

§ 485.74

(m) A speech-language pathologist must meet the qualifications set forth in part 484 of this chapter.

[48 FR 56293, Dec. 15, 1982. Redesignated and amended at 50 FR 33034, Aug. 16, 1985; 51 FR 41352, Nov. 14, 1986; 60 FR 2327, Jan. 9, 1995; 72 FR 66408, Nov. 27, 2007; 73 FR 69941, Nov. 19, 2008; 74 FR 62014, Nov. 25, 2009]

§ 485.74 Appeal rights.

The appeal provisions set forth in part 498 of this chapter, for providers, are applicable to any entity that is participating or seeks to participate in the Medicare program as a CORF.

[48 FR 56293, Dec. 15, 1982, as amended at 52 FR 22454, June 12, 1987]

Subparts C–E [Reserved]

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

SOURCE: 58 FR 30671, May 26, 1993, unless otherwise noted.

§ 485.601 Basis and scope.

(a) *Statutory basis.* This subpart is based on section 1820 of the Act which sets forth the conditions for designating certain hospitals as CAHs.

(b) *Scope.* This subpart sets forth the conditions that a hospital must meet to be designated as a CAH.

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

§ 485.603 Rural health network.

A rural health network is an organization that meets the following specifications:

(a) It includes—

(1) At least one hospital that the State has designated or plans to designate as a CAH; and

(2) At least one hospital that furnishes acute care services.

(b) The members of the organization have entered into agreements regarding—

(1) Patient referral and transfer;

(2) The development and use of communications systems, including, where feasible, telemetry systems and systems for electronic sharing of patient data; and

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(3) The provision of emergency and nonemergency transportation among members.

(c) Each CAH has an agreement with respect to credentialing and quality assurance with at least—

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

(2) One QIO or equivalent entity; or

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

[58 FR 30671, May 26, 1993, as amended at 62 FR 46035, Aug. 29, 1997; 63 FR 26359, May 12, 1998]

§ 485.604 Personnel qualifications.

Staff that furnish services in a CAH must meet the applicable requirements of this section.

(a) *Clinical nurse specialist.* A clinical nurse specialist must be a person who—

(1) Is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed in accordance with State nurse licensing laws and regulations; and

(2) Holds a master’s or doctoral level degree in a defined clinical area of nursing from an accredited educational institution.

(b) *Nurse practitioner.* A nurse practitioner must be a registered professional nurse who is currently licensed to practice in the State, who meets the State’s requirements governing the qualification of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses’ Association or by the National Board of Pediatric Nurse Practitioners and Associates.

(2) Has successfully completed a 1 academic year program that—

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program.

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (a)(2) of this section, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

(c) *Physician assistant.* A physician assistant must be a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians.

(2) Has satisfactorily completed a program for preparing physician assistants that—

(i) Was at least one academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the 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.

(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 recent 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

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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 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 QIO or equivalent entity; or

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

(c) *Standard: Agreements for credentialing and privileging of telemedicine physicians and practitioners.* (1) The governing body of the CAH must ensure that, when telemedicine services are furnished to the CAH's patients through an agreement with a distant-site hospital, the agreement is written and specifies that it is the responsibility of the governing body of the distant-site hospital to meet the following requirements with regard to its physicians or practitioners providing telemedicine services:

(i) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.

(ii) Appoint members of the medical staff after considering the rec-

ommendations of the existing members of the medical staff.

(iii) Assure that the medical staff has bylaws.

(iv) Approve medical staff bylaws and other medical staff rules and regulations.

(v) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.

(vi) Ensure the criteria for selection are individual character, competence, training, experience, and judgment.

(vii) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship or membership in a specialty body or society.

(2) When telemedicine services are furnished to the CAH's patients through an agreement with a distant-site hospital, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decisions made by the governing body of the distant-site hospital regarding individual distant-site physicians or practitioners. The CAH's governing body or responsible individual must ensure, through its written agreement with the distant-site hospital, that the following provisions are met:

(i) The distant-site hospital providing telemedicine services is a Medicare-participating hospital.

(ii) The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician's or practitioner's privileges at the distant-site hospital;

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the CAH is located; and

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the CAH whose patients are receiving the telemedicine services, the CAH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital such information for

use in the periodic appraisal of the individual distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the CAH's patients and all complaints the CAH has received about the distant-site physician or practitioner.

(3) The governing body of the CAH must ensure that when telemedicine services are furnished to the CAH's patients through an agreement with a distant-site telemedicine entity, the agreement is written and specifies that the distant-site telemedicine entity is a contractor of services to the CAH and as such, in accordance with § 485.635(c)(4)(ii), furnishes the contracted services in a manner that enables the CAH to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in this section with regard to its physicians and practitioners providing telemedicine services.

(4) When telemedicine services are furnished to the CAH's patients through an agreement with a distant-site telemedicine entity, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decisions made by the governing body of the distant-site telemedicine entity regarding individual distant-site physicians or practitioners. The CAH's governing body or responsible individual must ensure, through its written agreement with the distant-site telemedicine entity, that the following provisions are met:

(i) The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at paragraphs (c)(1)(i) through (c)(1)(vii) of this section.

(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides a current list to the CAH of the distant-site physician's or practitioner's privileges at the distant-site telemedicine entity.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the CAH whose patients are receiving the telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the CAH whose patients are receiving the telemedicine services, the CAH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site telemedicine entity such information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the CAH's patients and all complaints the CAH has received about the distant-site physician or practitioner.

[62 FR 46036, Aug. 29, 1997, as amended at 76 FR 25564, May 5, 2011]

§ 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.* (1) Except as specified in paragraph (d)(3) of this section, there must be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, 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:

(i) 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)(1)(ii) of this section; or

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

(A) 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 the criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Act.

(B) 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.

(C) 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.

(2) A registered nurse with training and experience in emergency care can be utilized to conduct specific medical screening examinations only if—

(i) The registered nurse is on site and immediately available at the CAH when a patient requests medical care; and

(ii) The nature of the patient's request for medical care is within the scope of practice of a registered nurse and consistent with applicable State laws and the CAH's bylaws or rules and regulations.

(3) A registered nurse satisfies the personnel requirement specified in paragraph (d)(1) of this section for a temporary period if—

(i) The CAH has no greater than 10 beds;

(ii) The CAH is located in an area designated as a frontier area or remote location as described in paragraph (d)(1)(ii)(A) of this section;

(iii) The State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation on the issue of using RNs on a temporary basis as part of their State rural healthcare plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered nurse with training and experience in emergency care be included in the list of personnel specified in paragraph (d)(1) of this section. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the States. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in paragraph (d)(1) of this section;

(iv) Once a Governor submits a letter, as specified in paragraph (d)(3)(iii) of this section, a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate

coverage as specified in this paragraph (d).

(4) The request, as specified in paragraph (d)(3)(iii) of this section, and the withdrawal of the request, may be submitted to us at any time, and are effective upon submission.

(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 on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 64 FR 41544, July 30, 1999; 67 FR 80041, Dec. 31, 2002; 69 FR 49271, Aug. 11, 2004; 71 FR 68230, Nov. 24, 2006]

§ 485.620 Condition of participation: Number of beds and length of stay.

(a) *Standard: Number of beds.* Except as permitted for CAHs having distinct part units under § 485.647, the CAH maintains no more than 25 inpatient beds. Inpatient beds may be used for either inpatient or swing-bed services.

(b) *Standard: Length of stay.* The CAH provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.

[62 FR 46036, Aug. 29, 1997, as amended at 65 FR 47052, Aug. 1, 2000; 69 FR 49271, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004; 78 FR 50970, Aug. 19, 2013]

§ 485.623 Condition of participation: Physical plant and environment.

(a) *Standard: Construction.* The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of services.

(b) *Standard: Maintenance.* The CAH has housekeeping and preventive maintenance programs to ensure that—

(1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;

(2) There is proper routine storage and prompt disposal of trash;

(3) Drugs and biologicals are appropriately stored;

(4) The premises are clean and orderly; and

(5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

(c) *Standard: Emergency procedures.* The CAH assures the safety of patients in non-medical emergencies by—

(1) Training staff in handling emergencies, including prompt reporting of fires, extinguishing of fires, protection and, where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;

(2) Providing for emergency power and lighting in the emergency room and for battery lamps and flashlights in other areas;

(3) Providing for an emergency fuel and water supply; and

(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 otherwise provided in this section—

(i) The CAH 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 CAH, but only if the waiver will not adversely affect the health and safety of the patients.

(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

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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.

(5) A CAH may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

(6) When a sprinkler system is shut down for more than 10 hours, the CAH 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.

(7) 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.

(i) The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours.

(ii) Special nursing care areas of new occupancies shall not exceed 60 inches.

(e) *Standard: Building safety.* Except as otherwise provided in this section, the CAH 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 CAH.

(2) If application of the Health Care Facilities Code required under paragraph (e) of this section would result in unreasonable hardship for the CAH, 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) 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]

[58 FR 30671, May 26, 1993, as amended at 62 FR 46036, 46037, Aug. 29, 1997; 68 FR 1387, Jan. 10, 2003; 69 FR 49271, Aug. 11, 2004; 70 FR 15239, Mar. 25, 2005; 71 FR 55341, Sept. 22, 2006; 77 FR 29076, May 16, 2012; 81 FR 26901, May 4, 2016]

EFFECTIVE DATE NOTE: At 81 FR 64036, Sept. 16, 2016, § 485.623 was amended by removing paragraph (c) and redesignating paragraphs (d) through (f) as paragraphs (c) through (e), effective Nov. 15, 2016.

§ 485.625 Condition of participation: Emergency preparedness.

The CAH must comply with all applicable Federal, State, and local emergency preparedness requirements. The

CAH must develop and maintain a comprehensive emergency preparedness program, utilizing an all-hazards approach. The emergency preparedness plan must include, but not be limited to, the following elements:

(a) *Emergency plan.* The CAH must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, persons at-risk; the type of services the CAH has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the CAH's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The CAH must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to—

(i) Food, water, medical, and pharmaceutical supplies;

(ii) Alternate sources of energy to maintain:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions;

(B) Emergency lighting;

(C) Fire detection, extinguishing, and alarm systems; and

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered patients in the CAH's care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the CAH must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the CAH, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other CAHs or other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to CAH patients.

(8) The role of the CAH under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The CAH must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

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(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other CAHs and hospitals.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) CAH's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the CAH's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the CAH's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) *Training and testing.* The CAH must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The CAH must do all of the following:

(i) Initial training in emergency preparedness policies and procedures, including prompt reporting and extinguishing of fires, protection, and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with firefighting and disaster authorities, to all new and existing staff, individuals providing services

under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Demonstrate staff knowledge of emergency procedures.

(2) *Testing.* The CAH must conduct exercises to test the emergency plan at least annually. The CAH must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based exercise. If the CAH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CAH is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the CAH's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CAH's emergency plan, as needed.

(e) *Emergency and standby power systems.* The CAH must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section.

(1) *Emergency generator location.* The generator must be located in accordance with the location requirements found in 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), Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4), and NFPA 110, when a new structure is built or when

an existing structure or building is renovated.

(2) *Emergency generator inspection and testing.* The CAH must implement emergency power system inspection and testing requirements found in the Health Care Facilities Code, NFPA 110, and the Life Safety Code.

(3) *Emergency generator fuel.* CAHs that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

(f) *Integrated healthcare systems.* If a CAH is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the CAH may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include—

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication

plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

(g) 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 obtain the material from the sources listed below. 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, Health Care Facilities Code, 2012 edition, issued August 11, 2011.

(ii) Technical interim amendment (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.

(xii) [Reserved]

(xiii) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

(2) [Reserved]

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EFFECTIVE DATE NOTE: At 81 FR 64036, Sept. 16, 2016, § 485.625 was added, effective Nov. 15, 2016.

§ 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.

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

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(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 all inpatients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants.

(v) Periodically reviews and signs a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants only to the extent required under State law where State law requires record reviews or co-signatures, or both, by a collaborating physician.

(2) A doctor of medicine or osteopathy is present for sufficient periods of time to provide medical direction, consultation, and supervision for the services provided in the CAH, and is available through direct radio or telephone communication or electronic communication for consultation, assistance with medical emergencies, or patient referral.

(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; 70 FR 68728, Nov. 10, 2005; 79 FR 27155, May 12, 2014]

§ 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 members of the CAH's professional healthcare staff, including 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).

(3) The policies include the following:
(i) A description of the services the CAH furnishes, including 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, mislabeled, or otherwise unusable drugs are not available for patient use.

(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.

(vi) A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

(vii) Procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of § 483.25(i) of this chapter is met with respect to inpatients receiving posthospital SNF care.

(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

(b) *Standard: Patient services—(1) General:* (i) The CAH provides those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These CAH services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

(ii) The CAH furnishes acute care inpatient services.

(2) *Laboratory services.* The CAH provides basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include the following:

(i) Chemical examination of urine by stick or tablet method or both (including urine ketones).

(ii) Hemoglobin or hematocrit.

(iii) Blood glucose.

(iv) Examination of stool specimens for occult blood.

(v) Pregnancy tests.

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(vi) Primary culturing for transmittal to a certified laboratory.

(3) *Radiology services.* Radiology services furnished by the CAH are provided by personnel qualified under State law, and do not expose CAH patients or personnel to radiation hazards.

(4) *Emergency procedures.* In accordance with requirements of § 485.618, the CAH provides medical services as a first response to common life-threatening injuries and acute illness.

(c) *Standard: Services provided through agreements or arrangements.* (1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including—

(i) Services of doctors of medicine or osteopathy;

(ii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH; and

(iii) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.

(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

(3) The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.

(4) The person principally responsible for the operation of the CAH under § 485.627(b)(2) of this chapter is also responsible for the following:

(i) Services furnished in the CAH whether or not they are furnished under arrangements or agreements.

(ii) Ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.

(5) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, the distant-site telemedicine entity is not required to be a

Medicare-participating provider or supplier.

(d) *Standard: Nursing services.* Nursing services must meet the needs of patients.

(1) A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.

(2) A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.

(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.

(4) A nursing care plan must be developed and kept current for each inpatient.

(e) *Standard: Rehabilitation Therapy Services.* Physical therapy, occupational therapy, and speech-language pathology services furnished at the CAH, if provided, are provided by staff qualified under State law, and consistent with the requirements for therapy services in § 409.17 of this subpart.

(f) *Standard: Patient visitation rights.* A CAH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and the reasons for the clinical restriction or limitation. A CAH must meet the following requirements:

(1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, in advance of furnishing patient care whenever possible.

(2) Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive

the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.

(3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

[58 FR 30671, May 26, 1993; 58 FR 49935, Sept. 24, 1993, as amended at 59 FR 45403, Sept. 1, 1994; 62 FR 46037, Aug. 29, 1997; 72 FR 66408, Nov. 27, 2007; 73 FR 69941, Nov. 19, 2008; 75 FR 70844, Nov. 19, 2010; 76 FR 25564, May 5, 2011; 77 FR 29076, May 16, 2012; 78 FR 50970, Aug. 19, 2013; 79 FR 27156, May 12, 2014]

§ 485.638 Conditions of participation: Clinical records.

(a) *Standard: Records system*—(1) The CAH maintains a clinical records system in accordance with written policies and procedures.

(2) The records are legible, complete, accurately documented, readily accessible, and systematically organized.

(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable—

(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the pa-

tient's progress, such as temperature graphics, progress notes describing the patient's response to treatment; and

(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.

(b) *Standard: Protection of record information*—(1) The CAH maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

(2) Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.

(3) The patient's written consent is required for release of information not required by law.

(c) *Standard: Retention of records*. The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.

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

§ 485.639 Condition of participation: Surgical services.

If a CAH provides surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body, or responsible individual, of the CAH in accordance with the designation requirements under paragraph (a) of this section.

(a) *Designation of qualified practitioners*. The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by—

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(2) A doctor of dental surgery or dental medicine; or

(3) A doctor of podiatric medicine.

(b) *Anesthetic risk and evaluation*. (1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

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(2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.

(c) *Administration of anesthesia.* The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope-of-practice laws.

(1) Anesthesia must be administered by only—

- (i) A qualified anesthesiologist;
- (ii) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;
- (iii) A doctor of dental surgery or dental medicine;
- (iv) A doctor of podiatric medicine;
- (v) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter;
- (vi) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter; or
- (vii) A supervised trainee in an approved educational program, as described in § 413.85 or § 413.86 of this chapter.

(2) In those cases in which a CRNA administers the anesthesia, the anesthesiologist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

(d) *Discharge.* All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

(e) *Standard: State exemption.* (1) A CAH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (c)(2) of this section, if the State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting ex-

emption from physician supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[60 FR 45851, Sept. 1, 1995, as amended at 62 FR 46037, Aug. 29, 1997; 66 FR 39938, Aug. 1, 2001; 66 FR 56769, Nov. 13, 2001; 77 FR 29076, May 16, 2012]

§ 485.641 Condition of participation: Periodic evaluation and quality assurance review.

(a) *Standard: Periodic evaluation.*—(1) The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of—

- (i) The utilization of CAH services, including at least the number of patients served and the volume of services;
- (ii) A representative sample of both active and closed clinical records; and
- (iii) The CAH's health care policies.

(2) The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.

(b) *Standard: Quality assurance.* The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that—

- (1) All patient care services and other services affecting patient health and safety, are evaluated;
- (2) Nosocomial infections and medication therapy are evaluated;
- (3) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a

member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;

(4) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by—

(i) One hospital that is a member of the network, when applicable;

(ii) One QIO or equivalent entity;

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

(iv) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site hospital, the distant-site hospital; or

(v) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, one of the entities listed in paragraphs (b)(4)(i) through (iii) of this section; and

(5)(i) The CAH staff considers the findings of the evaluations, including any findings or recommendations of the QIO, and takes corrective action if necessary.

(ii) The CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program.

(iii) The CAH documents the outcome of all remedial action.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 63 FR 26359, May 12, 1998; 76 FR 25564, May 5, 2011]

§ 485.643 Condition of participation: Organ, tissue, and eye procurement.

The CAH must have and implement written protocols that:

(a) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the defi-

nition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose;

(b) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(c) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its option to either donate or not donate organs, tissues, or eyes. The individual designated by the CAH to initiate the request to the family must be a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(d) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(e) Ensure that the CAH works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(f) For purposes of these standards, the term "organ" means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).

[65 FR 47110, Aug. 1, 2000, as amended at 66 FR 39938, Aug. 1, 2001]

§ 485.645 Special requirements for CAH providers of long-term care services ("swing-beds")

A CAH must meet the following requirements in order to be granted an approval from CMS to provided post-hospital SNF care, as specified in § 409.30 of this chapter, and to be paid

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for SNF-level services, in accordance with paragraph (c) of this section.

(a) *Eligibility.* A CAH must meet the following eligibility requirements:

(1) The facility has been certified as a CAH by CMS under § 485.606(b) of this subpart; and

(2) The facility provides not more than 25 inpatient beds. Any bed of a unit of the facility that is licensed as a distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under paragraph (a) of this section.

(b) *Facilities participating as rural primary care hospitals (RPCHs) on September 30, 1997.* These facilities must meet the following requirements:

(1) Notwithstanding paragraph (a) of this section, a CAH that participated in Medicare as a RPCH on September 30, 1997, and on that date had in effect an approval from CMS to use its inpatient facilities to provide post-hospital SNF care may continue in that status under the same terms, conditions and limitations that were applicable at the time those approvals were granted.

(2) A CAH that was granted swing-bed approval under paragraph (b)(1) of this section may request that its application to be a CAH and swing-bed provider be reevaluated under paragraph (a) of this section. If this request is approved, the approval is effective not earlier than October 1, 1997. As of the date of approval, the CAH no longer has any status under paragraph (b)(1) of this section and may not request reinstatement under paragraph (b)(1) of this section.

(c) *Payment.* Payment for inpatient RPCH services to a CAH that has qualified as a CAH under the provisions in paragraph (a) of this section is made in accordance with § 413.70 of this chapter. Payment for post-hospital SNF-level of care services is made in accordance with the payment provisions in § 413.114 of this chapter.

(d) *SNF services.* The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:

(1) Residents rights (§ 483.10(b)(3) through (b)(6), (d) (e), (h), (i), (j)(1)(vii) and (viii), (l), and (m) of this chapter).

(2) Admission, transfer, and discharge rights (§ 483.12(a) of this chapter).

(3) Resident behavior and facility practices (§ 483.13 of this chapter).

(4) Patient activities (§ 483.15(f) of this chapter), except that the services may be directed either by a qualified professional meeting the requirements of § 485.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

(5) Social services (§ 483.15(g) of this chapter).

(6) Comprehensive assessment, comprehensive care plan, and discharge planning (§ 483.20(b), (k), and (l) of this chapter, except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under § 483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in § 413.343(b) of this chapter).

(7) Specialized rehabilitative services (§ 483.45 of this chapter).

(8) Dental services (§ 483.55 of this chapter).

(9) Nutrition (§ 483.25(i) of this chapter).

[63 FR 26359, May 12, 1998, as amended at 64 FR 41544, July 30, 1999; 67 FR 50120, Aug. 1, 2002; 69 FR 49272, Aug. 11, 2004]

§ 485.647 Condition of participation: psychiatric and rehabilitation distinct part units.

(a) *Conditions.* (1) If a CAH provides inpatient psychiatric services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in subparts A, B, C, and D of part 482 of this subchapter, the common requirements of § 412.25(a)(2) through (f) of part 412 of this chapter for hospital units excluded from the prospective payment systems, and the additional requirements of § 412.27 of part 412 of this chapter for excluded psychiatric units.

(2) If a CAH provides inpatient rehabilitation services in a distinct part unit, the services furnished by the distinct part unit must comply with the

hospital requirements specified in subparts A, B, C, and D of part 482 of this subchapter, the common requirements of § 412.25(a)(2) through (f) of part 412 of this chapter for hospital units excluded from the prospective payments systems, and the additional requirements of §§ 412.29 and § 412.30 of part 412 of this chapter related specifically to rehabilitation units.

(b) *Eligibility requirements.* (1) To be eligible to receive Medicare payments for psychiatric or rehabilitation services as a distinct part unit, the facility provides no more than 10 beds in the distinct part unit.

(2) The beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in § 485.620(a).

(3) The average annual 96-hour length of stay requirement specified under § 485.620(b) does not apply to the 10 beds in the distinct part units specified in paragraph (b)(1) of this section, and admissions and days of inpatient care in the distinct part units are not taken into account in determining the CAH's compliance with the limits on the number of beds and length of stay in § 485.620.

[69 FR 49272, Aug. 11, 2004]

Subpart G [Reserved]

Subpart H—Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

§ 485.701 Basis and scope.

This subpart implements section 1861(p)(4) of the Act, which—

(a) Defines outpatient physical therapy and speech pathology services;

(b) Imposes requirements with respect to adequate program, facilities, policies, staffing, and clinical records; and

(c) Authorizes the Secretary to establish by regulation other health and safety requirements.

[60 FR 2327, Jan. 9, 1995]

§ 485.703 Definitions.

Clinic. A facility that is established primarily to furnish outpatient physician services and that meets the following tests of physician involvement:

(1) The medical services are furnished by a group of three or more physicians practicing medicine together.

(2) A physician is present during all hours of operation of the clinic to furnish medical services, as distinguished from purely administrative services.

Extension location. A location or site from which a rehabilitation agency provides services within a portion of the total geographic area served by the primary site. The extension location is part of the rehabilitation agency. The extension location should be located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the extension location to independently meet the conditions of participation as a rehabilitation agency.

Organization. A clinic, rehabilitation agency, or public health agency.

Public health agency. An official agency established by a State or local government, the primary function of which is to maintain the health of the population served by performing environmental health services, preventive medical services, and in certain cases, therapeutic services.

Rehabilitation agency. An agency that—

(1) Provides an integrated interdisciplinary rehabilitation program designed to upgrade the physical functioning of handicapped disabled individuals by bringing specialized rehabilitation staff together to perform as a team; and

(2) Provides at least physical therapy or speech-language pathology services.

Supervision. Authoritative procedural guidance that is for the accomplishment of a function or activity and that—

(1) Includes initial direction and periodic observation of the actual performance of the function or activity; and

(2) Is furnished by a qualified person—

(i) Whose sphere of competence encompasses the particular function or activity; and