciplinary team services.
 - 5.1.4 Bereavement services.
 - 5.1.5 Home care services.
 - 5.1.6 Inpatient services.
 - 5.1.7 Palliative services.
 - 5.1.8 A written policy denoting care of patients:
 - 5.1.8.1 In an emergency.
 - 5.1.8.2 During a communicable disease episode.
 - 5.1.9 Criteria for discharge from hospice programs.
- 5.2 The policies should reflect the philosophy and objectives of the hospice program.
- 5.3 Admission to a hospice is limited to the following:
 - 5.3.1 Patient in the terminal state of illness whose survival is anticipated to be less than six months.
 - 5.3.2 Patients who are no longer receiving treatment for cure.
 - 5.3.3 The patient and physician agree that palliative care is appropriate.
 - 5.3.4 The patient or the patient's legal guardian choose hospice care.
 - 5.3.5 A hospice program shall not admit any persons under the age of eighteen (18) years without a signed parent/guardian consent.
 - 5.3.6 Each hospice program must have a policy and procedures regarding informed consent agreement.
 - 5.3.7 At the time of admission to the hospice and thereafter, a patient/family must be under the care of a physician who shall be responsible for medical care.
 - 5.3.8 Admission is limited to those patients who have a family member, or designated person who is able and willing to assume the role of primary care giver.
- 5.4 The patient/family is the unit of care.
- 5.5 The hospice program must establish written policies regarding the rights and responsibilities of patients and these policies and procedures are to be made available to patient/family or patient/guardian. The rights of patients shall be consistent with Titles 16 and 31 of the Delaware Code and the Department of Health and Social Services Regulations regarding Patient's Rights.
- 5.6 The program shall exhibit with the admission agreement to all patients or their sponsors a complete statement enumerating all charges for services, materials and equipment which shall, or may be, furnished to the patient during the period of participation in the program.
- 5.7 The hospice program shall present to the patient, in writing, the prepayment and refund policies at the time of admission, and in the case of third party payment, an exact statement of responsibility in the event of retroactive denial. The patient shall be notified in writing of any changes in third party coverage prior to the implementation of such changes.

6.0 Service to Patients

- 6.1 General services:
 - 6.1.1 The hospice organization shall be considered the responsible provider of the services and shall be ultimately responsible for the quality of services rendered.
 - 6.1.2 A hospice contracting for components of its program shall require as part of the contract, that the contractor comply with the provisions of the hospice regulation regarding a coordinated program of home and inpatient care services.
 - 6.1.3 The hospice organization shall develop, implement and revise, as necessary, written policies and procedures for the operation of a coordinated program of home and inpatient services to cover at least the following:
 - 6.1.3.1 Delineation of responsibility for delivering and for maintaining coordinate care.
 - 6.1.3.2 Direct provision of services provided by the hospice organization.
 - 6.1.3.3 Mechanisms for assuring quality hospice care when segments of care are provided by contracting parties.
 - 6.1.3.4 Statement of how coordination of services is to be assured.

- 6.1.3.5 Home care services shall be provided by an organization which has received Medicare/Medicaid certification.
- 6.1.3.6 Inpatient care shall be provided in a licensed facility which is primarily engaged in providing to inpatients those services defined in Title 16 of the Delaware Code pertaining to Acute Care Hospitals, Intermediate Care Facilities and Skilled Care Facilities.
- 6.1.3.7 Bereavement services shall be available to the family for at least one year following the death of the patient.

6.2 Medical services:

- 6.2.1 All persons admitted to a hospice shall be under the care of a licensed physician.
- 6.2.2 All hospice programs shall arrange for one (1) or more licensed physicians to be called in an emergency. Names and phone numbers should be posted.
- 6.2.3 Patient/physician encounters shall be at a frequency not less than that described in the written plan of care or as otherwise required to meet demonstrated patient/family needs.
- 6.2.4 Medical services to be provided in an inpatient setting shall be consistent with those regulations established in Title 16 of the Delaware Code pertaining to Acute Care Hospitals, ICF and SNF.
- 6.2.5 Transfer Agreements shall be negotiated between the hospice organization and inpatient facilities to insure a smooth transition should the need for such services develop.

6.3 Specialized services:

- 6.3.1 All specialized services shall be ordered, in writing, by the interdisciplinary care team physician, such as physical therapy, occupational therapy, speech therapy, etc.
- 6.3.2 An interdisciplinary care team member will notify the patient/family, as soon as possible, when a special service has been ordered.

6.4 Nursing services:

- 6.4.1 Nursing services provided within an inpatient facility will be consistent with the regulations contained within Title 16 of the Delaware Code pertaining to Acute Care Hospitals, ICF and SNF.
- 6.4.2 Hospice nursing services shall be available directly, via written agreement seven days a week, 24 hours per day under the supervision of a director of nurses who is licensed in the State of Delaware.
- 6.4.3 Written policies and procedures for nursing services shall be developed and implemented by the hospice to incorporate objectives and maintain the standards of nursing practice as well as coordinate, integrate and provide continuity of patient/family care in conjunction with other services during illness and after discharge/death to assure physician orders are followed.

6.5 Medications:

- 6.5.1 All medications administered to patients shall be ordered in writing and signed by the patient's physician or the interdisciplinary care physician.
- 6.5.2 Existing regulations for medications administered to patients in inpatient facilities will be applicable to hospice patients in inpatient facilities.
- 6.5.3 Medication administered to hospice patients should be consistent with the hospice philosophy which focuses on palliation; i.e., controlling pain and relieving other symptoms which are manifested during the dying process.
- 6.5.4 Resource materials relating to the administration and untoward effects of medications and treatments used in pain and symptom control will be readily available to nursing personnel.
- 6.5.5 The hospice must develop and implement written policies and procedures to include the requirements of the Department of Health and Social Services' Protocol Regarding the Safe Disposal of Unused Prescription Medication Following the Death of an In-Home Hospice Patient (refer to Appendix A).

6.6 Inpatient services:

- 6.6.1 Develop and implement written policies and procedures for inpatient services which provide for facilities and services which create a home-like atmosphere and reflect hospice philosophy insofar as possible under physical and utilization constraints. These policies may include, but should not be limited to, the following:
 - Visiting.
 - Food preparation by the patient and family.
 - Provision for family sleeping area.
 - Personal items.

- 6.7 Inservice training and continuing education shall be offered on a regular basis. Documentation of this training and continuing education will be maintained and available on request to the licensing authority.

6.8 Records:

- 6.8.1 The hospice organization shall maintain a complete record for each patient/family which contains all information pertaining to supportive management of the patient/family and which is maintained in conformance with generally accepted medical record practices. Records necessary to record the daily treatment of the patient should be maintained at the site of treatment.
- 6.8.2 Each patient/family record shall be retained by the hospice organization for a five-year period after death or discharge from the hospice. In the case of a minor, records shall be kept for a five year period after death. If the minor is discharged from the hospice, records shall be kept for a five year period after the minor attains majority.
- 6.8.3 The patient care plan will give direction to the care given in meeting the physiological, psychological, sociological and spiritual needs of patient/family. The plan will identify those care givers who will be participating in this plan. The plan will specifically address maintenance of patient independence and control.
- 6.8.4 The plan will be recorded in ink and maintained as part of the patient/family record.
- 6.8.5 All services ordered and rendered shall be entered in the patient/family record.
- 6.8.6 Written documentation of all interdisciplinary care team meetings is necessary.
- 6.8.7 The plan of care must be prepared within three days of the patient's admission to the home care component of the hospice program and within two days of admission to the inpatient component of the hospice program.
- 6.8.8 All required records maintained by the hospice organization shall be open to inspection by the authorized representatives of the Department of Health and Social Services.

7.0 Suspension or Revocation of Licenses

- 7.1 The Department of Health and Social Services may suspend or revoke a license issued pursuant to these regulations on any of the following grounds:
 - 7.1.1 Violation of these rules and regulations issued pursuant thereto.
 - 7.1.2 Permitting, aiding or abetting the commission of any illegal act in the hospice operation.
 - 7.1.3 Conduct or practices detrimental to the health or welfare of the patient.
- 7.2 Before any license issued pursuant to these regulations is suspended or revoked, thirty (30) days notice shall be given in writing to the holder of the license, during which time he may appeal for a hearing before the Department of Health and Social Services. The Department of Health and Social Services shall hear the appeal at the next regularly scheduled meeting of the Department of Health and Social Services and shall render its decision within fifteen (15) days following such hearing.

8.0 Renewal of License After Suspension or Revocation

If and when the conditions upon which the suspension or revocation of a license are based have been corrected, a new license may be granted.

9.0 Severability

Should any section, sentence, clause or phrase of these regulations be legally declared unconstitutional or invalid for any reason, the remainder of said regulations shall not be affected thereby.

Appendix A

Protocol Regarding the Safe Disposal of Unused Prescription Medication Following the Death of an In-Home Hospice Patient

The Department of Health and Social Services expects that each in-home hospice agency's policies and procedures will address each of the following:

A. Medication Disposal Following the Death of an In-Home Hospice Patient

- 1. Designation of hospice staff that will assist in the disposal of all unused prescription medications, regardless of the prescriber.
- 2. Definition of the timeframe in which the designated staff must:
 - a. Assist in the disposal of the unused prescription medications following the death on an in-home hospice patient; or

- b. Contact the family member/designated primary care giver to arrange an appointment to assist in the disposal of the unused prescription medications if the in-home hospice patient was transferred to an inpatient hospice unit prior to the death.
 - c. Dispose of the unused prescription medication in the presence of another designated hospice staff in the event that the in-home hospice patient does not have a family member or designated primary care giver.
 3. Checking of the medication label to confirm that the medication belonged to the patient, prior to assisting in the disposal of the unused prescription medication
 4. Disposal of the unused prescription medications by at least one family member/designated primary care giver with the assistance of the designated hospice staff.
 5. Disposal of the medications in accordance with the United States Food and Drug Administration guidelines which can be found at <http://www.fda.gov>.
 6. Prohibition of removal by designated hospice staff of the unused prescription medications from the patient's residence.
 7. Actions the designated hospice staff must take upon evidence of missing unused prescription medication(s).
 8. Diversion/retention of the deceased patient's unused prescription medications could result in criminal offenses.

B. Education

1. Education of the family member/designated primary caregiver upon the in-home hospice patient's admission and death, as follows:
 - a. Provision of a copy of the written hospice policies and procedures on the disposal of all prescription medications following the death of an in-home hospice patient.
 - b. Discussion of the prescription medication disposal policy in a language and manner that they understand to ensure that these parties are educated regarding the following:
 - the hospice's policies and procedures for the safe disposal of all prescription medications following the death of an in-home hospice patient
 - the diversion/retention of the deceased patient's unused prescription medications could result in criminal offenses
2. Education of hospice staff regarding the hospice's prescription medication disposal policy at the following times:
 - prior to implementation of the policies and procedures
 - prior to any policy and procedure revision
 - upon hire (if applicable)

C. Patient Record Documentation

1. Storage of patient records readily retrievable for 5 years after the patient's death.
2. Inclusion of the following in the patient's record:
 - a. Documentation that the hospice's policies and procedures regarding the safe disposal of all unused prescription medications were provided and discussed with the family member/designated primary care giver upon the patient's admission and in-home death.
 - b. Documentation of one of the following:
 - an inventory of all disposed prescription medications and the signature of the family member/designated primary care giver that witnessed the disposal
 - family member/designated primary care giver refusal to dispose of prescription medications

D. Personnel Education Documentation

1. Education regarding the hospice's prescription medication disposal policy must be documented at the following times:
 - prior to implementation of the policies and procedures
 - prior to any policy and procedure revision
 - upon hire (if applicable)