

aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation.

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (c)(2) of this section and has been assisting primary care physicians for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 77 FR 29076, May 16, 2012]

§ 485.606 Designation and certification of CAHs.

(a) *Criteria for State designation.* (1) A State that has established a Medicare rural hospital flexibility program described in section 1820(c) of the Act may designate one or more facilities as CAHs if each facility meets the CAH conditions of participation in this subpart F.

(2) The State must not deny any hospital that is otherwise eligible for designation as a CAH under this paragraph (a) solely because the hospital has entered into an agreement under which the hospital may provide posthospital SNF care as described in § 482.58 of this chapter.

(b) *Criteria for CMS certification.* CMS certifies a facility as a CAH if—

(1) The facility is designated as a CAH by the State in which it is located and has been surveyed by the State survey agency or by CMS and found to meet all conditions of participation in this part and all other applicable requirements for participation in part 489 of this chapter.

(2) The facility is a medical assistance facility operating in Montana or a rural primary care hospital designated by CMS before August 5, 1997, and is otherwise eligible to be designated as a 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; 79 FR 27155, May 12, 2014]

§ 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 the effective date of its designation; 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 in a rural area or treatment as rural.* The CAH meets the requirements of either paragraph (b)(1) or (b)(2) of this section or the requirements of paragraph (b)(3), (b)(4), or (b)(5) of this section.

§ 485.610

42 CFR Ch. IV (10–1–15 Edition)

(1) The CAH meets the following requirements:

(i) 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 §412.64(b), excluding paragraph (b)(3) of this chapter;

(ii) The CAH has not been classified as an urban hospital for purposes of the standardized payment amount by CMS 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.

(2) The CAH is located within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, but is being treated as being located in a rural area in accordance with §412.103 of this chapter.

(3) Effective for October 1, 2004 through September 30, 2006, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2004, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2005 was included as part of such a Metropolitan Statistical Area as a result of the most recent census data and implementation of the new Metropolitan Statistical Area definitions announced by the Office of Management and Budget on June 3, 2003.

(4) Effective for October 1, 2009 through September 30, 2011, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2009, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but, as of FY 2010, was included as part of such a Metropolitan Statistical Area as a result of the most recent census data and implementation of the new Metropolitan Statistical Area definitions announced by the Office of Management and Budget on November 20, 2008.

(5) Effective on or after October 1, 2014, for a period of 2 years beginning with the effective date of the most re-

cent Office of Management and Budget (OMB) standards for delineating statistical areas adopted by CMS, the CAH no longer meets the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, prior to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, was located in a rural area as defined by OMB, but under the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, is located in an urban area.

(c) *Standard: Location relative to other facilities or necessary provider certification.* 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 before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider on or before December 31, 2005, will maintain its necessary provider designation after January 1, 2006.

(d) *Standard: Relocation of CAHs with a necessary provider designation.* A CAH that has a necessary provider designation from the State that was in effect prior to January 1, 2006, and relocates its facility after January 1, 2006, can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the relocated facility meets the requirements as specified in paragraph (d)(1) of this section.

(1) If a necessary provider CAH relocates its facility and begins providing services in a new location, the CAH can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the CAH in its new location—

(i) Serves at least 75 percent of the same service area that it served prior to its relocation;

(ii) Provides at least 75 percent of the same services that it provided prior to the relocation; and

(iii) Is staffed by 75 percent of the same staff (including medical staff,

contracted staff, and employees) that were on staff at the original location.

(2) If a CAH that has been designated as a necessary provider by the State begins providing services at another location after January 1, 2006, and does not meet the requirements in paragraph (d)(1) of this section, the action will be considered a cessation of business as described in § 489.52(b)(3).

(e) *Standard: Off-campus and co-location requirements for CAHs.* A CAH may continue to meet the location requirements of paragraph (c) of this section only if the CAH meets the following:

(1) If a CAH with a necessary provider designation is co-located (that is, it shares a campus, as defined in § 413.65(a)(2) of this chapter, with another hospital or CAH), the necessary provider CAH can continue to meet the location requirement of paragraph (c) of this section only if the co-location arrangement was in effect before January 1, 2008, and the type and scope of services offered by the facility co-located with the necessary provider CAH do not change. A change of ownership of any of the facilities with a co-location arrangement that was in effect before January 1, 2008, will not be considered to be a new co-location arrangement.

(2) If a CAH or a necessary provider CAH operates an off-campus provider-based location, excluding an RHC as defined in § 405.2401(b) of this chapter, but including a department or remote location, as defined in § 413.65(a)(2) of this chapter, or an off-campus distinct part psychiatric or rehabilitation unit, as defined in § 485.647, that was created or acquired by the CAH on or after January 1, 2008, the CAH can continue to meet the location requirement of paragraph (c) of this section only if the off-campus provider-based location or off-campus distinct part unit 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.

(3) If either a CAH or a CAH that has been designated as a necessary provider by the State does not meet the requirements in paragraph (e)(1) of this section, by co-locating with another hospital or CAH on or after January 1,

2008, or creates or acquires an off-campus provider-based location or off-campus distinct part unit on or after January 1, 2008, that does not meet the requirements in paragraph (e)(2) of this section, the CAH's provider agreement will be subject to termination in accordance with the provisions of § 489.53(a)(3) of this subchapter, unless the CAH terminates the off-campus arrangement or the co-location arrangement, or both.

[62 FR 46036, Aug. 29, 1997, as amended at 65 FR 47052, Aug. 1, 2000; 66 FR 39938, Aug. 1, 2001; 69 FR 49271, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004; 70 FR 47490, Aug. 12, 2005; 71 FR 48143, Aug. 18, 2006; 72 FR 66934, Nov. 27, 2007; 73 FR 9862, Feb. 22, 2008; 74 FR 44001, Aug. 27, 2009; 75 FR 50418, Aug. 16, 2010; 79 FR 50359, Aug. 22, 2014]

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

Except for recently closed facilities as described in § 485.610(a)(2), or health clinics or health centers as described in § 485.610(a)(3), the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.

[66 FR 32196, June 13, 2001]

§ 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