

§ 483.65

(2) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.

(d) *Labeling of drugs and biologicals.* Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

(e) *Storage of drugs and biologicals.* (1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.

(2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

[56 FR 48875, Sept. 26, 1991, as amended at 57 FR 43925, Sept. 23, 1992]

§ 483.65 Infection control.

The facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection.

(a) *Infection control program.* The facility must establish an infection control program under which it—

(1) Investigates, controls, and prevents infections in the facility;

(2) Decides what procedures, such as isolation, should be applied to an individual resident; and

(3) Maintains a record of incidents and corrective actions related to infections.

(b) *Preventing spread of infection.* (1) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.

(2) The facility must prohibit employees with a communicable disease or infected skin lesions from direct

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contact with residents or their food, if direct contact will transmit the disease.

(3) The facility must require staff to wash their hands after each direct resident contact for which handwashing is indicated by accepted professional practice.

(c) *Linens.* Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.

[56 FR 48876, Sept. 26, 1991, as amended at 57 FR 43925, Sept. 23, 1992]

§ 483.70 Physical environment.

The facility must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel and the public.

(a) *Life safety from fire.* (1) Except as otherwise provided in this section—

(i) The facility must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection 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. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to long-term care facilities.

(2) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not

adversely affect the health and safety of the patients.

(3) The provisions of the Life safety Code do not apply in a State where CMS finds, in accordance with applicable provisions of sections 1819(d)(2)(B)(ii) and 1919(d)(2)(B)(ii) of the Act, that a fire and safety code imposed by State law adequately protects patients, residents and personnel in long term care facilities.

(4) Beginning March 13, 2006, a long-term care facility must be in compliance with Chapter 19.2.9, Emergency Lighting.

(5) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to long-term care facilities.

(6) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a long-term care facility may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00-1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00-1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269; and

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

(7) A long term care facility must:

(i) Install, at least, battery-operated single station smoke alarms in accordance with the manufacturer's recommendations in resident sleeping rooms and common areas.

(ii) Have a program for inspection, testing, maintenance, and battery replacement that conforms to the manufacturer's recommendations and that verifies correct operation of the smoke alarms.

(iii) Exception:

(A) The facility has system-based smoke detectors in patient rooms and common areas that are installed, tested, and maintained in accordance with NFPA 72, *National Fire Alarm Code*, for system-based smoke detectors; or

(B) The facility is fully sprinklered in accordance with NFPA 13, *Standard for the Installation of Sprinkler Systems*.

(8) A long term care facility must:

(i) Install an approved, supervised automatic sprinkler system in accordance with the 1999 edition of NFPA 13, *Standard for the Installation of Sprinkler Systems*, as incorporated by reference, throughout the building by August 13, 2013. The Director of the Office of the Federal Register has approved the NFPA 13 1999 edition of the *Standard for the Installation of Sprinkler Systems*, issued July 22, 1999 for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection 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. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269.

(ii) Test, inspect, and maintain an approved, supervised automatic sprinkler system in accordance with the 1998 edition of NFPA 25, *Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems*, as

incorporated by reference. The Director of the Office of the Federal Register has approved the NFPA 25, *Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems*, 1998 edition, issued January 16, 1998 for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection 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. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269.

(b) *Emergency power.* (1) An emergency electrical power system must supply power adequate at least for lighting all entrances and exits; equipment to maintain the fire detection, alarm, and extinguishing systems; and life support systems in the event the normal electrical supply is interrupted.

(2) When life support systems are used, the facility must provide emergency electrical power with an emergency generator (as defined in NFPA 99, *Health Care Facilities*) that is located on the premises.

(c) *Space and equipment.* The facility must—

(1) Provide sufficient space and equipment in dining, health services, recreation, and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's plan of care; and

(2) Maintain all essential mechanical, electrical, and patient care equipment in safe operating condition.

(d) *Resident rooms.* Resident rooms must be designed and equipped for adequate nursing care, comfort, and privacy of residents.

(1) Bedrooms must—

(i) Accommodate no more than four residents;

(ii) Measure at least 80 square feet per resident in multiple resident bedrooms, and at least 100 square feet in single resident rooms;

(iii) Have direct access to an exit corridor;

(iv) Be designed or equipped to assure full visual privacy for each resident;

(v) In facilities initially certified after March 31, 1992, except in private rooms, each bed must have ceiling suspended curtains, which extend around the bed to provide total visual privacy in combination with adjacent walls and curtains;

(vi) Have at least one window to the outside; and

(vii) Have a floor at or above grade level.

(2) The facility must provide each resident with—

(i) A separate bed of proper size and height for the convenience of the resident;

(ii) A clean, comfortable mattress;

(iii) Bedding appropriate to the weather and climate; and

(iv) Functional furniture appropriate to the resident's needs, and individual closet space in the resident's bedroom with clothes racks and shelves accessible to the resident.

(3) CMS, or in the case of a nursing facility the survey agency, may permit variations in requirements specified in paragraphs (d)(1) (i) and (ii) of this section relating to rooms in individual cases when the facility demonstrates in writing that the variations—

(i) Are in accordance with the special needs of the residents; and

(ii) Will not adversely affect residents' health and safety.

(e) *Toilet facilities.* Each resident room must be equipped with or located near toilet and bathing facilities.

(f) *Resident call system.* The nurse's station must be equipped to receive resident calls through a communication system from—

(1) Resident rooms; and

(2) Toilet and bathing facilities.

(g) *Dining and resident activities.* The facility must provide one or more rooms designated for resident dining and activities. These rooms must—

(1) Be well lighted;

(2) Be well ventilated, with non-smoking areas identified;

(3) Be adequately furnished; and

(4) Have sufficient space to accommodate all activities.

(h) *Other environmental conditions.* The facility must provide a safe, functional, sanitary, and comfortable environment for the residents, staff and the public. The facility must—

(1) Establish procedures to ensure that water is available to essential areas when there is a loss of normal water supply;

(2) Have adequate outside ventilation by means of windows, or mechanical ventilation, or a combination of the two;

(3) Equip corridors with firmly secured handrails on each side; and

(4) Maintain an effective pest control program so that the facility is free of pests and rodents.

[56 FR 48876, Sept. 26, 1991, as amended at 57 FR 43925, Sept. 23, 1992; 68 FR 1386, Jan. 10, 2003; 69 FR 49268, Aug. 11, 2004; 70 FR 15238, Mar. 25, 2005; 71 FR 55340, Sept. 22, 2006; 73 FR 47091, Aug. 13, 2008]

§ 483.75 Administration.

A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

(a) *Licensure.* A facility must be licensed under applicable State and local law.

(b) *Compliance with Federal, State, and local laws and professional standards.* The facility must operate and provide services in compliance with all applicable Federal, State, and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility.

(c) *Relationship to other HHS regulations.* In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR part 80); nondiscrimination on the basis of handicap (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455). Although these regulations are not in themselves considered re-

quirements under this part, their violation may result in the termination or suspension of, or the refusal to grant or continue payment with Federal funds.

(d) *Governing body.* (1) The facility must have a governing body, or designated persons functioning as a governing body, that is legally responsible for establishing and implementing policies regarding the management and operation of the facility; and

(2) The governing body appoints the administrator who is—

(i) Licensed by the State where licensure is required; and

(ii) Responsible for management of the facility.

(e) *Required training of nursing aides—*
(1) *Definitions.*

Licensed health professional means a physician; physician assistant; nurse practitioner; physical, speech, or occupational therapist; physical or occupational therapy assistant; registered professional nurse; licensed practical nurse; or licensed or certified social worker.

Nurse aide means any individual providing nursing or nursing-related services to residents in a facility who is not a licensed health professional, a registered dietitian, or someone who volunteers to provide such services without pay. Nurse aides do not include those individuals who furnish services to residents only as paid feeding assistants as defined in § 488.301 of this chapter.

(2) *General rule.* A facility must not use any individual working in the facility as a nurse aide for more than 4 months, on a full-time basis, unless:

(i) That individual is competent to provide nursing and nursing related services; and

(ii)(A) That individual has completed a training and competency evaluation program, or a competency evaluation program approved by the State as meeting the requirements of §§ 483.151–483.154 of this part; or

(B) That individual has been deemed or determined competent as provided in § 483.150 (a) and (b).

(3) *Non-permanent employees.* A facility must not use on a temporary, per diem, leased, or any basis other than a permanent employee any individual who does not meet the requirements in