

(4) Taking other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located.

(d) *Standard: Life safety from fire*—(1) Except as provided in paragraphs (d)(2) and (d)(3) of this section, the CAH must meet the requirements of chapter 12, New Health Care Occupancy, or chapter 13, Existing Health Care Occupancy, of the 1985 edition of the Life Safety Code of the National Fire Protection Association. Incorporation by reference of the 1985 edition of the National Fire Protection Association's Life Safety Code (published February 7, 1985; ANSI/NFPA 101) was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Room C2-07-13, Central Building, Baltimore, MD 21244-1850, and 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, Batterymarch Park, Quincy, Mass. 02209. If any changes in this code are also to be incorporated by reference, a document to that effect will be published in the FEDERAL REGISTER.

(2) Any CAH that as a hospital on or before November 26, 1982, complied, with or without waivers, with the requirements of the 1967 edition of the Life Safety Code, or after November 26, 1982 and on or before May 9, 1988, complied with the 1981 edition of the Life Safety Code, is considered to be in compliance with this standard as long as the CAH continues to remain in compliance with that edition of the Code. The 1967 and 1981 Life Safety Codes are available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Room C2-07-13, Central Building, Baltimore, MD 21244-1850.

(3) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the CAH, but only if the waiver does not adversely affect the health and safety of patients.

(4) The CAH maintains written evidence of regular inspection and approval by State or local fire control agencies.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46036, 46037, Aug. 29, 1997]

§ 485.627 Condition of participation: Organizational structure.

(a) *Standard: Governing body or responsible individual.* The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH's total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.

(b) *Standard: Disclosure.* The CAH discloses the names and addresses of—

(1) Its owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with subpart C of part 420 of this chapter;

(2) The person principally responsible for the operation of the CAH; and

(3) The person responsible for medical direction.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.631 Condition of participation: Staffing and staff responsibilities.

(a) *Standard: Staffing*—(1) The CAH has a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.

(2) Any ancillary personnel are supervised by the professional staff.

(3) The staff is sufficient to provide the services essential to the operation of the CAH.

(4) A doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates.

(5) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients.

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(b) *Standard: Responsibilities of the doctor of medicine or osteopathy.* (1) The doctor of medicine or osteopathy—

(i) Provides medical direction for the CAH's health care activities and consultation for, and medical supervision of, the health care staff;

(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH's written policies governing the services it furnishes.

(iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically reviews the CAH's patient records, provides medical orders, and provides medical care services to the patients of the CAH; and

(iv) Periodically reviews and signs the records of patients cared for by nurse practitioners, clinical nurse specialists, or physician assistants.

(2) A doctor of medicine or osteopathy is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances) to provide the medical direction, medical care services, consultation, and supervision described in this paragraph, and is available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the CAH. A site visit is not required if no patients have been treated since the latest site visit.

(c) *Standard: Physician assistant, nurse practitioner, and clinical nurse specialist responsibilities.* (1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH's staff—

(i) Participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes; and

(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.

(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

(i) Provides services in accordance with the CAH's policies.

(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the CAH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.

(3) Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the CAH is notified of the admission.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.635 Condition of participation: Provision of services.

(a) *Standard: Patient care policies.* (1) The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of § 485.631(a)(1); at least one member is not a member of the CAH staff.

(3) The policies include the following: (i) A description of the services the CAH furnishes directly and those furnished through agreement or arrangement.

(ii) Policies and procedures for emergency medical services.

(iii) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.

(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated,