SUMMARY OF EXPRESS TERMS

This rule amends Sections 700.2 and Parts 717 and repeals and replaces Part 793 and 794 of Title 10 (Health) of NYCRR, the operational rules for hospices approved to provide services in New York State under Article 40 of the Public Health Law. The changes will make state regulations consistent with the federal conditions of participation/rules, which were revised and implemented on December 3, 2008, as well as consistent with Article 40 of Public Health Law.

Section 700.2(a)(27) (Definitions) is amended to increase the maximum bed capacity from 8 to 16 beds in a hospice residence.

Section 700.2(c)(55) (Definitions) is amended to define hospice patient as a person certified as being terminally ill, who, alone or in conjunction with designated family member(s), has voluntarily requested admission and been accepted into a hospice for which the Department has issued a certificate of approval; and clarifies that nothing provided herein shall be construed to require provision of services to a patient that are not covered by the patient's payment source.

Section 700.2(c)(58) (Definitions) is amended to clarify that palliative and supportive care is provided to a hospice patient for the reduction and abatement of pain and other symptoms and stresses associated with terminal illness and dying. This terminology (palliative and supportive care) is used in the definition of hospice found in 700.2(a)(23).

Section 700.2(c)(60) (Definitions) is added to include the definition of palliative care, as defined in Public Health Law Section 4012-b, provided to a person with advanced, life limiting illness.

Section 717.2 (Construction standards) is amended to increase the maximum bed capacity from 8 to 16 beds in a free standing hospice residence.

Section 717.3 (Patient and service areas in hospice inpatient facilities and units) is amended to reduce maximum room capacity from four to two patients as required by new federal rules.

Section 717.4 (Functional areas in hospice residences) is amended to allow a hospice to operate a maximum of twenty five percent of total residence beds as dually certified beds at any given time.

Section 793.1 (Governing authority) is repealed and replaced with a new section, entitled Patient Rights, which sets forth patient rights for hospice patients and requires alleged violations of mistreatment, neglect or abuse to be investigated and reported to the State, if verified.

Section 793.2 (Contracts) is repealed and replaced with a new section, entitled Eligibility, Election, Admission and Discharge, which sets forth provisions for determining

eligibility for and admitting persons into a hospice program as well as requirements for discharging a hospice patient.

Section 793.3 (Administration) is repealed and replaced with a new section, entitled Initial and Comprehensive Assessment, which requires hospices to complete initial and comprehensive assessments and reassessments within specified time periods and identifies the information required in such assessments.

Section 793.4 (Staff Services) is repealed and replaced with a new section, entitled Patient Plan of Care, Interdisciplinary Group and Coordination of Care, which defines the interdisciplinary group members responsible for management of hospice care, identifies the responsibilities of the group, and lists the information required in the hospice plan of care.

Section 793.5 (Personnel) is repealed and replaced with a new section, entitled Quality Assessment and Performance Improvement, which sets forth requirements for the hospice quality assessment and performance improvement program. Hospices will be required to track performance indicators and conduct performance improvement projects.

Section 793.6 (Patient referral, admission and discharge) is repealed and replaced with a new section, entitled Infection Control, which sets forth requirements for management of an infection control program including policies and procedures for preventing and managing persons exposed to blood-borne pathogens and appropriate training of staff.

Section 793.7 (Records and reports) is repealed and replaced with a new section, entitled Staff and Services, which identifies the types of personnel a hospice is expected to employ and their responsibilities. This section also clarifies employment options (direct or contract), qualifications and supervision requirements strengthening the onsite supervision home health aide requirement.

Section 793.8 is repealed.

Section 794.1 (Patient/family rights) is repealed and replaced with a new section, entitled Governing Authority, which lists the responsibilities of the governing authority. It also sets forth requirements for a patient complaint investigation process and emergency plan. This section also requires hospices to obtain and maintain a Health Commerce System account as a communication link with the Department of Health.

Section 794.2 (Patient/family plan of care) is repealed and replaced with a new section, entitled Contracts, which sets forth contract requirements between the hospice and individual, facility or agency providers delivering services on behalf of the hospice. This section also specifies requirements for management contracts and explains those responsibilities that may not be delegated by the governing body.

Section 794.3 (Medical records systems and charts) is repealed and replaced with a new section, entitled Personnel, which sets forth personnel requirements including health

requirements, identification and reference checks, maintenance and content of personnel records, job descriptions and orientation, performance appraisal and inservice education.

Section 794.4 (Hospice inpatient and residence services) is repealed and replaced with a new section, entitled Clinical Record, which sets forth requirements for maintenance and content of clinical records. Record retention standards are also included in this section.

Section 794.5 (Short Term Inpatient Service) is added and sets forth structural and operational standards for the provision of short-term inpatient service by the hospice. Physical plant, staffing, quality of life and patient comfort measures are addressed. This section also sets forth operational requirement for management and coordination of care.

Section 794.6 (Hospice Residence Service) is added and sets forth requirements for hospice residences, for those situations when a hospice chooses to offer a hospice operated home to a hospice patient without a suitable home in which to receive services, and increases maximum bed capacity from 8 to 16 beds.

Section 794.7 (Leases) is added and sets forth information which must be included in a lease agreement between a hospice and an inpatient setting or hospice residence.

Section 794.8 (Hospice Care Provided to Residents of a Skilled Nursing Facility (SNF) or Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID)) is added and identifies responsibilities of the hospice and the facility when a resident elects

the hospice benefit. Services expected to be provided by the hospice and the facility are clarified, and development and implementation of collaborative plans of care and care coordination between the two entities is required.

Section 794.9 (Records and Reports) is added and identifies those records which must be maintained by the hospice, and the retention timeframes. This section also specifies reports which must be submitted to the Department of Health.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by subdivision (4) of section 4010 of the Public Health Law, Sections 700.2 and Parts 717, 793 and 794 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) are amended, repealed and/or replaced to be effective upon publication of a Notice of Adoption in the New York State Register, as follows:

* * *

Paragraph (27) of subdivision (a) of Section 700.2 (Definitions) is amended as follows:

(a) The following definitions of medical facilities, based on standards approved by the commissioner, shall apply to this Chapter unless the context otherwise requires:

(27) Hospice residence shall mean a hospice operated home which is residential in character and physical structure, and operated for the purpose of providing more than two hospice patients, but not more than [eight] <u>sixteen (16)</u> hospice patients, with hospice care.

Paragraph (55) and (58) of subdivision (c) of Section 700.2 (Definitions) is amended as follows:

(c) The following general definitions, based on standards approved by the commissioner, shall apply to this Chapter, unless the context otherwise requires:

* * *

(55) Hospice patient shall mean a person in the terminal stage of illness, with a life expectancy of approximately twelve [six] months or less, who, alone or in conjunction with designated family member(s), has voluntarily requested admission and has been accepted into a hospice for which the Department has issued a certificate of approval; provided, however, that nothing herein shall be construed to require provision of services to a patient that are not covered by the patient's payment source.

(58) Palliative and supportive care shall mean services provided to a hospice patient for the reduction and abatement of pain and other symptoms and stresses associated with terminal illness and dying.

Paragraph (60) of subdivision (c) of Section 700.2 (Definitions) is added as follows:

(60) Palliative care shall mean active, interdisciplinary care provided to a patient and/or a hospice patient with advanced, life-limiting illness, focusing on relief of distressing physical and psychosocial symptoms and meeting spiritual needs with the goal of achievement of the best quality of life for patients and families.

* * *

Section 717.2 is amended as follows:

Section 717.2 - Construction standards

717.2 Construction standards.

(a) An inpatient hospice unit, if attached to or part of a general hospital, nursing home or health-related facility, shall comply with the same provisions for institutional occupancies required by NFPA 101, Life Safety Code, as the facility would be required

to meet if such unit were used to house hospital inpatients, nursing home patients or health-related facility residents. Further details concerning this referenced material are contained in section 711.2(a) of this Title.

(b) A free-standing inpatient hospice facility or unit shall comply with the pertinent provisions for either residential occupancies or institutional occupancies as required by NFPA 101. The determination as to which of these chapters and provisions contained therein are applicable shall be dependent upon an assessment of the requirements of the approved operational and functional inpatient programs of the hospice. Further details concerning this referenced material are contained in section 711.2(a) of this Title.

(c) A free-standing hospice residence shall have a minimum capacity of three (3) residents and a maximum capacity of [eight] sixteen (16) residents. For the purposes of local laws and ordinances governing fire safety and building construction standards, any such residence shall be deemed either a one- or two-family dwelling. All free-standing hospice residences that do not operate beds dually certified for inpatient care shall comply, at a minimum, with the requirements for small residential board and care facilities as contained in chapter 21, section 21-2 of the 1985 National Fire Protection Association (NFPA) 101 Life Safety Code, applicable to small facilities with an evacuation capability classification of impractical. These codes and standards were published by the National Fire Protection Association, Batterymarch Park, Quincy, MA 02269, and are available for public inspection and copying at the [Office of Regulatory Reform] Regulatory Affairs Unit, New York State Department of Health, Corning Tower Building, Empire State Plaza, Albany, New York 12237. Hospice residences that operate beds dually certified for inpatient care shall comply with the pertinent provisions for

either residential occupancies or institutional occupancies as required by NFPA 101 in accordance with subdivision (b) of this section.

Section 717.3 is amended as follows:

Section 717.3 - Patient and service areas in hospice inpatient facilities [or] and units.

(a) Patient rooms and facilities shall meet the following requirements:

(1) be at or above grade level;

(2) At least two rooms shall be designed for one bed and equipped with a private sink and toilet.

(3) Maximum room capacity shall be [four] for two patients and their families.

(4) Minimum net room areas exclusive of toilet rooms, and space occupied by furniture, lockers or wardrobes, or used for closets, alcoves or vestibule shall be 100 square feet in single-bed rooms and 80 square feet per bed in [multi-bed] double rooms.

(5) Each patient room shall have a window which can be opened without the use of tools.

(6) Each patient shall be provided with a separate nurse's calling device, furniture and closet space adequate for storage of clothing and personal items.

(7) Each patient in a [multi-bed] double room shall be provided with visual privacy by use of flame retardant cubicle curtains.

(8) Each patient room shall be accessible to a conveniently located toilet room. One room containing a toilet and a sink shall serve no more than [four] two beds.

(9) One bathtub or shower shall be provided for each 10 beds which are not otherwise served by bathing facilities within patient rooms. A minimum of one bathtub shall be provided to serve the hospice inpatient facility. Each tub or shower shall provide for

privacy and sufficient space to permit assistance, if necessary.

(10) Corridors, aisles, alcoves, vestibules and door widths shall be designed to make all toilets, wardrobes, closets and furniture accessible to and usable by the physically disabled.

(b) Patient and family areas shall include a dining area, space for recreation and private interactions including pastoral care, and accommodations for family privacy after the patient's death.

(c) As a minimum, sufficient areas shall be provided for staff and administrative functions to include but not necessarily be limited to:

(1) working area for conducting business transactions, completing medical and financial records, and performing other administrative and professional staff functions;

(2) storage space for medical records and administrative supplies;

(3) staff lounge and toilet rooms;

(4) clean work area or clean holding area which contains a work counter, handwashing and storage facilities;

(5) soiled work area or soiled holding area which contains a clinical sink or equivalent flushing rim fixture, sink equipped for handwashing, work counter, and waste receptacle;

(6) pharmaceutical distribution area which contains a work counter, refrigerator, sink and locked storage for biologicals and drugs;

(7) equipment storage area, including accommodations for wheelchairs and stretchers;

(8) interview space(s) for private interviews;

(9) multi-purpose room for conferences, meetings, and health education purposes; and

(10) food service facilities designed and equipped to meet the requirements of the hospice

program, including but not limited to:

(i) storage space for four days' supply of food, including cold storage;

(ii) food preparation facilities as required by the program, including space and equipment for preparing and serving;

(iii) handwashing facilities in the food preparation area;

(iv) dishwashing facilities; and

(v) waste storage and disposal equipment.

Section 717.4 is amended as follows:

717.4 Functional areas in hospice residences.

(a) A hospice residence shall be residential in character and physical structure, and shall not be located in a facility licensed under Article 28 of the Public Health Law. The physical layout shall be designed to accommodate the functional and operational program for the facility. All residents shall be provided opportunities for individual privacy, and all resident areas and functions shall be designed to accommodate the physically disabled.

(b) Each hospice residence shall comply with the following standards:

(1) The maximum bedroom capacity shall be one resident.

(2) Each resident bedroom shall be of sufficient size to accommodate wheelchair access to all functional areas of the room. All necessary equipment and accessories for daily living shall be residential in scale and appropriate for care of the resident.

(3) Common space(s) adequate to accommodate staff, residents, family members and other visitors, shall be provided for congregate meals, recreational, religious and social activities.

(4) Provisions for the preparation and serving of meals shall be conveniently located. Such dietary/kitchen facilities shall be available for use by staff, residents, family members and other visitors.

(5) Private areas shall be provided to accommodate visitation by family members and others.

(6) A hospice residence may be approved to operate a maximum of twenty five percent (25%) of its total residence capacity as [two] dually certified beds at any given time, which beds may be used alternately for the provision of residential hospice care and inpatient hospice care, provided there is existing hospice inpatient bed need remaining in the county where the residence shall be located. Inpatient care shall be provided, as needed, to patients residing in the residence to ensure continuity of care and avoid transfer to an inpatient facility or unit. Patients shall be admitted directly from the community into a dually certified bed for inpatient care only when such patients shall continue to reside in the residence to receive routine home care following cessation of inpatient care. First priority for inpatient care in a dually certified bed shall be given to patients already residing in the residence. Should a dually certified bed be unavailable to an existing resident due to a community admission, the community admission shall be transferred to another inpatient facility.

(7) A hospice residence shall not be combined with a hospice inpatient unit. The hospice residence shall be separate and distinct from an inpatient unit, and physically separated by walls, doors or other physical structures. The inpatient unit and the hospice residence, when adjacent to each other, shall have separate entrances onto each unit, but may share a common exterior main entrance and common areas for meals, family interactions, and

spiritual and recreational activities.

Parts 793 (Organization and Administration) and 794 (Patient/Family Care Services) are repealed and replaced by new Parts 793 (Patient/Family Care Services) and 794 (Organization and Administration) to read as follows:

Part 793 Patient/Family Care Services

Section 793.1 Patient rights. (a) The governing authority shall establish written policies regarding the rights and responsibilities of the patient and shall assure the development of procedures implementing such policies to ensure that, as a minimum, the patient has a right to:

(1) be fully informed of these rights prior to or at the time of admission, verbally and in writing, in a language and manner that the patient understands, as evidenced by written acknowledgment of receipt signed by the patient or the patient’s representative, pursuant to subdivision (b) of this Section;

(2) be given a statement of the services provided by the hospice and covered under the hospice benefit, including any limitations on those services, and of related charges including charges for services not covered by third-party payors or not covered by the hospice basic rate;

(3) be fully informed of the patient's medical condition;

(4) adequate, appropriate and timely care and services, including effective pain management and symptom control for conditions relating to the patient’s terminal illness, for the duration of the illness for which hospice was elected;

(5) be involved in developing his or her hospice plan of care;

(6) choose his or her attending physician;

(7) refuse to participate in experimental research;

(8) refuse medication, care and treatment after being fully informed of and understanding the consequences of such actions;

(9) voice complaints and recommend changes in policies and services to hospice staff, the New York State Department of Health or any outside representative of the patient's choice. The expression of such complaints by the patient or his/her designee shall be free from restraint, interference, coercion, discrimination or reprisal;

(10) express complaints about the care and services provided and to have the program investigate such complaints as specified in section 794.1 (l) of this Title. The program is responsible for notifying the patient or his/her designee that if the patient is not satisfied by the response the patient may complain to the Department of Health;

(11) be treated with consideration, respect and full recognition of the patient’s dignity and individuality;

(12) make independent personal decisions and have knowledge of available choices;

(13) be assured of confidential treatment of patient records in accordance with applicable state and federal laws;

(14) be informed of the name and function of any person and/or agency providing care and services;

(15) receive services and/or continue to receive services without regard to age, race, color, creed, gender, national origin, sexual orientation, disability or source of payment;

(16) receive services without discontinuation or diminishment because of the inability to

pay for care;

(17) receive written information and assistance with executing advance directives as set forth in Article 29-CC of the Public Health Law and implementing regulations, as well as applicable federal regulations;

(18) exercise his or her rights without fear of discrimination or reprisal; and

(19) have his or her person and property treated with respect and to be free from mistreatment, neglect, or verbal, mental, sexual and/or physical abuse, including injuries of unknown source, and misappropriation of property.

(b) If a patient lacks capacity to exercise these rights, the rights shall be exercised by an individual, guardian or entity legally authorized to represent the patient.

(c) The governing authority must:

(1) ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by anyone furnishing services on behalf of the hospice, are reported immediately by hospice employees and contracted staff to the hospice administrator;

(2) immediately investigate all alleged violations involving anyone furnishing services on behalf of the hospice and immediately take action to prevent further potential violations while the alleged violation is being verified. Investigations and/or documentation of all alleged violations must be conducted in accordance with established procedures;

(3) take appropriate corrective action in accordance with state law if the alleged violation is verified by the hospice administration or an outside body having jurisdiction, such as the Department of Health or local law enforcement agency; and

(4) ensure that verified violations are reported to State and local bodies having

jurisdiction including the Department of Health within 5 working days of becoming aware of the violation.

Section 793.2 - Eligibility, Election, Admission and Discharge

The governing authority shall ensure that:

(a) except as prohibited by article 45 of the Public Health Law or any other law or regulation, a patient referred to a hospice may be accepted from any source;

(b) policies and procedures for admission and discharge are developed and implemented;

(c) any individual admitted to hospice is certified as being terminally ill consistent with state and/or federal definitions. Written certification of terminal illness is required for each election period defined in paragraph (d)(4) of this Section. If the hospice cannot obtain the written certification within 2 calendar days after the election period begins, it must obtain an oral certification within 2 calendar days and the written certification before it submits a claim for payment.

(1) Initial certification of terminal illness must be obtained from either the medical director of the hospice or the physician member of the hospice interdisciplinary group provided for in Section 793.4 of this Part, and also from the individual's attending physician, if the individual has an attending physician. In connection with the initial certification, the medical director or physician designee must consider the following:

(i) diagnosis of the primary terminal condition, along with any supporting current clinically relevant information;

(ii) related diagnoses, if any, along with any supporting current clinically relevant information;

(iii) current subjective and objective medical findings;

(iv) current medication and treatment orders; and

(v) information about the medical management of any of the patient's conditions unrelated to the terminal illness.

(2) Subsequent certifications of terminal illness are obtained from the medical director of the hospice or the physician member of the hospice interdisciplinary group and must be based on the certifying individual's clinical judgment regarding the normal course of the individual's illness.

(3) All certifications must:

(i) specify that the individual's prognosis is for a life expectancy consistent with applicable state and federal statutes for purposes of payment;

(ii) include clinical information and other documentation that support the medical prognosis; and

(iii) be filed in the clinical record.

(d) an individual who meets the hospice eligibility requirements files an election statement with a particular hospice. If the individual is physically or mentally incapacitated, his or her representative as provided for in subdivision (b) of Section 793.1 of this Part may file the election statement;

(1) The election statement shall remain in effect as long as the individual remains in the care of a hospice unless the individual revokes the election in accordance with paragraph 3 of this subdivision or is discharged from the hospice in accordance with subdivision (e) of this Section. He/she may at any time file an election if again eligible for hospice care.

(2) The signed election statement must:

(i) identify the hospice that will provide care;

(ii) include the individual's or representative's acknowledgment that he or she has been given a full understanding of the palliative rather than curative nature of hospice care; and

(iii) include the effective date of the election, which may be the first day of hospice care or a later date, but no earlier than the date of the election statement.

(3) An individual or representative may revoke the election of hospice care at any time by filing a signed and dated revocation statement with the hospice. This statement must include the effective date for the revocation.

(4) An individual may elect to receive hospice care during one or more of the following election periods, which are available in the order listed and may be selected separately at different times:

(i) an initial 90-day period;

(ii) a subsequent 90-day period;

(iii) an unlimited number of subsequent 60-day periods.

(e) a patient is discharged only if:

(1) the patient moves out of the hospice's service area or transfers to another hospice;

(2) the hospice determines that the patient no longer meets the eligibility criteria set forth in paragraph (c) of this Section; or

(3) the hospice determines, under a policy set by the hospice for the purpose of addressing discharge for cause that the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the hospice to operate effectively is seriously impaired.

(i) The hospice must do the following before it seeks to discharge a patient for cause:

(a) advise the patient that a discharge for cause is being considered;

(b) make a serious effort to resolve the problem(s) presented by the patient's behavior or situation;

(c) ascertain that the patient's proposed discharge is not due to the patient's use of necessary hospice services; and

(d) document the problem(s) and efforts made to resolve the problem(s) and enter this documentation into the clinical record.

(ii) prior to discharging a patient, a written discharge order must be obtained from the hospice medical director. If a patient has an attending physician involved in his or her care, this physician should be consulted before discharge and his or her review and decision included in the discharge note.

(iii) prior to discharging or transferring the patient from one hospice to another, continuing care and services are arranged and a discharge summary completed as specified in Section 794.4 of this Title.

Section 793.3 Initial and Comprehensive Assessment. (a) The hospice registered nurse, as a member of the interdisciplinary group identified in Section 793.4 of this Part, must complete an initial assessment within 48 hours after the election of hospice care in accordance with Section 793.2 of this Part unless the physician, patient, or representative requests that the initial assessment be completed in less than 48 hours. Initial assessment means an evaluation of the patient’s physical, psychosocial and emotional status related to the terminal illness and related conditions to determine the patient’s immediate care

and support needs.

(b) The hospice interdisciplinary group, in consultation with the individual's attending physician (if any), shall conduct and document in writing a patient-specific comprehensive assessment no later than 5 calendar days after the election of hospice care. Comprehensive assessment means a thorough evaluation of the patient's physical, psychosocial, emotional and spiritual status related to the terminal illness and related conditions including the caregiver's and family's willingness and capability to care for the patient.

(c) The comprehensive assessment must take into consideration the following factors:

(1) the nature and condition causing admission (including the presence or lack of objective data and subjective complaints);

(2) complications and risk factors that affect care planning;

(3) functional status, including the patient's ability to understand and participate in his or her own care;

(4) imminence of death;

(5) severity of symptoms;

6) a review of all of the patient's prescription and over-the counter drugs, herbal remedies and other alternative treatments that could affect drug therapy. This includes, but is not limited to, identification of the following:

(i) effectiveness of drug therapy;

(ii) drug side effects;

(iii) actual or potential drug interactions;

(iv) duplicate drug therapy; and

(v) drug therapy currently associated with laboratory monitoring;

(7) an initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the plan of care and considered in the bereavement plan of care; and

(8) the need for referrals and further evaluation by appropriate health professionals.

(d) The comprehensive assessment must include data elements that allow for measurement of outcomes. The data elements must:

(1) take into consideration aspects of care related to hospice and palliation;

(2) be measured and documented in the same way for all patients;

(3) be an integral part of the comprehensive assessment and documented in a systematic and retrievable way for each patient;

(4) be used in individual patient care planning and in the coordination of services; and

(5) be used in the aggregate for the hospice's quality assessment and performance improvement program.

(e) The hospice interdisciplinary group must update the comprehensive assessment in collaboration with the individual's attending physician, if any, as frequently as the condition of the patient requires, but no less frequently than every 15 days. The update must consider changes that have taken place since the initial assessment and include information on the patient's progress toward desired outcomes, as well as a reassessment of the patient's response to care.

793.4 Patient Plan of Care, Interdisciplinary Group and Coordination of Care. The governing authority must:

(a) designate an interdisciplinary group or groups composed of individuals who work together to meet the physical, medical, psychosocial, emotional, and spiritual needs of the hospice patients and families facing terminal illness and bereavement. The members of the interdisciplinary group are responsible for providing the care and services offered by the hospice, and the group must collectively supervise the care and services.

(1) The interdisciplinary group must include, but is not limited to:

(i) a doctor of medicine or osteopathy (who is an employee or under contract with the hospice);

(ii) a registered nurse;

(iii) a social worker; and

(iv) a pastoral or other counselor.

(2) The governing authority must designate a registered nurse who is a member of the interdisciplinary group to coordinate care and ensure continuous assessment of each patient's and family's needs and implementation of the interdisciplinary plan of care;

(b) if the hospice has more than one interdisciplinary group, specifically designate an interdisciplinary group to establish policies governing the day-to-day provision of hospice care and services;

(c) ensure that all hospice care and services furnished to patients and their families follow an individualized written plan of care established by the interdisciplinary group in collaboration with the patient's attending physician, if any, and, if they so desire, the

patient or representative and the primary caregiver. The plan of care shall indicate for each patient/family how palliative and supportive care is to be achieved including:

(1) goals and interventions based on the problems identified in the initial, comprehensive, and updated comprehensive assessments;

(2) all services necessary for the palliation and management of the terminal illness and related conditions and the individual(s) who will provide those services, including:

(i) interventions to manage pain and symptoms;

(ii) a detailed statement of the scope and frequency of services necessary to meet the specific patient and family needs;

(iii) measurable outcomes anticipated from implementing and coordinating the plan of care;

(iv) drugs, biologicals, treatments, medical supplies, appliances and durable medical equipment that must be provided by the hospice while the patient is under hospice care;

(v) identification of the registered nurse responsible for coordinating care; and

(vi) documentation in the clinical record of the patient's or representative's level of understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policies;

(d) ensure that the hospice interdisciplinary group confers with an individual educated and trained in drug management to ensure that drugs and biologicals meet each patient's needs;

(e) ensure that each patient and the primary care giver(s) receives education and training

regarding their responsibilities for the care and services identified in the plan of care followed by an assessment of their ability to provide care including their ability to self-administer drugs and biologicals;

(f) ensure discussion and written instructions are provided to the patient/family regarding the management and disposal of controlled drugs in the home when controlled drugs are initially ordered and documentation of such in the clinical record;

(g) ensure that the hospice interdisciplinary group reviews, revises and documents the individualized plan as frequently as the patient's condition requires, but no less frequently than every 15 calendar days. A revised plan of care must include information from the patient's updated comprehensive assessment, must note the patient's progress toward the outcomes and goals specified in the plan of care, and must be documented in the clinical record; and

(h) develop and maintain a system of communication and integration, in accordance with the hospice's own policies and procedures, to:

(1) ensure that the interdisciplinary group maintains responsibility for directing, coordinating, and supervising the care and services provided by all hospice and non-hospice healthcare providers;

(2) ensure that care and services provided are based on all assessments of the patient and family needs;

(3) provide for and ensure the ongoing sharing of information between all disciplines providing care and services in all settings, whether the care and services are provided directly or under arrangement; and

(4) provide for an ongoing sharing of information with other non-hospice healthcare

providers furnishing services unrelated to the terminal illness and related conditions.

Section 793.5 - Quality Assessment and Performance Improvement

The governing authority must ensure that the hospice:

(a) develops, implements, and maintains an ongoing, effective, hospice-wide data-driven program for quality assessment and performance improvement, which shall be evaluated annually. The program must:

(1) reflect the complexity of the hospice organization and services;

(2) involve all hospice services, including those services furnished under contract or arrangement, and all locations;

(3) include the use of quality indicator data in the design of the program, which focuses on improved palliative and end of life outcomes;

(4) take actions to demonstrate improvement in hospice performance;

(5) address priorities for improved quality of care and patient safety; and

(6) be capable of showing measurable improvement in indicators related to improved palliative outcomes and hospice services.

(b) maintains documentary evidence of the program, and be capable of demonstrating its operation;

(c) designates one or more individual(s) responsible for operating the program;

(d) designates a committee which includes licensed professionals, representative of the services provided by the hospice, and administrative personnel to participate in and make recommendations to the governing authority regarding the quality program and perform other quality management activities including:

(1) review of quality assessment and performance improvement efforts, at least annually, and in collaboration with the hospice interdisciplinary group recommend revisions to the governing authority, as necessary, of policies and procedures;

(2) review of patient care records for appropriateness of admission, adequacy of assessment of patient/family needs and quality and quantity of services provided;

(3) review of complaints and other investigations; and

(4) review of the effectiveness of the hospice's infection control program, including appropriate identification of infection and communicable disease transmission and control problems and plans for appropriate corrective action, improvement and subsequent prevention.

(e) measures, analyzes, and tracks quality indicators, including adverse patient events and/or potentially avoidable events and other aspects of performance, in the frequency and detail approved by the governing authority. The data shall include patient care data and other relevant data reflective of the hospice operation, the quality of all services provided and all activities that may impact patient care and must enable the hospice to:

(1) assess processes of care, hospice services, and operations;

(2) monitor the effectiveness and safety of services and quality of care; and

(3) identify opportunities and priorities for improvement.

(f) develops, implements and evaluates performance improvement projects conducted annually, sufficient in number and scope to reflect the hospice's population, internal organizational needs, and scope, complexity and past performance of services and operation, using quality indicator data collected. These projects must:

(1) focus on high risk, high volume, or problem-prone areas;

(2) consider incidence, prevalence, and severity of problems in those areas;

(3) take actions aimed at performance improvement in palliative outcomes, patient safety, and quality of care;

(4) measure the success of such actions and track performance to ensure that improvements are sustained;

(5) track and analyze the cause of any adverse patient event;

(6) implement preventive actions and mechanisms that include feedback and learning throughout the hospice; and

(7) be documented by the hospice including the reasons for conducting the project and the measurable progress achieved.

Section 793.6 Infection Control. The hospice must:

(a) implement and enforce an agency wide program for the surveillance, identification, prevention, control and investigation of infectious and communicable diseases, which could result in staff, volunteers, visitors, or patients and family members becoming exposed to such communicable diseases or infections. Such a program shall include:

(1) policies and procedures for maintaining and documenting an effective infection control program in all settings where patients reside, including but not limited to protocols for addressing patient care issues and prevention of infection related to airborne pathogens, infusion therapy, urinary tract care, respiratory tract care, wound care and multi-drug resistant organisms;

(2) following accepted standards of practice to prevent transmission of infections and communicable disease;

(3) monitoring staff for compliance with hospice policies and procedures related to infection control;

(4) protocols for educating staff, contracted personnel, patients, families and other caregivers in infectious disease transmission, standard precautions and the prevention and control of infection; and

(5) a specific program for protecting patients, staff and families from bi-directional spread of HIV and other blood borne pathogens, as specified in subdivision (b) of this Section.

(b) assure that a program be implemented and enforced for the prevention of circumstances which could result in staff, including housekeeping, direct care staff and volunteers, or patients and family members becoming exposed to significant risk body substances which could put them at significant risk of HIV infection, as defined in section 63.1 of this Title, or other blood borne pathogen infection, during the provision of services. Such a program shall include:

(1) use of scientifically accepted protective barriers during job-related activities which involve, or may involve, exposure to significant risk body substances. Such preventative action shall be taken by the staff with each patient and shall constitute an essential element for the prevention of bi-directional spread of HIV or other blood borne pathogens.

(2) use of scientifically accepted preventive practices during job-related activities which involve the use of contaminated instruments or equipment which may cause puncture injuries;

(3) training at the time of employment and yearly staff development programs on the use

of protective equipment, preventive practices, and circumstances which represent a significant risk for all employees whose job-related tasks involve, or may involve, exposure to significant risk body substances;

(4) provision of personal protective equipment for staff which is appropriate to the tasks being performed; and

(5) a system for monitoring preventive programs to assure compliance and safety.

(c) implement and enforce a policy/procedure for the management of individuals who are exposed to significant risk body substances under circumstances which constitute significant risk of transmitting or contracting HIV or other blood borne pathogen infection. The policy/procedure shall include:

(1) a system for reporting to a designated individual in the hospice any exposure thought to represent a circumstance which constitutes significant risk of transmitting or contracting HIV or other blood-borne pathogen infection;

(2) evaluation of the circumstances of a reported exposure and services providing follow-up of the exposed individual which includes:

(i) medical and epidemiological assessment of the individual who is the source of the exposure, where that individual is known and available;

(ii) if indicated epidemiologically, HIV or other blood-borne pathogen counseling and voluntary testing of the source individual. Disclosure of the HIV status of the source individual can be made, consistent with Article 27-f of Public Health Law and Part 63 of this Title, with the express written consent of the protected individual, or a person authorized pursuant to law to consent to health care for the protected individual if such

person lacks capacity to consent, or pursuant to court order, if the HIV status is not known to the exposed individual;

(iii) appropriate medical follow-up of the exposed individual; and

(iv) assurances for protection of confidentiality for those involved in reported exposures.

Section 793.7 Staff and services. (a) At a minimum, hospice staff shall be composed of:

(1) a hospice administrator who is appointed by the governing authority and is an employee of the hospice who works a minimum of half-time for the hospice. The administrator is responsible for the day-to-day management of the hospice.

(2) a hospice medical director who is:

(i) a doctor of medicine or osteopathy who is licensed and registered to practice in New York State or maintains a current license and who is an employee or is under contract with the hospice. When the medical director is not available, a physician designated by the hospice shall assume the same responsibilities and obligations as the medical director; and

(ii) responsible for supervision of all physician employees and physicians under contract;

(3) a hospice nurse coordinator;

(4) a hospice social worker;

(5) a pastoral care coordinator; and

(6) a coordinator of volunteer services, whose responsibilities shall include:

(i) ensuring implementation of policies and procedures related to volunteer services;

(ii) providing and documenting volunteer orientation and training;

(iii) ensuring that volunteers are used in defined administrative or direct patient care roles under the supervision of a designated hospice employee;

(iv) ongoing efforts to recruit and retain volunteers; and

(v) demonstrating and documenting cost savings achieved through the use of volunteers including:

(*a*) identification of each position that is occupied by a volunteer and his or her work time; and

(*b*) estimates of the dollar costs that the hospice would have incurred if paid employees occupied the positions. Volunteers must provide services in an amount that, at a minimum, equals 5 percent of the total patient care hours of all paid hospice employees and contract staff.

(b) As the needs of the patient dictate, the hospice shall provide the following services:

(1) core services, which include nursing, physician, medical social services, dietary, bereavement and spiritual or pastoral care counseling; and

(2) non-core services which include physical therapy, occupational therapy, speech and language pathology, audiology, respiratory therapy, psychological, drugs and biologicals, laboratory, medical supplies, equipment and appliances, home health aide, personal care, housekeeper, homemaker, and inpatient services.

(c) With the exception of physician services, core services must routinely be provided directly by hospice employees. A hospice may use contracted staff only if necessary to supplement hospice employees in order to meet the needs of patients under extraordinary or other non-routine circumstances such as unanticipated periods of high patient loads, staffing shortages due to illness or other short-term temporary situations that interrupt

patient care such as natural disasters and temporary travel of a patient outside the hospice's service area.

(d) Non-core services as specified in subdivision (b) of this Section may be provided directly by the hospice or under contractual arrangements made by the hospice as specified in Section 794.2 of this Title.

(e) Physician, nursing, medical social services counseling and volunteer services shall be provided by the same health care practitioners to the same patient and family, whenever possible.

(f) Nursing services, physician services and drugs and biologicals must be routinely available on a 24-hour basis, 7 days a week. Other services must be available on a 24-hour basis when reasonable and necessary to meet the needs of the patient and family.

(g) The hospice medical director, physician employees, and contracted physician(s) of the hospice, in conjunction with the patient's attending physician, must assume responsibility for the palliation and management of the terminal illness and conditions related to the terminal illness. If the attending physician is unavailable, the medical director, contracted physician, and/or hospice physician employee is responsible for meeting the medical needs of the patient.

(h) Nursing care and services must be provided by or under the supervision of a registered nurse in accordance with patient assessments and plans of care:

(1) Nursing services in the home shall be provided by or under the direction of hospice personnel who meet the requirements of community health nurse as defined in section 700.2 of this Title.

(2) Highly specialized nursing services that are provided so infrequently that the

provision of such services by direct hospice employees would be impracticable and prohibitively expensive, may be provided under contract.

(3) Registered nurses certified as nurse practitioners may treat and write orders for hospice patients to the extent permitted by New York State Education Law.

(i) Medical social services must be provided by a qualified social worker, under the direction of a physician. Medical social services must be based on the patient's psychosocial assessment and the patient's and family's needs and acceptance of services.

(j) Counseling services must be available to the patient and family to assist the patient and family in minimizing the stress and problems that arise from the terminal illness, related conditions, and the dying process. Counseling services must include, but are not limited to:

(1) an organized program of bereavement counseling furnished under the supervision of a qualified professional with experience or education in grief or loss counseling. Bereavement services shall be available to the family and other individuals in the bereavement plan of care up to 1 year following the death of the patient;

(2) dietary counseling performed by a qualified individual, which include dietitians as well as nurses and other individuals who are able to address and assure that the dietary needs of the patient are met; and

(3) spiritual counseling which is provided in accordance with the patient's and family's acceptance of this service, and in a manner consistent with patient and family beliefs and desires. All reasonable efforts should be made to facilitate visits by local clergy, pastoral counselors, or other individuals who can support the patient's spiritual needs to the best of its ability.

(k) All aide services must be provided by individuals who:

(1) have successfully completed a home health aide training and competency evaluation program as required by paragraph (9) of subdivision (b) of Section 700.2 or this Part; and

(2) are currently listed in good standing on the Home Care Registry in the State.

(l) Aide services must be ordered by a member of the interdisciplinary team, included in the plan of care and consistent with training and tasks permitted to be performed by home health aides, including but not limited to personal care and simple procedures as an extension of nursing or therapies.

(m) A registered nurse who is a member of the interdisciplinary group must make patient assignments, prepare written patient care instructions and provide supervision of aides.

(n) A registered nurse must make an on-site visit to the patient's home no less frequently than every 14 days to assess the quality of care and services provided by the aide and to ensure that services ordered by the hospice interdisciplinary group meet the patient's needs.

(1) The aide should be present during the registered nurse's on-site visit periodically, but no less frequently than every ninety days, or more frequently if an area of concern is noted by the supervising nurse.

(2) If an area of concern is verified by the nurse during the on-site visit, then the hospice must conduct, and the aide must successfully complete a competency evaluation.

(3) The supervising nurse must assess an aide's ability to demonstrate initial and continued satisfactory performance in meeting outcome criteria that include, but are not limited to:

(i) following the patient's plan of care for completion of tasks assigned to the aide by the registered nurse;

(ii) creating successful interpersonal relationships with the patient and family;

(iii) demonstrating competency with assigned tasks;

(iv) complying with infection control policies and procedures;

(v) reporting changes in the patient's condition; and

(vi) completing appropriate records and documentation of care provided.

(o) The hospice must ensure that staff are adequately supervised. The department shall consider the following factors as evidence of adequate supervision:

(1) supervision of nursing personnel is conducted by a supervising nurse;

(2) personnel regularly provide services at the frequencies specified in the patient's plan of care, and in accordance with the policies and procedures of their respective services;

(3) personnel are assigned to the care of patients in accordance with their licensure, as appropriate, and their training, orientation and demonstrated skills;

(4) clinical records are kept complete, and changes in patient condition, adverse reactions, and problems with informal supports or home environment are charted promptly and reported to supervisory personnel;

(5) plans of care are revised as determined by patient condition, and changes are reported to the authorized practitioner and other personnel providing care to the patient;

(6) in-home visits are made by supervisory personnel to direct, demonstrate and evaluate the delivery of patient care and to provide clinical consultation;

(7) professional guidance on agency policies and procedures is provided;

(8) supervision of a home health aide is conducted by a registered professional nurse; and

(9) in-home supervision, by professional personnel, of home health aides takes place:

(i) to demonstrate to and instruct the aide in the treatments or services to be provided, with successful redemonstration by the aide during the initial service visit, or where there is a change in personnel providing care, if the aide does not have documented training and experience in performing the tasks prescribed in the plan of care;

(ii) to evaluate changes in patient condition reported by the aide and initiate any revision in the plan of care which may be needed; and

(iii) to instruct the aide as to the observations and written reports to be made to the supervising nurse.

(p) Homemaker services shall be provided to assist in patient care. A qualified homemaker is an individual who has successfully completed hospice orientation and training in the tasks to be performed.

(1) Homemaker services must be assigned, coordinated and supervised by a member of the interdisciplinary group.

(2) Homemakers must report all concerns about the patient or family to the member of the interdisciplinary group and complete appropriate documentation of care provided.

Part 794 Organization and Administration

Section 794.1 Governing authority. The governing authority, as defined in Part 790 of this Title shall:

(a) be responsible for the management and fiscal operations of the hospice, the provision of all hospice services, and continuous quality assessment and performance improvement;

(b) ensure compliance with all applicable Federal, State and local laws, rules and regulations;

(c) provide for coordinated, interdisciplinary inpatient and home care services, 24 hours a day, 7 days a week;

(d) ensure adequate staff and resources to provide continuity of care based on the needs of the persons served;

(e) adopt, amend and implement bylaws regarding the responsibilities, functions and activities of the governing body;

(f) adopt the hospice budgets, control assets and funds, and provide for annual fiscal audits;

(g) prohibit any employee of the hospice to be reimbursed by any party other than the hospice for service provided as part of the hospice program, or the splitting or sharing of fees between a referral agency/facility or individual and the hospice;

(h) ensure the prompt submission of all records and reports required by the department;

(i) ensure compliance with the pertinent provisions regarding the discontinuance of operations of a medical facility, as set forth in section 401.3 of this Chapter, in the event the hospice discontinues operation for any reason;

(j) negotiate agreements with other patient care facilities/agencies for the referral and acceptance of hospice patients;

(k) adopt and amend policies and procedures regarding management and operation of the hospice and the provision of patient care services;

(l) ensure the development and implementation of a patient complaint procedure to include:

(1) documentation of receipt, investigation and resolution of any complaint, including maintenance of a complaint log indicating the dates of receipt and resolution of all complaints received by the program;

(2) review of each complaint with a written response to all written complaints and to oral complaints, if requested by the individual making the oral complaint, explaining the complaint investigation findings and the decisions rendered to date by the program within 15 days of receipt of such complaint; and

(3) an appeals process with review by a member or committee of the governing authority within 30 days of receipt of the appeal.

(m) ensure the development, implementation and annual review of a written emergency plan which is current and includes hospice emergency contact information, current staff call down list, and community partners contact list and procedures to be followed to assure health care needs of patients continue to be met in emergencies that interfere with the delivery of services, and orientation of all employees to their responsibilities in carrying out such a plan;

(n) obtain, from the Department's Health Commerce System (HCS), accounts for each hospice it operates and ensure that sufficient, knowledgeable staff maintain and keep current such accounts. At a minimum, twenty-four hour, seven-day a week contacts for emergency communication and alerts must be designated by each hospice in the HCS Communications Directory. A policy defining the hospice's HCS coverage consistent with the hospice's hours of operation shall be created and reviewed by the hospice no less than annually. Maintenance of each hospice's HCS accounts shall consist of, but not be limited to, the following:

(1) sufficient designation of the hospice's HCS coordinator(s) to allow for HCS individual user application;

(2) designation by the governing authority of the hospice of sufficient staff users of the HCS accounts to ensure rapid response to requests for information by the State and/or local Department of Health;

(3) adherence to the requirements of the HCS user contract; and

(4) current and complete updates of the Communications Directory reflecting changes that include, but are not limited to, general information and personnel role changes as soon as they occur, and at a minimum, on a monthly basis.

Section 794.2 Contracts. (a) The governing authority may enter into contracts with appropriate qualified individuals, organizations, agencies and/or facilities, when necessary, to provide for those services required by patients/families when the hospice itself does not have sufficient staff or necessary equipment available to render such services directly.

(1) Such contracts shall meet all applicable State and Federal requirements and shall specify:

(i) each party's responsibilities, functions, objectives, financial arrangements and charges, including responsibility for supervision;

(ii) that personnel meet the personnel requirements as set forth in section 794.3 of this Part, which can be verified by written documented evidence accessible to the hospice or department on request;

(iii) that services provided by contract to the patient shall be authorized by the hospice in

accordance with the plan of care developed by the hospice and that the contract provider agrees to abide by the patient care policies established by the hospice for its patients;

(iv) that the contracting provider agrees to participate in patient/family care planning conferences as requested by the hospice;

(v) that contracting providers who are licensed professionals agree to participate in:

(*a*) the coordination of all aspects of the patient's hospice care, including ongoing interdisciplinary comprehensive assessments, developing and evaluating the plan of care, and contributing to patient and family counseling and education;

(*b*) the hospice's quality assessment and performance improvement program; and

(*c*) hospice sponsored in-service training.

(vi) any provisions made for indemnification between the hospice and contracting providers; and

(vii) the following terms and conditions: "Notwithstanding any other provision in this contract, the hospice remains responsible for (a) ensuring that any service provided pursuant to this contract complies with all pertinent provisions of Federal, State and local statutes, rules and regulations; (b) planning, coordinating and ensuring the quality of all services provided; and (c) ensuring adherence to the plan of care established for patients."

(2) When a contract is with a licensed medical facility or certified home health agency, the service provided must be in compliance with the applicable provisions of article 28 or 36 of the Public Health Law, respectively, and the applicable rules and regulations promulgated thereunder. If such statutory and regulatory provisions are inconsistent with the provisions of article 40 of the Public Health Law or the regulations promulgated thereunder, then the contracting provider shall comply with the applicable provisions of

article 40 of the Public Health Law and the regulations promulgated thereunder.

(3) When a contract is between the hospice and a Skilled Nursing Facility (SNF) /Intermediate Care Facility (ICF) to provide hospice services to residents of the SNF/ICF, the provisions of section 794.8 of this Part related to contracts shall also apply.

(b) Except when a management contract has been approved pursuant to this section, the governing authority may not delegate its responsibility for the operation of the hospice to another organization, a parent or subsidiary corporation or through a managing authority contract. An improper delegation may be found to exist where the governing authority no longer retains authority over the operation and management of the hospice, including but not limited to such areas as:

(1) authority to hire or fire the administrator;

(2) authority for the maintenance and control of the books and records;

(3) authority over the disposition of assets and the incurring of liabilities on behalf of the hospice; or

(4) authority over the adoption and enforcement of policies regarding the operation of the hospice.

(c) If the governing authority enters into a management contract, the requirements of this subdivision shall be met.

(1) For the purpose of this section, a management contract is an agreement between a hospice's governing authority and a managing authority for the purpose of managing the day-to-day operation of the hospice or any portion thereof.

(2) Management contracts shall be effective only with the prior written consent of the Commissioner, and shall include the following:

(i) a description of the proposed roles of the governing authority and managing authority during the period of the proposed management contract. The description shall clearly reflect retention by the governing authority of ongoing responsibility for statutory and regulatory compliance;

(ii) a provision that clearly recognizes that the responsibilities of the hospice's governing authority are in no way obviated by entering into the management contract, and that any powers not specifically delegated to the managing authority through the provisions of the contract remain with the governing authority;

(iii) a clear acknowledgment of the authority of the Commissioner to void the contract pursuant to paragraph (9) of this subdivision;

(iv) a plan for assuring maintenance of the fiscal stability, the level of service provided and the quality of care rendered by the hospice during the term of the management contract;

(v) an acknowledgment that the costs of the contract are subject to all applicable provisions of Part 86 of this Title;

(vi) a requirement that the reports described in paragraph (10) of this subdivision will be provided to the department and to the governing authority annually for the term of the management contract;

(vii) an express representation that any management contract approved by the Commissioner is the sole agreement between the managing authority and the governing authority for the purpose of managing the day-to-day operation of the hospice or any portion thereof, and that any amendments or revisions to the management contract shall be effective only with the prior written consent of the Commissioner; and

(viii) a provision that includes the terms of paragraph (8) of this subdivision.

(3) No management contract shall be approved if the governing authority does not retain sufficient authority and control to discharge its responsibility as the certified operator. The following elements of control shall not be delegated to a managing authority;

(i) direct independent authority to hire or fire the administrator;

(ii) independent control of the books and records;

(iii) authority over the disposition of assets and the authority to incur on behalf of the hospice liabilities not normally associated with the day-to-day operation of a hospice; and

(iv) independent adoption of policies affecting the delivery of health care services.

(4) In addition to a proposed written contract complying with the provisions of paragraph (2) of this subdivision, a governing authority seeking to enter into a management contract shall submit to the department, at least 60 days prior to the intended effective date, unless a shorter period is approved by the Commissioner due to extraordinary circumstances, the following:

(i) documentation indicating that the proposed managing authority holds all necessary approvals to do business in New York State;

(ii) documentation of the goals and objectives of the management contract, including a mechanism for periodic evaluation of the effectiveness of the arrangement in meeting these goals and objectives;

(iii) evidence of the managing authority's financial stability;

(iv) information necessary to determine that the character and competence of the proposed managing authority, and its principals, officers and directors, are satisfactory, including evidence that all agencies or health care facilities managed or operated, in or

outside of New York State, have provided a high level of care; and

(v) evidence that it is financially feasible for the hospice to enter into the proposed management contract, recognizing that the costs of the contract are subject to all applicable provisions of Part 86 of this Title.

(5) During the period between a hospice's submission of a request for approval of a management contract and disposition of that request, a hospice may not enter into any arrangement for management contract services other than a written interim consultative agreement with the proposed managing authority. Any interim agreement shall reflect consistency with the provisions of this section, and shall be submitted to the department no later than five days after its effective date.

(6) The term of a management contract shall be limited to three years and may be renewed only when authorized by the Commissioner, provided compliance with this section and the following provisions can be demonstrated:

(i) that the goals and objectives of the contract have been met within specified timeframes;

(ii) that the quality of care provided by the hospice during the term of the contract has been maintained or has improved; and

(iii) that the reporting requirements contained in paragraph (10) of this subdivision have been met.

(7) Any application for renewal shall be submitted at least 90 days prior to the expiration of the existing contract.

(8) A hospice’s governing authority shall, within the terms of the contract, retain the authority to discharge the managing authority and its employees from their positions at

the hospice with or without cause on not more than 90 days notice. In such event, the hospice shall notify the department in writing at the time the managing authority is notified. The hospice's governing authority shall provide a plan for the operation of the hospice subsequent to the discharge, to be submitted with the notification to the department.

(9) A management contract shall terminate and be deemed cancelled, without financial penalty to the governing authority, not more than 60 days after notification to the parties by the department of a determination that the management of the hospice is so deficient that the health and safety of patients would be threatened by continuation of the contract.

(10) Each managing authority shall submit annual reports to the department and the governing authority providing measurements of hospice performance in the following areas:

(i) financial operations, including a balance sheet, any change in financial position, and a statement of revenues and expenses sufficient to determine liquidity, working capital, net operating margin and age, extent and type of payables and receivables;

(ii) personnel; and

(iii) services delivered.

Section 794.3 Personnel. The governing authority shall ensure for all personnel, which includes direct employees, contract staff and volunteers:

(a) the development and implementation of written personnel policies and procedures, which are reviewed annually and revised as necessary;

(b) that personnel are qualified as specified in section 700.2 of this Title;

(c) that the health status of all new personnel is assessed prior to the beginning of patient/family contact. The assessment shall be of sufficient scope to ensure that no person shall assume his/her duties unless he/she is free from a health impairment that is of potential risk to the patient/family or to employees or that may interfere with the performance of his/her duties including the habituation or addiction to depressants, stimulants, alcohol, or other drugs or substances which may alter the individual's behavior;

(d) that a record of the following tests and examinations is maintained for all employees, and those volunteers who have direct patient/family contact:

(1) a certificate of immunization against rubella which means:

(i) a document prepared by a physician, physician assistant, specialist assistant, nurse practitioner or a laboratory possessing a laboratory permit issued pursuant to Part 58 of this Title, demonstrating a serologic evidence of rubella antibodies, or

(ii) a document indicating one dose of live virus rubella vaccine was administered on or after the age of twelve months, showing the product administered and the date of administration, and prepared by the health practitioner who administered the immunization, or

(iii) a copy of a document described in (i) or (ii) of this paragraph which comes from a previous employer or the school which the employee attended as a student;

(2) a certificate of immunization against measles, for all personnel born on or after January 1, 1957, which means:

(i) a document prepared by a physician, physician assistant, specialist assistant, nurse practitioner or a laboratory possessing a laboratory permit issued pursuant to Part 58 of

this Title, demonstrating serologic evidence of measles antibodies, or

(ii) a document indicating two doses of live virus measles vaccine were administered with the first dose administered on or after the age of 12 months and the second dose administered more than 30 days after the first dose but after 15 months of age showing the product administered and the date of administration, and prepared by the health practitioner who administered the immunization, or

(iii) a document, indicating a diagnosis of the employee as having had measles disease, prepared by the physician, physician assistant/specialist assistant or nurse practitioner who diagnosed the employee's measles, or

(iv) a copy of a document described in (i), (ii) or (iii) of this paragraph which comes from a previous employer or the school which the employee attended as a student;

(3) if any licensed physician, physician assistant/specialist assistant or nurse practitioner certifies that immunization with measles or rubella vaccine may be detrimental to the employee's health, the requirements of paragraph (1) and/or (2) of this subdivision relating to measles and/or rubella immunization shall be inapplicable until such immunization is found no longer to be detrimental to such employee's health. The nature and duration of the medical exemption must be stated in the employee's employment medical record; and must be in accordance with generally accepted medical standards, (see, for example, the recommendations of the American Academy of Pediatrics and the Immunization Practices Advisory Committee of the U.S. Department of Health and Human Services);

(4) either tuberculin skin test or Food and Drug Administration (FDA) approved blood assay for the detection of latent tuberculosis infection, prior to employment or voluntary

service, and no less than every year thereafter for negative findings. Positive findings shall require appropriate clinical follow-up but no repeat tuberculin skin test or blood assay. The hospice shall develop and implement policies regarding follow-up of positive test results;

(5) documentation of any immunization(s) required by the Department;

(6) documentation of vaccination against influenza, or wearing of a surgical or procedure mask during the influenza season, for personnel who have not received the influenza vaccine for the current influenza season, pursuant to section 2.59 of this Title; and

(7) an annual, or more frequent if necessary, health status assessment to assure that all personnel are free from health impairment that is of potential risk to the patient/family or to employees or that may interfere with the performance of his/her duties;

(e) that a record of all tests, examinations, health assessments and immunizations required by this section is maintained for all personnel who have direct patient contact;

(f) that personal identification is produced by each applicant and verified by the program prior to retention of an applicant by the program;

(g) that prior to patient contact, employment history from previous employers, if applicable, and recommendations from other persons unrelated to the applicant if not previously employed, are verified;

(h) that personnel records include, as appropriate, records of professional licenses and registrations; verifications of employment history and qualifications for the duties assigned; signed and dated applications for employment; records of pre-employment physical examinations and health status assessments; criminal background check; performance evaluations; time and payroll records; dates of employment, resignations,

dismissals, inservice training and other pertinent data; provided that all documentation and information pertaining to an employee's medical condition or health status, including such records of physical examinations and health status assessments shall be maintained separate and apart from the non-medical personnel record information and shall be afforded the same confidential treatment given patient clinical records under section 794.4 of this Part;

(i) that time and payment records are maintained for all personnel;

(j) that there is a current written job description for each position which delineates responsibilities and specific education and experience requirements;

(k) that all personnel, including hospice employees, volunteers and contract staff with direct patient and family contact, receive orientation to the concept of hospice care, his or her specific job duties, and the policies and procedures for the hospice operation, inservice education necessary to perform his/her responsibilities and continuing programs for development and support. At a minimum home health aides shall participate in 12 hours of inservice education per year, which may occur while the aide is furnishing care. Inservice may be offered by any organization and must be supervised by a registered nurse;

(l) that employees providing care in the home display proper and current identification, including name, title and current photograph of care provider and name of the program providing the service, to be returned to the program upon termination of employment; and

(m) that an annual assessment of the performance and effectiveness of all personnel is conducted. Such assessment shall include an assessment of skills and competence of

individuals providing care including volunteers and include:

(1) written policies and procedures describing the methods of competency assessment, which shall be implemented; and

(2) training and education to personnel to improve competency in areas identified by the assessment process as requiring such improvement.

Section 794.4 Clinical record. The governing authority shall ensure that:

(a) there is a standardized clinical record system which is maintained in conformance with generally accepted medical record practices;

(b) a clinical record containing past and current findings is maintained for each hospice patient. The clinical record must contain correct clinical information that is available to the patient's attending physician and hospice staff including:

(1) initial assessment, comprehensive assessments and updated comprehensive assessments;

(2) initial plan of care and updated plans of care;

(3) clinical notes. A clinical note means a notation of a contact with the patient and/or the family that is written and dated by any person providing services and that describes signs and symptoms, treatments and medications administered, including the patient's reaction and/or response, any changes in physical, emotional, psychosocial or spiritual condition during a given period of time;

(4) signed copies of the notice of patient rights pursuant to Section 793.1 of this Title and election statement pursuant to Section 793.2 of this Title;

(5) responses to medications, symptom management, treatments and services;

(6) outcome measure data elements;

(7) physician certification and recertification of terminal illness;

(8) any advance directives;

(9) physician orders;

(10) documentation regarding instructions and written information provided to patients and families on the use, management and disposal of controlled substances and durable medical equipment and supplies; and

(11) a discharge summary if the patient is discharged from hospice, completed by appropriate personnel, including but not limited to:

(i) reason for discharge and date;

(ii) a summary of the hospice care given including treatments, symptoms and pain management; and

(iii) patient status upon discharge including a description of any remaining needs.

(c) the clinical record for each patient is in a form that can be summarized for transferral of information for inpatient care, home care services, and bereavement services, as appropriate;

(d) the clinical record meets the following requirements as applicable:

(1) all entries shall be current;

(2) all entries shall be legible and recorded in dark ink to facilitate photocopying;

(3) all entries shall be signed and dated, including the time of day and authenticated; and

(4) all records shall be kept in a place convenient to and easily retrievable by the hospice staff;

(e) the clinical record, whether hard copy or in electronic form, is readily available on request by an appropriate authority;

(f) the clinical record, its contents and the information contained is safeguarded against loss or unauthorized use. The hospice must be in compliance with state and federal requirements, including Section 18 of the Public Health Law, governing the disclosure of personal health information.

(g) each patient's clinical record shall be retained by the hospice for at least a six-year period after death or discharge from the hospice. In the case of a minor who is discharged from the hospice, clinical records shall be retained for at least a six-year period after death or discharge or, if the minor attains majority (18 years), for a three-year period thereafter, whichever period is longer.

Section 794.5 – Short-term Inpatient Service.

(a) Part 702 of this Title, Section 717.3 of this Title and Part 14 of the Sanitary Code shall apply to hospice inpatient settings as applicable.

(b) The hospice may provide short-term inpatient services for respite and for pain control and management of symptoms related to the terminal illness in a free-standing hospice facility, a skilled nursing facility or a general hospital.

(c) The provision of inpatient services shall be consistent with applicable Federal requirements and with the definition of hospice as defined in section 700.2 of this Title, and shall include, but not be limited to:

(1) 24-hour nursing services that meet the needs of all patients and are furnished in accordance with the patient's plan of care, including the services of a registered

professional nurse if a hospice patient has been admitted to inpatient services for other than respite care. Each patient must receive all nursing services as prescribed and must be comfortable, clean, well groomed, and protected from accident, injury and infection;

(2) accommodations to enable families to store and prepare food brought in by the family;

(3) accommodations to enable families to remain with the patient throughout the night;

(4) flexible visitation policies which include 24-hour a day visiting privileges regardless of age of visitor;

(5) provision of adequate and wholesome food and supplemental nourishments under the direction of a dietician;

(6) flexibility in meal times and in selection of food based on individual needs of patients;

(7) accommodations for recreational and religious activities;

(8) adequate space for private small group interactions;

(9) retention and use of personal possessions as space and safety permits;

(10) a telephone accessible to the patient; and

(11) oxygen available to each patient, as necessary.

(d) In addition to meeting the provisions of section 794.2 of this Part and any applicable State and Federal requirements, contractual arrangements with a facility for inpatient services must include a written agreement describing the arrangements and the agreement shall specify that:

(1) a member of the hospice interdisciplinary care group shall conduct onsite reviews of the inpatient services provided to ensure conformance with the established plan of care, at

least weekly;

(2) the hospice supplies the inpatient provider with a copy of the patient's plan of care and specifies the inpatient services to be furnished;

(3) the inpatient provider has established patient care policies consistent with those of the hospice and agrees to abide by the palliative care protocols and plan of care established by the hospice for its patients;

(4) the hospice patient's inpatient clinical record includes a record of all inpatient services furnished and events regarding care that occurred at the facility;

(5) upon discharge from the inpatient service, a copy of the discharge summary and if requested a copy of the inpatient medical record will be forwarded to the hospice and retained as part of the hospice clinical record;

(6) the inpatient facility has identified an individual within the facility who is responsible for the implementation of the provisions of the agreement;

(7) the hospice retains responsibility for ensuring that the training of personnel who will be providing the patient's care in the inpatient facility has been provided and that a description of the training and the names of those giving the training are documented; and

(8) a method for verifying that the requirements in paragraphs (d)(1) through (d)(6) of this section are met.

(e) The hospice that provides inpatient care directly in its own facility must demonstrate compliance with all of the following standards:

(1) ensuring that staffing for all services reflects its volume of patients, their acuity, and the level of intensity of services needed to ensure that plan of care outcomes are achieved and negative outcomes are avoided;

(2) providing 24-hour nursing services that meet the nursing needs of all patients and are furnished in accordance with each patient's plan of care;

(3) providing pharmacy services under the direction of a licensed pharmacist responsible for evaluating the patient's response to drug therapy, identification of potential drug reactions and recommend corrective action;

(4) having a written policy for dispensing drugs accurately and maintaining records of receipt and disposition of controlled drugs;

(5) maintaining a safe physical environment free of hazards for patients, staff, and visitors which includes:

(i) addressing real or potential threats to health and safety of patients, others and property;

(ii) having a written disaster plan in effect for managing power failures, natural disasters and other emergencies affecting the ability to provide care. The plan must be periodically reviewed and rehearsed with staff;

(iii) developing and implementing procedures for routine storage and prompt disposal of trash and medical waste; light, temperature and ventilation/air exchanges; emergency gas and water supply; and scheduled and emergency maintenance and repair of all equipment;

(6) ensuring that patient areas are designed to preserve the dignity, comfort, and privacy of patients; and

(7) developing and implementing policies that meet federal standards for use of seclusion and restraints.

Section 794.6 Hospice Residence Service. (a) Part 702 of this Title, Section 717.4 of Part 717 of this Title and Part 14 of the Sanitary Code shall apply to all hospice residence settings, as applicable.

(b) Hospice residence as defined in Part 702 of this Title shall mean a hospice operated home which is residential in character and physical structure, and operated for the purpose of providing more than two hospice patients, but not more than sixteen hospice patients, with hospice care.

(c) Hospice residence service shall include, but not be limited to:

(1) the provision of services as specified in Section 794.5(c)(2), (3), (4), (6), (7), (8), (9), (10) and (11) of this Part.

(2) the provision of either home health aide, licensed practical nurse or registered nurse services, as appropriate, to address the medical needs and ensure the safety and well-being of residents on a 24-hour a day basis;

(3) the provision of adequate and wholesome food and supplemental nutrition under the direction of a dietician. The hospice residence must:

(i) store, prepare, distribute and serve food under sanitary conditions in accordance with the sanitary requirements of Part 14 (Service Food Establishments) of Chapter 1 (State Sanitary Code) of this Title;

(ii) offer each resident at least three meals, or their equivalent, each day at regular times, with not more than 14 hours between a substantial evening meal and breakfast; and

(iii) prepare and serve therapeutic diets, prescribed by a physician, and planned and supervised by a professionally qualified dietitian; and

(4) routine and emergency drugs and biologicals, provided either directly to residents, or obtained under contract as described in section 794.2 of this Part, in accordance with Article 33 of the Public Health Law and Part 80 of this Title.

Section 794.7 Leases. (a) Whenever a hospice leases premises in which the inpatient component of a hospice or a hospice residence is to be provided, the hospice shall ensure that the lease contains the following language:

"The landlord acknowledges that its rights of reentry into the premises set forth in this lease do not confer on it the authority to operate a hospital or hospice as defined in articles 28 and 40, respectively, of the Public Health Law on the premises and agrees to provide the New York State Department of Health with notification by certified mail of intent to reenter the premises or to initiate dispossess proceedings or that the lease is due to expire, at least 30 days prior to the date on which the landlord intends to exercise a right of reentry or to initiate such proceedings or at least 60 days before expiration of the lease."

(b) Upon receipt of notice from the landlord of its intent to exercise its right of reentry or upon the service of process in dispossess proceedings and 60 days prior to the expiration of the lease, the hospice shall immediately notify by certified mail the New York State Department of Health of receipt of such notice or service of such process or that the lease is about to expire.

(c) No lease covering the administrative office site or the premises in which the inpatient component of a hospice or a hospice residence as defined in Article 40 of the Public

Health Law is to be conducted and no lease covering any equipment used in the operation of a hospice may contain any provision whereby rent, or any increase therein, is based upon the Consumer Price Index or any other cost of living index. In the event the lease covering such hospice premises or equipment contains provisions whereby it is the lessor's responsibility to pay necessary expenses associated with such premises or equipment, such as real estate taxes, utilities, heat, insurance, maintenance and operating supplies, such lease may contain provisions which allow adjustments to the rent only to the extent necessary to compensate the lessor for changes in such expenses.

Section 794.8 Hospice care provided to residents of a Skilled Nursing Facility (SNF) or Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID).

(a) A hospice that provides hospice care to residents of a SNF or ICF/IID, hereafter referred to as the facility, must assume responsibility for professional management of the hospice services provided to the resident, in accordance with the hospice plan of care, including assessing, planning, monitoring, directing and evaluating the patient’s/resident’s hospice care across all settings.

(b) The hospice and the facility must have a written agreement for the provision of hospice services between the two entities signed by an authorized representative of the hospice and the facility. The written agreement must include the following provisions:

(1) the manner in which the facility and the hospice are to communicate with each other and document such communications to ensure that the needs of patients are addressed and met 24 hours a day;

(2) that the facility immediately notifies the hospice if:

(i) a significant change in a patient's physical, mental, social, or emotional status occurs;

(ii) clinical complications appear that suggest a need to alter the plan of care;

(iii) a need to transfer a patient from the facility arises, and the hospice makes arrangements for, and remains responsible for, any necessary continuous care or inpatient care necessary which is related to the terminal illness and related conditions; or

(iv) a patient dies;

(3) that the hospice is responsible for determining the appropriate course of hospice care, including the determination to change the level of services provided;

(4) that the facility is responsible for furnishing 24-hour room and board care; and for meeting the personal care and nursing needs that would have been provided by the primary caregiver at home and at the same level of care provided before hospice care was elected;

(5) a delineation of the hospice's responsibilities, which include, but are not limited to providing:

(i) medical direction and management of the patient;

(ii) core services including nursing and counseling (including spiritual, dietary and bereavement), as well as medical social services; medical supplies, durable medical equipment and drugs necessary for the palliation of pain and symptoms associated with the terminal illness and related conditions; and all other hospice services that are necessary for the care of the resident's terminal illness and related conditions; and

(iii) services at the same level and to the same extent as those services would be provided if the resident were in his or her own home;

(6) that the hospice may use the facility nursing personnel where permitted by State and

Federal law and as specified by the SNF or ICF/IID to assist in the administration of prescribed therapies included in the plan of care only to the extent that the hospice would routinely use the services of a hospice patient's family in implementing the plan of care;

(7) that the hospice must report all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by anyone unrelated to the hospice to the facility administrator within 24 hours of the hospice becoming aware of the alleged violation; and

(8) a delineation of the responsibilities of the hospice and the SNF or ICF/IID to provide bereavement services to facility staff.

(c) A written hospice plan of care must be established and maintained in consultation with facility representatives.

(1) The hospice plan of care must identify the care and services that are needed and specifically identify which provider is responsible for performing the respective functions that have been agreed upon and included in the hospice plan of care.

(2) The hospice plan of care should reflect the participation of the hospice, the facility staff, and the patient and family to the extent possible.

(3) Based on collaboration between the hospice and the facility, the hospice plan of care should reflect:

(i) a common problem list;

(ii) palliative interventions;

(iii) palliative outcomes;

(iv) responsible discipline;

(v) responsible provider; and

(vi) patient goals.

(4) The hospice must approve any changes in the hospice plan of care before implementation and discuss such changes with the patient or representative, and facility representatives.

(d) For each patient, the hospice must designate a member of the interdisciplinary group who will be responsible for:

(1) providing overall coordination of the hospice care of the resident with the facility representatives and communicating with facility representatives and other health care providers and physicians participating in the provision of care;

(2) providing the facility, for each hospice patient, with:

(i) the most recent hospice plan of care;

(ii) the hospice election form and any advance directives;

(iii) the physician certification and recertification of the terminal illness;

(iv) the names and contact information for hospice personnel involved in hospice care;

(v) hospice medication information;

(vi) hospice physician and attending physician (if any) orders; and

(vii) instructions on how to access the hospice's 24-hour on-call system;

(e) Hospice staff must orient facility staff furnishing care to hospice patients to the hospice philosophy; hospice policies and procedures regarding methods of comfort, pain control, and symptom management; principles about death and dying and individual responses to death; patient rights; appropriate forms; and record keeping requirements.

Section 794.9 Records and reports. (a) The governing authority shall ensure that:

(1) the following records are retained on file at the principal office of the hospice within its approved geographic service area and available to the Department upon request:

(i) the certificate of incorporation, if applicable;

(ii) the certificate of approval;

(iii) all current contracts, leases and other agreements entered into by the hospice;

(iv) current operating policies and procedures; and

(v) a current patient/family roster;

(2) copies of the documents under subparagraphs (1)(iv) and (v) of this subdivision are retained on file at each suboffice of the hospice, if applicable;

(3) the following reports and records are retained by the hospice and available to the department upon request:

(i) minutes of the meetings of the hospice governing authority and the quality assurance committee which shall be retained for three years from the date of the meeting;

(ii) the reports of hospice surveys and inspections by outside agencies with statements attached thereto specifying the steps taken to correct any deficiencies or to carry out the recommendations contained therein which shall be retained for five years from the date of such survey or inspection;

(iii) records of all financial transactions which shall be retained eight years from the date of the transaction;

(iv) personnel records, which shall be retained six years from the date of employee termination or resignation;

(v) records of complaints and appeals, which shall be retained three years from

resolution; and

(vi) records of tracking, receipt and resolution of accident and incidents.

(b) The hospice shall furnish annually to the department a copy of:

(1) the current annual report submitted to its governing body; and

(2) other such data, records and reports as may be required by the department.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Section 4010(4) of the Public Health Law authorizes the adoption and amendment of regulations for hospice providers approved pursuant to PHL Article 40 (Hospices). Section 4002 of the Public Health Law was amended by adding a new subdivision 5 to read as follows: "Terminally ill" means an individual has a medical prognosis that the individual's life expectancy is approximately one year or less if the illness runs its normal course.

Legislative Objective:

PHL Article 40 provides that hospice care may offer persons with terminal illness an appropriate palliative care alternative to curative treatments and protects such vulnerable individuals through the imposition of care delivery standards for providers. It is the legislative intent that hospice's interdisciplinary program and innovative approach to home and inpatient services be available statewide.

The proposed regulations attempt to achieve these legislative objectives by expanding the definition of terminal illness to conform with the statutory language as well as allow individuals the opportunity to receive hospice care earlier in their terminal illness – providing care to those who need it and reducing the need for emergency room visits and hospital stays.

Needs and Benefits:

The proposed rule making was necessitated by changes in the federal conditions of participation/rules for hospice providers and recent Medicaid Redesign Initiatives. State

rules have been revised and reordered to be consistent with federal rules thereby facilitating provider compliance and surveillance activities. The intent of these revisions is to improve care delivery processes and support performance improvement activity at the provider level. Additionally, amendments were a result of changes made in Chapter 441 of the Laws of 2011 and Medicaid Redesign efforts to expand hospice benefits. Individuals could benefit from receiving hospice services earlier in their terminal illness and having their symptoms managed on an on-going basis, thereby reducing the need for emergency room visits and hospital stays.

Costs:

Costs to Regulated Parties:

Nominal costs may be incurred by hospice providers if coordination, management and documentation of care has not been effectively implemented by the hospice; or if data-driven, outcome-based quality assessment and performance improvement activities have not been taking place. These nominal costs are associated with federal quality assessment and performance improvement program requirements and would have to be incurred regardless of the proposed regulatory changes. There are currently 45 hospices in New York State.

Costs to the Agency and to the State and Local Governments Including this Agency:

The change in hospice patient eligibility which allows individuals with a 12-month life expectancy to elect the hospice benefit, has been estimated to have a net aggregate increase in gross Medicaid expenditures of $1,704,658. The aggregate NY State and Local Government share of the increase in Medicaid expenditures is approximately $400,000 for State government, and another $400,000 for local

governments in the aggregate. Pursuant to 42 CFR Section 447.205, the Department gave public notice in December 2011 to amend the NYS Medicaid Plan for hospice services to expand access to the hospice benefit. No additional costs are anticipated for the Agency or for State and Local Governments.

Local Government Mandates:

There are no local mandates in this rule. However, 6 counties operate hospice programs and will be required to meet these rules in the same manner as will private entities, as there is no exemption authority for publicly sponsored programs.

Paperwork:

Under the proposed rules, providers will now be required to report verified incidences of mistreatment or abuse to the Department of Health and or state/local bodies having jurisdiction, as required by federal rules. All other reporting requirements are consistent with existing regulations.

Duplication:

Proposed rules will be duplicative of, but consistent with, federal rules. There are no known conflicts with federal rules; consistency should facilitate provider compliance and improve effectiveness of surveillance processes.

Alternatives:

The Department could choose to retain existing standards in which case federal rules would supersede State rules where gaps or inconsistency exist. This option was rejected as it would be confusing to both providers and surveyors. Furthermore, conforming state requirements to the federal requirements will facilitate the enforcement of both.

Federal Standards:

Section 418 of 42 CFR sets forth the federal rules for hospices. The proposed State rules are consistent with federal rules, but do exceed federal rules as follows:

- The quality assessment and performance improvement section includes the requirement to have a quality committee to assure comprehensive representation and involvement in quality activities and to assure a broader quality oversight process at the provider level. This is a state requirement that is not included in the federal rules.
- Infection control includes standards for prevention and management of HIV and other bloodborne pathogen infections, consistent with existing standards for all provider types in NYS. The standards exceed federal rules by including the required program specifications.
- The responsibilities of the governing body are more clearly delineated in the proposed rules than in the federal rules, including implementation of a complaint investigation procedure and requiring that the governing body obtain a Health Commerce System account for communication with the Department.
- The proposed rule specifically states the requirements for contracts, including management contracts, to ensure hospice and provider accountability and governing body responsibilities. Such requirements are not stated in the federal rules.
- Health requirements for personnel are specific and consistent with other provider types in NYS to assure adequate patient care protection. Job descriptions, employee identification and personnel records are also required as appropriate business practices. These requirements are not stated in the federal rules.

Compliance Schedule:

As the amendments ensure conformance with federal standards that were already in effect as of December 3, 2008, and any state requirements exceeding federal rules are already in effect, regulated parties should already be in compliance, and should readily be able to comply as of the effective date of these regulations.

Contact Person: Katherine Ceroalo
New York State Department of Health
Bureau of House Counsel, Regulatory Affairs Unit
Corning Tower Building, Rm. 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

Local governments will not be affected by this rule except to the extent that they are providers of hospice services. There are 6 county-based hospice providers. The small businesses which will be affected are hospice providers which employ fewer than 100 persons. There are approximately 36 small business hospices in NYS.

Compliance Requirements:

Regulated parties are expected to be in immediate compliance as these rules are consistent with federal standards already in effect as of Dec. 3, 2008, and rules that exceed the federal rules are already in place for existing hospice providers in NYS. The proposed regulations will create a new state reporting requirement, consistent with federal rules, for reporting verified instances of patient mistreatment, abuse or neglect to the Department or to other state and local authorities. The reporting will be done through existing complaint reporting mechanisms. The proposed regulations also require the hospice to report to the Department data on quality indicators and patient outcomes, which will be the basis for performance improvement activities. This may require additional staff training and electronic data systems at the hospice. The Department implemented a hospice quality initiative intended to assist hospices with meeting this requirement. All other reporting requirements mentioned in the proposed regulations currently exist for the hospice providers.

The Department does not intend to publish a small business regulation guide in connection with this regulation. Although a number of hospices are small businesses, the impact is not expected to be substantial. Additional guidance will be posted on the web as needed after the regulation is promulgated.

Professional Services:

No additional professional staff are expected to be needed as a result of the regulations. Quality assessment and performance improvement requirements could be handled by existing staff with appropriate training, unless staff shortages already exist at the hospice.

Compliance Costs:

There are no capital costs associated with these proposed rules. Additional costs may be associated with maintaining and analyzing data and carrying out performance improvement activities. The costs for small businesses and county sponsored hospices should not be significantly different from the costs to other affected providers.

Economic and Technological Feasibility:

The Department has considered feasibility and believes the rules can be met with minimal economic and technological impact. Departmental resources have been identified to assist hospices with quality indicators and performance improvement. Other regulations should not affect the routine cost of doing business.

Minimizing Adverse Impact:

While the Department has considered the options of State Administrative Procedure Act (SAPA) Section 202-b(1) in developing this rule, flexibility does not exist

for any particular entity since the new requirements are consistent with new federal rules already in effect.

Small Business and Local Government Participations:

The Hospice and Palliative Care Association of NYS, which represents the majority of the hospices statewide, were included during the development of the proposed rulemaking. The Department will meet the requirements of SAPA Section 202-b(6) in part by publishing a notice of proposed rulemaking in the State Register with a comment period.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

All counties in NYS have rural areas with the exception of 7 downstate counties. Counties with rural areas are served by 34 of the existing 47 hospices in NYS.

Reporting, Record Keeping and Other Compliance Requirements and Professional Services:

Regulated parties are expected to be in immediate compliance as these rules are consistent with federal standards already in effect as of Dec. 3, 2008, and rules that exceed the federal rules are already in place for existing hospice providers in NYS.

The proposed regulations will create a new state reporting requirement, consistent with federal rules, for reporting verified instances of patient mistreatment, abuse or neglect to the Department or other state and local authorities. The reporting will be done through existing complaint reporting mechanisms. The proposed regulations also require the hospice to report to the Department data on quality indicators and patient outcomes, which will be the basis for performance improvement activities. This may require additional staff training and electronic data systems at the hospice. The Department implemented a hospice quality initiative intended to assist hospices with meeting this requirement. All other reporting requirements mentioned in the proposed regulations currently exist for the hospice providers.

Additional quality indicator and outcome data will need to be maintained in support of the reporting of the quality indicators and patient outcomes. This can be

accomplished by existing clinical and/or administrative staff with appropriate training. Professional personnel required of the hospice is unchanged from existing requirements.

Costs:

There are no capital costs associated with these rules; any such costs would result from new federal rules, regardless of whether amendments were made to state regulation. Additional training of staff in quality assessment and performance improvement may be required to be in compliance with the requirements of the new federal rules.

Minimizing Adverse Impact:

While the Department has considered the options in State Administrative Procedure Act (SAPA) Section 202-bb(2)(b), the proposed regulatory changes are consistent with new federal requirements. Therefore, Department authority to minimize impact is limited. Adverse impact is expected to be minimal.

Rural Area Impact:

The Department will meet the requirements of SAPA Section 202-bb(7) in part by publishing a notice of proposed rulemaking in the State Register with a comment period.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

A Job Impact Statement is not required pursuant to Section 201-a(2)(a) of the State Administrative Procedure Act. The proposed regulations are intended to be consistent with current federal rules and also expand the definition of "terminal illness" to allow expanded access to hospice services and improve patient care. It is apparent, from the nature and purpose of the proposed rule, that it will not have a substantial adverse impact on jobs or employment opportunities.