ELECTRONIC CODE OF FEDERAL REGULATIONS

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Title 42: Public Health
PART 418—HOSPICE CARE
Subpart D—Conditions of participation: Organizational Environment

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§418.110 Condition of participation: Hospices that provide inpatient care directly.

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

(a) *Standard: Staffing.* The hospice is responsible for 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.

(b) *Standard: Twenty-four hour nursing services.* (1) The hospice facility must provide 24-hour nursing services that meet the nursing needs of all patients and are furnished in accordance with each patient's plan of care. Each patient must receive all nursing services as prescribed and must be kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.

(2) If at least one patient in the hospice facility is receiving general inpatient care, then each shift must include a registered nurse who provides direct patient care.

(c) *Standard: Physical environment.* The hospice must maintain a safe physical environment free of hazards for patients, staff, and visitors.

(1) *Safety management.* The hospice must address real or potential threats to the health and safety of the patients, others, and property.

(2) *Physical plant and equipment.* The hospice must develop procedures for controlling the reliability and quality of—

(i) The routine storage and prompt disposal of trash and medical waste;

(ii) Light, temperature, and ventilation/air exchanges throughout the hospice;

(iii) Emergency gas and water supply; and

(iv) The scheduled and emergency maintenance and repair of all equipment.

(d) *Standard: Fire protection.* (1) Except as otherwise provided in this section—

(i) The hospice must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.)

(ii) Notwithstanding paragraph (d)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.

(2) In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a hospice facility, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the adopted edition of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in hospices.

(4) A hospice may place alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against access by vulnerable populations.

(5) When a sprinkler system is shut down for more than 10 hours, the hospice must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(ii) Establish a fire watch until the system is back in service.

(6) Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.

(e) *Standard: Building Safety.* Except as otherwise provided in this section, the hospice must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a hospice.

(2) If application of the Health Care Facilities Code required under paragraph (e) of this section would result in unreasonable hardship for the hospice, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.

(f) *Standard: Patient areas.* The hospice must provide a home-like atmosphere and ensure that patient areas are designed to preserve the dignity, comfort, and privacy of patients.

(1) The hospice must provide—

(i) Physical space for private patient and family visiting;

(ii) Accommodations for family members to remain with the patient throughout the night; and

(iii) Physical space for family privacy after a patient's death.

(2) The hospice must provide the opportunity for patients to receive visitors at any hour, including infants and small children.

(g) *Standard: Patient rooms.* (1) The hospice must ensure that patient rooms are designed and equipped for nursing care, as well as the dignity, comfort, and privacy of patients.

(2) The hospice must accommodate a patient and family request for a single room whenever possible.

(3) Each patient's room must—

(i) Be at or above grade level;

(ii) Contain a suitable bed and other appropriate furniture for each patient;

(iii) Have closet space that provides security and privacy for clothing and personal belongings;

(iv) Accommodate no more than two patients and their family members;

(v) Provide at least 80 square feet for each residing patient in a double room and at least 100 square feet for each patient residing in a single room; and

(vi) Be equipped with an easily-activated, functioning device accessible to the patient, that is used for calling for assistance.

(4) For a facility occupied by a Medicare-participating hospice on December 2, 2008, CMS may waive the space and occupancy requirements of paragraphs (g)(2)(iv) and (g)(2)(v) of this section if it determines that—

(i) Imposition of the requirements would result in unreasonable hardship on the hospice if strictly enforced; or jeopardize its ability to continue to participate in the Medicare program; and

(ii) The waiver serves the needs of the patient and does not adversely affect their health and safety.

(h) *Standard: Toilet and bathing facilities.* Each patient room must be equipped with, or conveniently located near, toilet and bathing facilities.

(i) *Standard: Plumbing facilities.* The hospice must—

(1) Have an adequate supply of hot water at all times; and

(2) Have plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by patients.

(j) *Standard: Infection control.* The hospice must maintain an infection control program that protects patients, staff and others by preventing and controlling infections and communicable disease as stipulated in §418.60.

(k) *Standard: Sanitary environment.* The hospice must provide a sanitary environment by following current standards of practice, including nationally recognized infection control precautions, and avoid sources and transmission of infections and communicable diseases.

(l) *Standard: Linen.* The hospice must have available at all times a quantity of clean linen in sufficient amounts for all patient uses. Linens must be handled, stored, processed, and transported in such a manner as to prevent the spread of contaminants.

(m) *Standard: Meal service and menu planning.* The hospice must furnish meals to each patient that are—

(1) Consistent with the patient's plan of care, nutritional needs, and therapeutic diet;

(2) Palatable, attractive, and served at the proper temperature; and

(3) Obtained, stored, prepared, distributed, and served under sanitary conditions.

(n) *Standard: Restraint or seclusion.* All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(1) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm.

(2) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

(3) The use of restraint or seclusion must be—

(i) In accordance with a written modification to the patient's plan of care; and

(ii) Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospice policy in accordance with State law.

(4) The use of restraint or seclusion must be in accordance with the order of a physician authorized to order restraint or seclusion by hospice policy in accordance with State law.

(5) Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).

(6) The medical director or physician designee must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

(7) Unless superseded by State law that is more restrictive—

(i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:

(A) 4 hours for adults 18 years of age or older;

(B) 2 hours for children and adolescents 9 to 17 years of age; or

(C) 1 hour for children under 9 years of age; and

After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician authorized to order restraint or seclusion by hospice policy in accordance with State law must see and assess the patient.

(ii) Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospice policy.

(8) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

(9) The condition of the patient who is restrained or secluded must be monitored by a physician or trained staff that have

completed the training criteria specified in paragraph (o) of this section at an interval determined by hospice policy.

(10) Physician, including attending physician, training requirements must be specified in hospice policy. At a minimum, physicians and attending physicians authorized to order restraint or seclusion by hospice policy in accordance with State law must have a working knowledge of hospice policy regarding the use of restraint or seclusion.

(11) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention—

(i) By a—

(A) Physician; or

(B) Registered nurse who has been trained in accordance with the requirements specified in paragraph (n) of this section.

(ii) To evaluate—

(A) The patient's immediate situation;

(B) The patient's reaction to the intervention;

(C) The patient's medical and behavioral condition; and

(D) The need to continue or terminate the restraint or seclusion.

(12) States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (m)(11)(i) of this section.

(13) If the face-to-face evaluation specified in §418.110(n)(11) is conducted by a trained registered nurse, the trained registered nurse must consult the medical director or physician designee as soon as possible after the completion of the 1-hour face-to-face evaluation.

(14) All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored—

(i) Face-to-face by an assigned, trained staff member; or

(ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

(15) When restraint or seclusion is used, there must be documentation in the patient's clinical record of the following:

(i) The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior;

(ii) A description of the patient's behavior and the intervention used;

(iii) Alternatives or other less restrictive interventions attempted (as applicable);

(iv) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and the patient's response to the intervention(s) used, including the rationale for continued use of the intervention.

(o) *Standard: Restraint or seclusion staff training requirements.* The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) *Training intervals.* All patient care staff working in the hospice inpatient facility must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion—

(i) Before performing any of the actions specified in this paragraph;

(ii) As part of orientation; and

(iii) Subsequently on a periodic basis consistent with hospice policy.

(2) *Training content.* The hospice must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

(i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that

require the use of a restraint or seclusion.

(ii) The use of nonphysical intervention skills.

(iii) Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition.

(iv) The safe application and use of all types of restraint or seclusion used in the hospice, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia).

(v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

(vi) Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospice policy associated with the 1-hour face-to-face evaluation.

(vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

(3) *Trainer requirements.* Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.

(4) *Training documentation.* The hospice must document in the staff personnel records that the training and demonstration of competency were successfully completed.

(p) *Standard: Death reporting requirements.* Hospices must report deaths associated with the use of seclusion or restraint.

(1) The hospice must report the following information to CMS:

(i) Each unexpected death that occurs while a patient is in restraint or seclusion.

(ii) Each unexpected death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the hospice that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.

(2) Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death.

(3) Staff must document in the patient's clinical record the date and time the death was reported to CMS.

(q) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.* If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, *www.nfpa.org*, 1.617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.

(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]

[73 FR 32204, June 5, 2008, as amended at 81 FR 26879, May 4, 2016; 81 FR 64024, Sept. 16, 2016]