

## Health Care Financing Administration, HHS

## § 485.616

CAH by the State under the rules in this subpart.

[62 FR 46036, Aug. 29, 1997, as amended at 63 FR 26359, May 12, 1998]

### § 485.608 Condition of participation: Compliance with Federal, State, and local laws and regulations.

The CAH and its staff are in compliance with applicable Federal, State and local laws and regulations.

(a) *Standard: Compliance with Federal laws and regulations.* The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients.

(b) *Standard: Compliance with State and local laws and regulations.* All patient care services are furnished in accordance with applicable State and local laws and regulations.

(c) *Standard: Licensure of CAH.* The CAH is licensed in accordance with applicable Federal, State and local laws and regulations.

(d) *Standard: Licensure, certification or registration of personnel.* Staff of the CAH are licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations.

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

### § 485.610 Condition of participation: Status and location.

(a) *Standard: Status.* The facility is—

(1) A currently participating hospital that meets all conditions of participation set forth in this subpart;

(2) A recently closed facility, provided that the facility—

(i) Was a hospital that ceased operations on or after the date that is 10 years before November 29, 1999; and

(ii) Meets the criteria for designation under this subpart as of November 29, 1999; or

(3) A health clinic or a health center (as defined by the State) that—

(i) Is licensed by the State as a health clinic or a health center;

(ii) Was a hospital that was downsized to a health clinic or a health center; and

(iii) As of the effective date of its designation, meets the criteria for designation set forth in this subpart.

(b) *Standard: Location.* The CAH meets the following requirements:

(1) The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under the regulations in § 412.62(f) of this chapter.

(2) The CAH is not deemed to be located in an urban area under § 412.63(b) of this chapter.

(3) The CAH has not been classified as an urban hospital for purposes of the standardized payment amount by HCFA or the Medicare Geographic Classification Review Board under § 412.230(e) of this chapter, and is not among a group of hospitals that have been redesignated to an adjacent urban area under § 412.232 of this chapter.

(4) The CAH is being treated as being located in a rural area in accordance with § 412.103 of this chapter.

(5) The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or the CAH is certified by the State as being a necessary provider of health care services to residents in the area.

[62 FR 46036, Aug. 29, 1997, as amended at 65 FR 47052, Aug. 1, 2000]

### § 485.612 Condition of participation: Compliance with hospital requirements at time of application.

The hospital has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.

[62 FR 46036, Aug. 29, 1997]

### § 485.616 Condition of participation: Agreements.

(a) *Standard: Agreements with network hospitals.* In the case of a CAH that is a member of a rural health network as defined in § 485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for—

(1) Patient referral and transfer;

(2) The development and use of communications systems of the network, including the network's system for the electronic sharing of patient data, and telemetry and medical records, if the

network has in operation such a system; and

(3) The provision of emergency and nonemergency transportation between the facility and the hospital.

(b) *Standard: Agreements for credentialing and quality assurance.* Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least—

(1) One hospital that is a member of the network;

(2) One PRO or equivalent entity; or

(3) One other appropriate and qualified entity identified in the State rural health care plan.

[62 FR 46036, Aug. 29, 1997]

**§ 485.618 Condition of participation: Emergency services.**

The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients.

(a) *Standard: Availability.* Emergency services are available on a 24-hours a day basis.

(b) *Standard: Equipment, supplies, and medication.* Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases. The items available must include the following:

(1) *Drugs and biologicals* commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrhythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.

(2) *Equipment and supplies* commonly used in life-saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.

(c) *Standard: Blood and blood products.* The facility provides, either directly or under arrangements, the following:

(1) Services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis.

(2) Blood storage facilities that meet the requirements of 42 CFR part 493, subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy. If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.

(d) *Standard: Personnel.* There must be a doctor of medicine or osteopathy, a physician assistant, or a nurse practitioner with training or experience in emergency care on call and immediately available by telephone or radio contact, and available on site within the following timeframes:

(1) Within 30 minutes, on a 24-hour a day basis, if the CAH is located in an area other than an area described in paragraph (d)(2) of this section; or

(2) Within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met:

(i) The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets criteria for a remote location adopted by the State in its rural health care plan, and approved by HCFA, under section 1820(b) of the Act.

(ii) The State has determined under criteria in its rural health care plan that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH.

(iii) The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.

(e) *Standard: Coordination with emergency response systems.* The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide information