(5) *Recalculation decision.* CMS issues a written notification of findings. A recalculation decision is subject to the request for reconsideration process in accordance with paragraph (b) of this section.

(b) *Requests for reconsideration*—(1) *Matters for reconsideration.* A home health agency may request reconsideration of the recalculation of its annual total performance score and payment adjustment percentage following a decision on the HHA's recalculation request submitted under paragraph (a) of this section, or the decision to deny the recalculation request submitted under paragraph (a) of this section.

(2) *Time for filing a request for reconsideration.* The request for reconsideration must be submitted via the CMS website within 15 calendar days from CMS' notification to the HHA contact of the outcome of the recalculation process.

(3) *Content of request.* (i) The name of the HHA, address associated with the services delivered, and CMS Certification Number (CCN).

(ii) The basis for requesting reconsideration to include the specific data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.

(iii) Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).

(iv) The HHA may include in the request for reconsideration additional documentary evidence that CMS should consider. The documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.

(4) *Scope of review for reconsideration.* In conducting the reconsideration review, CMS reviews the applicable measures and performance scores, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the HHA. CMS may also review any other evidence it believes to be relevant to the reconsideration. The HHA must prove its case by a preponderance of the evidence with respect to issues of fact.

(5) *Reconsideration decision.* CMS reconsideration officials issue a written final determination.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

Subpart A [Reserved]

Subpart B—Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities

Sec.

Subparts C–D [Reserved]

Subpart E—Conditions of Participation: Rural Emergency Hospitals (REHs)

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

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

Subpart I [Reserved]

Subpart J—Conditions of Participation: Community Mental Health Centers (CMHCs)

AUTHORITY: 42 U.S.C. 1302 and 1395(hh).

SOURCE: 48 FR 56293, Dec. 15, 1982, unless otherwise noted. Redesignated at 50 FR 33034, Aug. 16, 1985.

Subpart A [Reserved]

Subpart B—Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities

§ 485.50 Basis and scope.

This subpart sets forth the conditions that facilities must meet to be certified as comprehensive outpatient rehabilitation facilities (CORFs) under section 1861(cc)(2) of the Social Security Act and be accepted for participation in Medicare in accordance with part 489 of this chapter.

§ 485.51 Definition.

As used in this subpart, unless the context indicates otherwise, ''*comprehensive outpatient rehabilitation facility*'', ''*CORF*'', or ''*facility*'' means a nonresidential facility that—

(a) Is established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons, at a single fixed location, by or under the supervision of a physician except as provided in paragraph (c) of this section;

(b) Meets all the requirements of this subpart.

(c) *Exception.* May provide influenza, pneumococcal and Hepatitis B vaccines provided the applicable conditions of coverage under § 410.58 and § 410.63 of this chapter are met.

[48 FR 56293, Dec. 15, 1982, as amended at 72 FR 66408, Nov. 27, 2007]

§ 485.54 Condition of participation: Compliance with State and local laws.

The facility and all personnel who provide services must be in compliance with applicable State and local laws and regulations.

(a) *Standard: Licensure of facility.* If State or local law provides for licensing, the facility must be currently licensed or approved as meeting the standards established for licensure.

(b) *Standard: Licensure of personnel.* Personnel that provide service must be licensed, certified, or registered in accordance with applicable State and local laws.

§ 485.56 Condition of participation: Governing body and administration.

The facility must have a governing body that assumes full legal responsibility for establishing and implementing policies regarding the management and operation of the facility.

(a) *Standard: Disclosure of ownership.* The facility must comply with the provisions of part 420, subpart C of this chapter that require health care providers and fiscal agents to disclose certain information about ownership and control.

(b) *Standard: Administrator.* The governing body must appoint an administrator who—

(1) Is responsible for the overall management of the facility under the authority delegated by the governing body;

(2) Implements and enforces the facility's policies and procedures;

(3) Designates, in writing, an individual who, in the absence of the administrator, acts on behalf of the administrator; and

(4) Retains professional and administrative responsibility for all personnel providing facility services.

(c) *Standard: Group of professional personnel.* The facility must have a group of professional personnel associated with the facility that—

(1) Develops and periodically reviews policies to govern the services provided by the facility; and

(2) Consists of at least one physician and one professional representing each of the services provided by the facility.

(d) *Standard: Institutional budget plan.* The facility must have an institutional budget plan that meets the following conditions:

(1) It is prepared, under the direction of the governing body, by a committee consisting of representatives of the governing body and the administrative staff.

(2) It provides for—

(i) An annual operating budget prepared according to generally accepted accounting principles;

(ii) A 3-year capital expenditure plan if expenditures in excess of $100,000 are anticipated, for that period, for the acquisition of land; the improvement of land, buildings, and equipment; and the replacement, modernization, and expansion of buildings and equipment; and

(iii) Annual review and updating by the governing body.

(e) *Standard: Patient care policies.* The facility must have written patient care policies that govern the services it furnishes. The patient care policies must include the following:

(1) A description of the services the facility furnishes through employees and those furnished under arrangements.

(2) Rules for and personnel responsibilities in handling medical emergencies.

(3) Rules for the storage, handling, and administration of drugs and biologicals.

(4) Criteria for patient admission, continuing care, and discharge.

(5) Procedures for preparing and maintaining clinical records on all patients.

(6) A procedure for explaining to the patient and the patient's family the extent and purpose of the services to be provided.

(7) A procedure to assist the referring physician in locating another level of care for—patients whose treatment has terminated and who are discharged.

(8) A requirement that patients accepted by the facility must be under the care of a physician.

(9) A requirement that there be a plan of treatment established by a physician for each patient.

(10) A procedure to ensure that the group of professional personnel reviews and takes appropriate action on recommendations from the utilization review committee regarding patient care policies.

(f) *Standard: Delegation of authority.* The responsibility for overall administration, management, and operation must be retained by the facility itself and not delegated to others.

(1) The facility may enter into a contract for purposes of assistance in financial management and may delegate to others the following and similar services:

(i) Bookkeeping.

(ii) Assistance in the development of procedures for billing and accounting systems.

(iii) Assistance in the development of an operating budget.

(iv) Purchase of supplies in bulk form.

(v) The preparation of financial statements.

(2) When the services listed in paragraph (f)(1) of this section are delegated, a contract must be in effect and:

(i) May not be for a term of more than 5 years;

(ii) Must be subject to termination within 60 days of written notice by either party;

(iii) Must contain a clause requiring renegotiation of any provision that CMS finds to be in contravention to any new, revised or amended Federal regulation or law;

(iv) Must state that only the facility may bill the Medicare program; and

(v) May not include clauses that state or imply that the contractor has power and authority to act on behalf of the facility, or clauses that give the contractor rights, duties, discretions, or responsibilities that enable it to dictate the administration, management, or operations of the facility.

§ 485.58 Condition of participation: Comprehensive rehabilitation program.

The facility must provide a coordinated rehabilitation program that includes, at a minimum, physicians' services, physical therapy services, and social or psychological services. These services must be furnished by personnel that meet the qualifications set forth in §§ 485.70 and 484.115 of this chapter and must be consistent with the plan of treatment and the results of comprehensive patient assessments.

(a) *Standard: Physician services.* (1) A facility physician must be present in the facility for a sufficient time to—

(i) Provide, in accordance with accepted principles of medical practice, medical direction, medical care services, consultation, and medical supervision of nonphysician staff;

(ii) Establish the plan of treatment in cases where a plan has not been established by the referring physician;

(iii) Assist in establishing and implementing the facility's patient care policies; and

(iv) Participate in plan of treatment reviews, patient case review conferences, comprehensive patient assessment and reassessments, and utilization review.

(2) The facility must provide for emergency physician services during the facility operating hours.

(b) *Standard: Plan of treatment.* For each patient, a physician must establish a plan of treatment before the facility initiates treatment. The plan of treatment must meet the following requirements:

(1) It must delineate anticipated goals and specify the type, amount, frequency and duration of services to be provided.

(2) It must be promptly evaluated after changes in the patient's condition and revised when necessary.

(3) It must, if appropriate, be developed in consultation with the facility physician and the appropriate facility professional personnel.

(4) It must be reviewed at least every 60 days by a facility physician who, when appropriate, consults with the professional personnel providing services. The results of this review must be communicated to the patient's referring physician for concurrence before treatment is continued or discontinued.

(5) It must be revised if the comprehensive reassessment of the patient's status or the results of the patient case review conference indicate the need for revision.

(c) *Standard: Coordination of services.* The facility must designate, in writing, a qualified professional to ensure that professional personnel coordinate their related activities and exchange information about each patient under their care. Mechanisms to assist in the coordination of services must include—

(1) Providing to all personnel associated with the facility, a schedule indicating the frequency and type of services provided at the facility;

(2) A procedure for communicating to all patient care personnel pertinent information concerning significant changes in the patient's status;

(3) Periodic clinical record entries, noting at least the patient's status in relationship to goal attainment; and

(4) Scheduling patient case review conferences for purposes of determining appropriateness of treatment, when indicated by the results of the initial comprehensive patient assessment, reassessment(s), the recommendation of the facility physician (or other physician who established the plan of treatment), or upon the recommendation of one of the professionals providing services.

(d) *Standard: Provision of services.* (1) All patients must be referred to the facility by a physician who provides the following information to the facility before treatment is initiated:

(i) The patient's significant medical history.

(ii) Current medical findings.

(iii) Diagnosis(es) and contraindications to any treatment modality.

(iv) Rehabilitation goals, if determined.

(2) Services may be provided by facility employees or by others under arrangements made by the facility.

(3) The facility must have on its premises the necessary equipment to implement the plan of treatment and sufficient space to allow adequate care.

(4) The services must be furnished by personnel that meet the qualifications

of § 485.70 and the number of qualified personnel must be adequate for the volume and diversity of services offered. Personnel that do not meet the qualifications specified in § 485.70(a) through (m) may be used by the facility in assisting qualified staff.

(5) A qualified professional must initiate and coordinate the appropriate portions of the plan of treatment, monitor the patient's progress, and recommend changes, in the plan, if necessary.

(6) A qualified professional representing each service made available at the facility must be either on the premises of the facility or must be available through direct telecommunication for consultation and assistance during the facility's operating hours. At least one qualified professional must be on the premises during the facility's operating hours.

(7) All services must be provided consistent with accepted professional standards and practice.

(e) *Standard: Scope and site of services*—(1) *Basic requirements*. The facility must provide all the CORF services required in the plan of treatment and, except as provided in paragraph (e)(2) of this section, must provide the services on its premises.

(2) *Exceptions*. Physical therapy, occupational therapy, and speech-language pathology services may be furnished away from the premises of the CORF including the individual's home when payment is not otherwise made under Title XVIII of the Act. In addition, a single home environment evaluation is covered if there is a need to evaluate the potential impact of the home environment on the rehabilitation goals. The single home environment evaluation requires the presence of the patient and the physical therapist, occupational therapist, or speech-language pathologist, as appropriate.

(f) *Standard: Patient assessment*. Each qualified professional involved in the patient's care, as specified in the plan of treatment, must—

(1) Carry out an initial patient assessment; and

(2) In order to identify whether or not the current plan of treatment is appropriate, perform a patient reassessment after significant changes in the patient's status.

(g) *Standard: Laboratory services*. (1) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(2) If the facility chooses to refer specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.

[48 FR 56293, Dec. 15, 1982, as amended at 56 FR 8852, Mar. 1, 1991; 57 FR 7137, Feb. 28, 1992; 73 FR 69941, Nov. 19, 2008; 82 FR 4591, Jan. 13, 2017; 86 FR 61622, Nov. 5, 2021; 88 FR 36510, June 5, 2023]

§ 485.60 Condition of participation: Clinical records.

The facility must maintain clinical records on all patients in accordance with accepted professional standards and practice. The clinical records must be completely, promptly, and accurately documented, readily accessible, and systematically organized to facilitate retrieval and compilation of information.

(a) *Standard: Content*. Each clinical record must contain sufficient information to identify the patient clearly and to justify the diagnosis and treatment. Entries in the clinical record must be made as frequently as is necessary to insure effective treatment and must be signed by personnel providing services. All entries made by assistant level personnel must be countersigned by the corresponding professional. Documentation on each patient must be consolidated into one clinical record that must contain—

(1) The initial assessment and subsequent reassessments of the patient's needs;

(2) Current plan of treatment;

(3) Identification data and consent or authorization forms;

(4) Pertinent medical history, past and present;

(5) A report of pertinent physical examinations if any;

(6) Progress notes or other documentation that reflect patient reaction to treatment, tests, or injury, or the

need to change the established plan of treatment; and

(7) Upon discharge, a discharge summary including patient status relative to goal achievement, prognosis, and future treatment considerations.

(b) *Standard: Protection of clinical record information.* The facility must safeguard clinical record information against loss, destruction, or unauthorized use. The facility must have procedures that govern the use and removal of records and the conditions for release of information. The facility must obtain the patient's written consent before releasing information not required to be released by law.

(c) *Standard: Retention and preservation.* The facility must retain clinical record information for 5 years after patient discharge and must make provision for the maintenance of such records in the event that it is no longer able to treat patients.

§ 485.62 Condition of participation: Physical environment.

The facility must provide a physical environment that protects the health and safety or patients, personnel, and the public.

(a) *Standard: Safety and comfort of patients.* The physical premises of the facility and those areas of its surrounding physical structure that are used by the patients (including at least all stairwells, corridors and passageways) must meet the following requirements:

(1) Applicable Federal, State, and local building, fire, and safety codes must be met.

(2) Fire extinguishers must be easily accessible and fire regulations must be prominently posted.

(3) A fire alarm system with local (in-house) capability must be functional, and where power is generated by electricity, an alternate power source with automatic triggering must be present.

(4) Lights, supported by an emergency power source, must be placed at exits.

(5) A sufficient number of staff to evacuate patients during a disaster must be on the premises of the facility whenever patients are being treated.

(6) Lighting must be sufficient to carry out services safely; room temperature must be maintained at comfortable levels; and ventilation through windows, mechanical means, or a combination of both must be provided.

(7) Safe and sufficient space must be available for the scope of services offered.

(b) *Standard: Sanitary environment.* The facility must maintain a sanitary environment and establish a program to identify, investigate, prevent, and control the cause of patient infections.

(1) The facility must establish written policies and procedures designed to control and prevent infection in the facility and to investigate and identify possible causes of infection.

(2) The facility must monitor the infection control program to ensure that the staff implement the policies and procedures and that the policies and procedures are consistent with current practices in the field.

(3) The facility must make available at all times a quantity of laundered linen adequate for proper care and comfort of patients. Linens must be handled, stored, and processed in a manner that prevents the spread of infection.

(4) Provisions must be in effect to ensure that the facility's premises are maintained free of rodent and insect infestation.

(c) *Standard: Maintenance of equipment, physical location, and grounds.* The facility must establish a written preventive maintenance program to ensure that—

(1) All equipment is properly maintained and equipment needing periodic calibration is calibrated consistent with the manufacturer's recommendations; and

(2) The interior of the facility, the exterior of the physical structure housing the facility, and the exterior walkways and parking areas are clean and orderly and maintained free of any defects that are a hazard to patients, personnel, and the public.

(d) *Standard: Access for the physically impaired.* The facility must ensure the following:

(1) Doorways, stairwells, corridors, and passageways used by patients are—

(i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs); and

(ii) In the case of stairwells, equipped with firmly attached handrails on at least one side.

(2) At least one toilet facility is accessible and constructed to allow utilization by ambulatory and nonambulatory individuals.

(3) At least one entrance is usable by individuals in wheelchairs.

(4) In multi-story buildings, elevators are accessible to and usable by the physically impaired on the level that they use to enter the building and all levels normally used by the patients of the facility.

(5) Parking spaces are large enough and close enough to the facility to allow safe access by the physically impaired.

§ 485.64 [Reserved]

§ 485.66 Condition of participation: Utilization review plan.

The facility must have in effect a written utilization review plan that is implemented annually, to assess the necessity of services and promotes the most efficient use of services provided by the facility.

(a) *Standard: Utilization review committee.* The utilization review committee, consisting of the group of professional personnel specified in § 485.56(c), a committee of this group, or a group of similar composition, comprised by professional personnel not associated with the facility, must carry out the utilization review plan.

(b) *Standard: Utilization review plan.* The utilization review plan must contain written procedures for evaluating—

(1) Admissions, continued care, and discharges using, at a minimum, the criteria established in the patient care policies;

(2) The applicability of the plan of treatment to established goals; and

(3) The adequacy of clinical records with regard to—

(i) Assessing the quality of services provided; and

(ii) Determining whether the facility's policies and clinical practices are compatible and promote appropriate and efficient utilization of services.

[48 FR 56293, Dec. 15, 1982. Redesignated at 50 FR 33034, Aug. 16, 1985, as amended at 84 FR 51826, Sept. 30, 2019]

§ 485.68 Condition of participation: Emergency preparedness.

The Comprehensive Outpatient Rehabilitation Facility (CORF) must comply with all applicable Federal, State, and local emergency preparedness requirements. The CORF must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The CORF must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. 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, the type of services the CORF 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.

(5) Be developed and maintained with assistance from fire, safety, and other appropriate experts.

(b) *Policies and procedures.* The CORF 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 every 2

years. At a minimum, the policies and procedures must address the following:

(1) Safe evacuation from the CORF, which includes staff responsibilities, and needs of the patients.

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

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

(4) The use of volunteers in an emergency and 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.

(c) *Communication plan.* The CORF 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 every 2 years. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other CORFs.

(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 CORF's staff, Federal, State, tribal, regional, and local emergency management agencies.

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

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

(d) *Training and testing.* The CORF 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 every 2 years.

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

(i) Provide initial training in emergency preparedness policies and procedures 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 every 2 years.

(iii) Maintain documentation of the training.

(iv) Demonstrate staff knowledge of emergency procedures. All new personnel must be oriented and assigned specific responsibilities regarding the CORF's emergency plan within 2 weeks of their first workday. The training program must include instruction in the location and use of alarm systems and signals and firefighting equipment.

(v) If the emergency preparedness policies and procedures are significantly updated, the CORF must conduct training on the updated policies and procedures.

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

(i) Participate in a full-scale exercise that is community-based every 2 years; or

(A) When a community-based exercise is not accessible, conduct an individual, facility-based functional exercise every 2 years; or

(B) If the CORF experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CORF is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional exercise every 2 years, opposite the year the full-scale or functional exercise under

paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

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

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, 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 CORF's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CORF's emergency plan, as needed.

(e) *Integrated healthcare systems.* If a CORF 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 CORF 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 the following:

(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.

[81 FR 64035, Sept. 16, 2016, as amended at 84 FR 51826, Sept. 30, 2019]

§ 485.70 Personnel qualifications.

This section sets forth the qualifications that must be met, as a condition of participation, under § 485.58, and as a condition of coverage of services under § 410.100 of this chapter.

(a) A facility physician must be a doctor of medicine or osteopathy who—

(1) Is licensed under State law to practice medicine or surgery; and

(2) Has had, subsequent to completing a 1-year hospital internship, at least 1 year of training in the medical management of patients requiring rehabilitation services; or

(3) Has had at least 1 year of full-time or part-time experience in a rehabilitation setting providing physicians' services similar to those required in this subpart.

(b) A licensed practical nurse must be licensed as a practical or vocational nurse by the State in which practicing, if applicable.

(c) An occupational therapist and an occupational therapy assistant must meet the qualifications in § 484.115 of this chapter.

(d) An orthotist must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program in orthotics that is jointly recognized by the American Council on Education and the American Board for Certification in Orthotics and Prosthetics; and

(3) Be eligible to take that Board's certification examination in orthotics.

(e) A physical therapist and a physical therapist assistant must meet the qualifications in § 484.115 of this chapter.

(f) A *prosthetist* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program in prosthetics that is jointly recognized by the American Council on Education and the American Board for Certification in Orthotics and Prosthetics; and

(3) Be eligible to take that Board's certification examination in prosthetics.

(g) A *psychologist* must be certified or licensed by the State in which he or she is practicing, if that State requires certification or licensing, and must hold a masters degree in psychology from and educational institution approved by the State in which the institution is located.

(h) A *registered nurse* must be a graduate of an approved school of nursing and be licensed as a registered nurse by the State in which practicing, if applicable.

(i) A *rehabilitation counselor* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Hold at least a bachelor's degree; and

(3) Be eligible to take the certification examination administered by the Commission on Rehabilitation Counselor Certification.

(j) A respiratory therapist must complete one the following criteria:

(1) *Criterion 1.* All of the following must be completed:

(i) Be licensed by the State in which practicing, if applicable.

(ii) Have successfully completed a nationally-accredited educational program for respiratory therapists.

(iii)(A) Be eligible to take the registry examination administered by the National Board for Respiratory Care for respiratory therapists; or

(B) Have passed the registry examination administered by the National Board for Respiratory Care for respiratory therapists.

(2) *Criterion 2:* All of the following must be completed:

(i) Be licensed by the State in which practicing, if applicable.

(ii) Have equivalent training and experience as determined by the National Board for Respiratory Care.

(k) A *respiratory therapy technician* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program accredited by the Committees on Allied Health Education and Accreditation (CAHEA) in collaboration with the Joint Review Committee for Respiratory Therapy Education; and

(3) Either—

(i) Be eligible to take the certification examination for respiratory therapy technicians administered by the National Board for Respiratory Therapy, Inc,; or

(ii) Have equivalent training and experience as determined by the National Board for Respiratory Therapy, Inc.

(l) A *social worker* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Hold at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education; and

(3) Have 1 year of social work experience in a health care setting.

(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; 82 FR 4591, Jan. 13, 2017; 86 FR 61622, Nov. 5, 2021; 88 FR 36510, June 5, 2023]

§ 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–D [Reserved]

Subpart E—Conditions of Participation: Rural Emergency Hospitals (REHs)

SOURCE: 87 FR 72293, Nov. 23, 2022, unless otherwise noted.

§ 485.500 Basis and scope.

Section 1861(kkk) of the Act requires the Secretary to establish the conditions REHs must meet in order to participate in the Medicare program and which are considered necessary to ensure the health and safety of patients receiving services at these entities.

§ 485.502 Definitions.

As used in this subpart, *rural emergency hospital or REH* means an entity that operates for the purpose of providing emergency department services, observation care, and other outpatient medical and health services specified by the Secretary in which the annual per patient average length of stay does not exceed 24 hours. The time calculation for determining the length of stay of a patient receiving REH services begins with the registration, check-in or triage of the patient (whichever occurs first) and ends with the discharge of the patient from the REH. The discharge occurs when the physician or other appropriate clinician has signed the discharge order, or at the time the outpatient service is completed and documented in the medical record. The entity must not provide inpatient services, except those furnished in a unit that is a distinct part licensed as a skilled nursing facility to furnish post-hospital extended care services.

§ 485.504 Basic requirements.

Participation as an REH is limited to facilities that—

(a) Meet the definition in § 485.502.

(b) Have in effect a provider agreement as defined at § 489.3 of this chapter to provide services.

(c) Meet the conditions of participation set out in this subpart.

§ 485.506 Designation and certification of REHs.

CMS certifies a facility as an REH if the facility was, as of December 27, 2020—

(a) A critical access hospital; or

(b) A hospital as defined in section 1886(d)(1)(B) of the Act with not more than 50 beds located in a county (or equivalent unit of local government) that is considered rural (as defined in section 1881(d)(2)(D) of the Act); or

(c) A hospital as defined in section 1881(d)(1)(B) of the Act with not more than 50 beds that was treated as being located in a rural area that has had an active reclassification from urban to rural status as specified in § 412.103 of this chapter as of December 27, 2020.

§ 485.508 Condition of participation: Compliance with Federal, state, and local laws and regulations.

(a) The REH must be in compliance with applicable Federal laws related to the health and safety of patients.

(b) The REH must be located in a state that provides for the licensing of such hospitals under state or applicable local law; and is

(1) Licensed in the state as an REH; or

(2) Approved as meeting standards for licensing established by the agency of the state or locality responsible for licensing hospitals.

(c) The REH must assure that personnel are licensed or meet other applicable standards that are required by state or local laws to provide services within the applicable scope of practice.

§ 485.510 Condition of participation: Governing body and organizational structure of the REH

There must be an effective governing body, or responsible individual or individuals, that is legally responsible for the conduct of the REH. If an REH does not have an organized governing body, the person or persons legally responsible for the conduct of the REH must carry out the functions specified in this subpart that pertain to the governing body.

(a) *Standard: Medical staff.* The governing body must:

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

(2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.

(3) Ensure that the medical staff has bylaws.

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

(5) Ensure that the medical staff is accountable to the governing body for

the quality of care provided to patients.

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

(i) Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The REH grants privileges in accordance with recommendations from qualified medical personnel.

(ii) Medical staff privileges must be periodically reappraised by the REH. The scope of procedures performed in the REH must be periodically reviewed and amended as appropriate.

(iii) If the REH assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

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

(8) Ensure that, when telemedicine services are furnished to the REH's patients through an agreement with a distant-site hospital, the agreement is written and that it specifies that it is the responsibility of the governing body of the distant-site hospital to meet the requirements in paragraphs (a)(1) through (7) of this section with regard to the distant-site hospital's physicians and practitioners providing telemedicine services. The governing body of the REH whose patients are receiving the telemedicine services may, in accordance with §485.512(a)(3), grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital.

(9) Ensure that when telemedicine services are furnished to the REH's patients through an agreement with a distant-site telemedicine entity, the written agreement specifies that the distant-site telemedicine entity is a contractor of services to the REH and as such, in accordance with paragraph (b) of this section, furnishes the contracted services in a manner that permits the REH to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in paragraphs (a)(1) through (7) of this section with regard to the distant-site telemedicine entity's physicians and practitioners providing telemedicine services. The governing body of the REH whose patients are receiving the telemedicine services may, in accordance with §485.512(a)(4), grant privileges to physicians and practitioners employed by the distant-site telemedicine entity based on such REH's medical staff recommendations; such staff recommendations may rely on information provided by the distant-site telemedicine entity.

(10) Consult directly with the individual assigned the responsibility for the organization and conduct of the REH's medical staff, or their designee. At a minimum, this direct consultation must occur periodically throughout the fiscal or calendar year and include discussion of matters related to the quality of medical care provided to patients of the REH. For a multi-facility system, including a multi-hospital or multi-REH system, using a single governing body, the single multi-facility or multi-REH system governing body must consult directly with the individual responsible for the organized medical staff (or their designee) of each hospital or REH within its system in addition to the other requirements of this paragraph (a).

(b) *Standard: Contracted services.* The governing body must be responsible for services furnished in the REH whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the REH to comply with all applicable conditions of participation and standards for the contracted services.

(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

(2) The REH must maintain a list of all contracted services, including the scope and nature of the services provided.

§ 485.512 Condition of participation: Medical staff.

The REH must have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the REH.

(a) *Standard: Eligibility and process for appointment to medical staff.* The medical staff must be composed of doctors of medicine or osteopathy. In accordance with state law, including scope-of-practice laws, the medical staff may also include other categories of physicians (as listed at § 482.12(c)(1) of this chapter and non-physician practitioners who are determined to be eligible for appointment by the governing body.

(1) The medical staff must periodically conduct appraisals of its members.

(2) The medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body on the appointment of these candidates in accordance with state law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations. A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained in this section.

(3) When telemedicine services are furnished to the REH's patients through an agreement with a distant-site hospital, the governing body of the REH whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the REH's governing body ensures, through its written agreement with the distant-site hospital, that all of the following provisions are met:

(i) The distant-site hospital providing the 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 REH 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 REH whose patients are receiving the telemedicine services, the REH 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 performance 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 REH's patients and all complaints the REH has received about the distant-site physician or practitioner.

(4) When telemedicine services are furnished to the REH's patients through an agreement with a distant-site telemedicine entity, the governing body of the REH whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the REH's governing body ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity furnishes services that, in accordance with paragraph (d) of this section, permit the REH to comply with all applicable conditions of participation for the contracted services. The REH's governing body must also ensure, through its written

agreement with the distant-site telemedicine entity, that all of 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 § 485.510(a)(1) through (7) and paragraphs (a)(1) and (2) 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 the REH with a current list 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 REH whose patients are receiving such telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the REH whose patients are receiving the telemedicine services, the REH 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 performance 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 REH's patients, and all complaints the REH has received about the distant-site physician or practitioner.

(b) *Standard: Medical staff organization and accountability.* The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to patients.

(1) The medical staff must be organized in a manner approved by the governing body.

(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(3) The responsibility for organization and conduct of the medical staff must be assigned only to one of the following:

(i) An individual doctor of medicine or osteopathy.

(ii) A doctor of dental surgery or dental medicine, when permitted by state law of the state in which the hospital is located.

(iii) A doctor of podiatric medicine, when permitted by state law of the state in which the hospital is located.

(4) If an REH is part of a system consisting of multiple separately certified hospitals, critical access hospitals, and/or REHs, and the system elects to have a unified and integrated medical staff for its member hospitals, critical access hospitals, and/or REHs after determining that such a decision is in accordance with all applicable state and local laws, each separately certified REH must demonstrate that:

(i) The medical staff members of each separately certified REH in the system (that is, all medical staff members who hold specific privileges to practice at that REH) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective REH;

(ii) The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified REH (that is, all medical staff members who hold specific privileges to practice at that REH) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their REH;

(iii) The unified and integrated medical staff is established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each hospital, critical access hospital (CAH), and REH; and

(iv) The unified and integrated medical staff establishes and implements

policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, CAHs, and REHs, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals, CAHs, and REHs are duly considered and addressed.

(c) *Standard: Medical staff bylaws.* The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

(1) Be approved by the governing body.

(2) Include a statement of the duties and privileges of each category of medical staff (for example, active, courtesy, etc.).

(3) Describe the organization of the medical staff.

(4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

(5) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the REH, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in §485.510(a)(8) and (9) and paragraphs (a)(3) and (4) of this section.

§485.514 Condition of participation: Provision of services.

(a) The REH's health care services must be furnished in accordance with appropriate written policies that are consistent with applicable state law.

(b) The policies must be developed with the advice of members of the REH's professional health care 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 §485.528(b)(1).

(c) The policies must include the following:

(1) A description of the services the REH furnishes, including those furnished through agreement or arrangement.

(2) Policies and procedures for emergency medical services.

(3) 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 REH.

(4) Policies and procedures that address the post-acute care needs of patients receiving services in the REH.

(d) The policies must be reviewed at least biennially by the group of professional personnel required under paragraph (b) of this section and updated as necessary by the REH.

§485.516 Condition of participation: Emergency services.

The REH must provide the emergency care necessary to meet the needs of its patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and direction.* The emergency services of the REH must be—

(1) Organized under the direction of a qualified member of the medical staff; and

(2) Integrated with other departments of the REH.

(b) *Standard: Personnel.* There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

(c) *Standard: Compliance with CAH requirements.* The REH must meet the requirements specified in §485.618, with respect to:

(1) 24-hour availability of emergency services (§485.618(a)).

(2) Equipment, supplies, and medication (§485.618(b)).

(3) Blood and blood products (§485.618(c)).

(4) Personnel (§485.618(d)).

(5) Coordination with emergency response systems (§485.618(e)).

§ 485.518 Condition of participation: Laboratory services.

The REH must provide basic laboratory services essential to the immediate diagnosis and treatment of the patient consistent with nationally recognized standards of care for emergency services, patient population, and services offered. The REH must ensure that—

(a) Laboratory services are available, either directly or through a contractual agreement with a certified laboratory that meets requirements of part 493 of this chapter.

(b) Emergency laboratory services are available 24 hours a day.

§ 485.520 Condition of participation: Radiologic services.

The REH must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, the therapeutic services, as well as the diagnostic services, must be furnished by the REH and provided by personnel qualified under state law. The REH must ensure that REH patients or personnel are not exposed to radiation hazards.

(a) *Standard: Radiologic services.* The REH must maintain, or have available, radiologic services according to needs of the patients.

(b) *Standard: Safety for patients and personnel.* The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

(1) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with state law, of other practitioners authorized by the medical staff and the governing body to order the services.

(c) *Standard: Personnel.* (1) The REH must have a full-time, part-time, or consulting qualified radiologist, or other personnel qualified under State law, to interpret only those radiologic tests that are determined by the medical staff to require specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

(d) *Standard: Records.* Records of radiologic services must be maintained.

(1) The radiologist or other practitioner who performs radiology services must sign reports of their interpretations.

(2) The REH must maintain the following for at least 5 years:

(i) Copies of reports and printouts.

(ii) Films, scans, and other image records, as appropriate.

§ 485.522 Condition of participation: Pharmaceutical services.

The REH must have pharmaceutical services that meet the needs of its patients. The REH must have a pharmacy or a drug storage area that is directed by a registered pharmacist or other qualified individual in accordance with state scope of practice laws. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the REH's registered pharmacist or other qualified individual.

(a) *Standard: Pharmacy management and administration.* The pharmacy or drug storage area must be administered in accordance with accepted professional principles and in accordance with state and Federal laws.

(1) A pharmacist or competent individual in accordance with state scope of practice laws must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacist or competent individual in accordance with state law and scope of practice must be available for a sufficient time to provide oversight of the REH's pharmacy

services based on the scope and complexity of the services offered at the REH.

(2) The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services for the provision of all services provided by the REH.

(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

(b) *Standard: Delivery of services.* Drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and state law, to ensure patient safety.

(1) All compounding, packaging, and dispensing of drugs must be done by a licensed pharmacist or a licensed physician, or under the supervision of a pharmacist or competent individual in accordance with state law and scope of practice and performed consistent with state and Federal laws.

(2) All drugs and biologicals must be kept in a secure area, and locked when appropriate.

(i) All drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 *et seq.*) must be kept locked within a secure area.

(ii) Only authorized personnel may have access to locked areas.

(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

(4) Drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and state law.

(c) *Standard: Administration of drugs.* Drugs must be prepared and administered according to established policies and acceptable standards of practice.

(1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.

(2) Blood transfusions, blood products, and intravenous medications must be administered in accordance with state law and approved medical staff policies and procedures.

(3) Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician or other authorized prescriber.

(4) There must be an REH procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

§ 485.524 Condition of participation: Additional outpatient medical and health services.

If the REH provides outpatient medical and health services in addition to providing emergency services and observation care, the medical and health services must be appropriately organized and meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Patient services.* The REH may provide outpatient and medical health diagnostic and therapeutic items and services that are commonly furnished in a physician's office or at another entry point into the health care delivery system that include, but are not limited to, radiology, laboratory, outpatient rehabilitation, surgical, maternal health, and behavioral health services. If the REH provides outpatient and medical health diagnostic and therapeutic items and services, those items and services must align with the health needs of the community served by the REH. If the REH provides outpatient medical and health services in addition to providing emergency services, the REH must—

(1) Provide items and services based on nationally recognized guidelines and standards of practice;

(2) Have a system in place for referral from the REH to different levels of care, including follow-up care, as appropriate;

(3) Have effective communication systems in place between the REH and the patient (or responsible individual) and their family, ensuring that the REH is responsive to their needs and preferences;

(4) Have established relationships with hospitals that have the resources and capacity available to deliver care that is beyond the scope of care delivered at the REH; and

(5) Have personnel providing these services who meet the requirements at paragraph (b) of this section.

(b) *Standard:* Personnel for additional outpatient and medical health services. The REH must—

(1) Assign one or more individuals to be responsible for outpatient services.

(2) Have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.

(3) For any specialty services offered at the REH, have a doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant providing services with experience and training in the specialty service area and in accordance with their scope of practice.

(c) Standard: Orders for outpatient medical and health services. Outpatient medical and health services must be ordered by a practitioner who meets the following conditions:

(1) Is responsible for the care of the patient.

(2) Is licensed in the state where they provide care to the patient.

(3) Is acting within their scope of practice under state law.

(4) Is authorized in accordance with state law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services. This applies to the following:

(i) All practitioners who are appointed to the REH's medical staff and who have been granted privileges to order the applicable outpatient services.

(ii) All practitioners not appointed to the medical staff, but who satisfy the requirements of paragraphs (c)(1) through (4) of this section for authorization by the medical staff and the REH for ordering the applicable outpatient services for their patients.

(d) *Standard: Surgical services.* If the REH provides outpatient 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 REH in accordance with the designation requirements under paragraph (a) of this section.

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

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

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

(iii) A doctor of podiatric medicine.

(2) Anesthetic risk and evaluation. (i) 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.

(ii) A qualified practitioner, as specified in paragraph (d)(3) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

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

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

(i) Anesthesia must be administered by only—

(A) A qualified anesthesiologist;

(B) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

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

(D) A doctor of podiatric medicine;

(E) A certified registered nurse anesthetist (CRNA), as defined in §410.69(b) of this chapter;

(F) An anesthesiologist's assistant, as defined in §410.69(b) of this chapter; or

(G) A supervised trainee in an approved educational program, as described in §413.85 or §§413.76 through 413.83 of this chapter.

(ii) In those cases in which a CRNA administers the anesthesia, the anesthetist 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.

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

(5) *Standard: State exemption.* (i) An REH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (d)(3) of this section, if the state in which the REH is located submits a letter to CMS signed by the Governor, following consultation with the state's Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that they have 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.

(ii) 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.

§ 485.526 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

The REH must have active facility-wide programs for the surveillance, prevention, and control of healthcare-associated infections (HAIs) and other infectious diseases, and for the optimization of antibiotic use through stewardship. The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in collaboration with the facility-wide quality assessment and performance improvement (QAPI) program.

(a) *Standard: Infection prevention and control program organization and policies.* The REH must demonstrate that:

(1) An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is appointed by the governing body, or responsible individual, as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership;

(2) The infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the REH and between the REH and other health care settings;

(3) The infection prevention and control program include surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and that the program also addresses any infection control issues identified by public health authorities; and

(4) The infection prevention and control program reflects the scope and complexity of the services furnished by the REH.

(b) *Standard: Antibiotic stewardship program organization and policies.* The REH must demonstrate that —

(1) An individual (or individuals), who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body, or responsible individual, as the leader(s) of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership;

(2) The facility-wide antibiotic stewardship program:

(i) Demonstrates coordination among all components of the REH responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff,

nursing services, and pharmacy services;

(ii) Documents the evidence-based use of antibiotics in all departments and services of the REH; and

(iii) Documents any improvements, including sustained improvements, in proper antibiotic use;

(3) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use; and

(4) The antibiotic stewardship program reflects the scope and complexity of the services furnished by an REH.

(c) *Standard: Leadership responsibilities.* (1) The governing body, or responsible individual, must ensure all of the following:

(i) Systems are in place and operational for the tracking of all infection surveillance, prevention and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities.

(ii) All HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with the REH's QAPI leadership.

(2) The infection prevention and control professional(s) are responsible for:

(i) The development and implementation of facility-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.

(ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.

(iii) Communication and collaboration with the REH's QAPI program on infection prevention and control issues.

(iv) Competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the practical applications of infection prevention and control guidelines, policies and procedures.

(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by REH personnel.

(vi) Communication and collaboration with the antibiotic stewardship program.

(3) The leader(s) of the antibiotic stewardship program is responsible for:

(i) The development and implementation of a facility-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.

(ii) All documentation, written or electronic, of antibiotic stewardship program activities.

(iii) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as the REH's infection prevention and control and QAPI programs, on antibiotic use issues.

(iv) Competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

(d) *Standard:Unified and integrated infection prevention and control and antibiotic stewardship programs for multi-facility systems.* If a REH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities after determining that such a decision is in accordance with all applicable state and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified REHs meets all of the requirements of this section. Each separately certified REH subject to the system governing body must demonstrate that:

(1) The unified and integrated infection prevention and control and antibiotic stewardship programs are established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each REH;

(2) The unified and integrated infection prevention and control and antibiotic stewardship programs establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified REHs, regardless of practice or location, are given due consideration;

(3) The unified and integrated infection prevention and control and antibiotic stewardship programs have mechanisms in place to ensure that issues localized to particular REHs are duly considered and addressed; and

(4) A qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship has been designated at the REH as responsible for communicating with the unified infection prevention and control and antibiotic stewardship programs, for implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs, and for providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to REH staff.

(e) *COVID–19 and seasonal influenza reporting.* Beginning at the conclusion of the COVID–19 Public Health Emergency, as defined in §400.200 of this chapter, and continuing until April 30, 2024, except when the Secretary specifies an earlier end date for the requirements of this paragraph (e), the REH must electronically report information about COVID–19 and seasonal influenza in a standardized format specified by the Secretary.

(1) Related to COVID–19, to the extent as required by the Secretary, this report must include the following data elements:

(i) Suspected and confirmed COVID–19 infections among patients and staff.

(ii) Total COVID–19 deaths among patients and staff.

(iii) Personal protective equipment and testing supplies.

(iv) Ventilator use, capacity, and supplies.

(v) Total patient census and capacity.

(vi) Staffing shortages.

(vii) COVID–19 vaccine administration data of patients and staff.

(viii) Relevant therapeutic inventories or usage, or both.

(2) Related to seasonal influenza, to the extent as required by the Secretary, this report must include the following data elements:

(i) Confirmed influenza infections among patients and staff.

(ii) Total influenza deaths among patients and staff.

(iii) Confirmed co-morbid influenza and COVID–19 infections among patients and staff.

(f) *Standard: Reporting of data related to viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential.* The REH must electronically report information on acute respiratory illness (including, but not limited to, seasonal influenza virus, influenza-like illness, and severe acute respiratory infection), SARS-CoV–2/COVID–19, and other viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential only when the Secretary has declared a Public Health Emergency (PHE), as defined in §400.200 of this chapter, directly related to such specific pathogens and infectious diseases. The requirements of this paragraph (f) will be applicable to local, state, regional, or national PHEs as declared by the Secretary.

(1) The REH must electronically report information about the infectious disease pathogen, relevant to the declared PHE, in a standardized format specified by the Secretary. To the extent as required by the Secretary, this report must include, the following:

(i) Suspected and confirmed infections of the relevant infectious disease pathogen among patients and staff.

(ii) Total deaths attributed to the relevant infectious disease pathogen among patients and staff.

(iii) Personal protective equipment and other relevant supplies in the REH.

(iv) Capacity and supplies in the REH relevant to the immediate and long term treatment of the relevant infectious disease pathogen, such as ventilator and dialysis/continuous renal replacement therapy capacity and supplies.

(v) Total patient census, capacity, and capability.

(vi) Staffing shortages.

(vii) Vaccine administration data of patients and staff for conditions monitored under this section and where a specific vaccine is applicable.

(viii) Relevant therapeutic inventories or usage, or both.

(ix) Isolation capacity, including airborne isolation capacity.

(x) Key co-morbidities or exposure risk factors, or both, of patients being treated for the pathogen or disease of interest in this section that are captured with interoperable data standards and elements.

(2) Unless the Secretary specifies an alternative format by which the REH must report these data elements, the REH must report the applicable infection (confirmed and suspected) and vaccination data in a format that provides person-level information, which must include medical record identifier, race, ethnicity, age, sex, residential county and zip code, and relevant comorbidities for affected patients. Facilities must not report any directly or potentially individually-identifiable information for affected patients (for example, name, social security number) that is not set out in this section or otherwise specified by the Secretary.

(3) The REH must provide the information specified in this paragraph (f) on a daily basis, unless the Secretary specifies a lesser frequency, to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network or other CDC-supported surveillance systems as determined by the Secretary.

(g) *Standard: COVID–19 vaccination of REH staff.* Until November 4, 2024, unless the Secretary specifies an earlier end date for the requirements of this paragraph (g), the REH must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following REH staff, who provide any care, treatment, or other services for the REH and/or its patients:

(i) REH employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the REH and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following REH staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the REH setting and who do not have any direct contact with patients and other staff specified in paragraph (f)(1) of this section; and

(ii) Staff who provide support services for the REH that are performed exclusively outside of the REH setting and who do not have any direct contact with patients and other staff specified in paragraph (f)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (f)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine prior to staff providing any care, treatment, or other services for the REH and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (f)(1) of this section are fully vaccinated for COVID–19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination

must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID–19, for all staff who are not fully vaccinated for COVID–19;

(iv) A process for tracking and securely documenting the COVID–19 vaccination status of all staff specified in paragraph (f)(1) of this section;

(v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the REH has granted, an exemption from the staff COVID–19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable state and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the REH's COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID–19.

§ 485.528 Condition of participation: Staffing and staff responsibilities.

(a) *Standard: Emergency department staffing.* The emergency department of the REH must be staffed 24 hours a day, 7 days a week by an individual or individuals competent in the skills needed to address emergency medical care. This individual(s) must be able to receive patients and activate the appropriate medical resources to meet the care needed by the patient.

(b) *Standard: Staffing.* (1) The REH must have 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 REH.

(4) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the REH has one or more patients receiving emergency care or observation care.

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

(i) Provide medical direction for the REH'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), participate in developing, executing, and periodically reviewing the REH's written policies governing the services it furnishes.

(iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically review the REH's patient records, provide medical

orders, and provide medical care services to the patients of the REH.

(iv) Periodically review and sign 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 where state law requires record reviews or co-signatures, or both, by a collaborating physician.

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

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

(i) Participate in the development, execution and periodic review of the written policies governing the services the REH 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 REH's policies.

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

(3) Whenever a patient is placed in observation care at the REH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the REH is notified of the patient's status.

(e) *Standard: Periodic review of clinical privileges and performance.* The REH requires that —

(1) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the REH must be evaluated by a member of the REH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the REH.

(2) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the REH must be evaluated by one of the following —

(i) One Quality Improvement Organization (QIO) or equivalent entity.

(ii) In the case of distant-site physicians and practitioners providing telemedicine services to the REH's patient under an agreement between the REH and a distant-site hospital, the distant-site hospital; or

(iii) In the case of distant-site physicians and practitioners providing telemedicine services to the REH's patients under a written agreement between the REH and a distant-site telemedicine entity, one Quality Improvement Organization (QIO) or equivalent entity.

(3) The REH staff consider the findings of the evaluation and make the necessary changes as specified in paragraphs (b) through (d) of this section.

§ 485.530 Condition of participation: Nursing services.

The REH must have an organized nursing service that is available to provide 24-hour nursing services for the provision of patient care. The nursing services must be furnished and supervised by a registered nurse. Nursing services must meet the needs of patients.

(a) *Standard: Organization and staffing.* Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice.

(b) *Standard: Nursing leadership.* The director of the nursing service must be a licensed registered nurse. The individual is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the REH.

§ 485.532 Condition of participation: Discharge planning.

An REH must have an effective discharge planning process that focuses on the patient's goals and treatment preferences and includes the patient and their caregivers/support person(s) as active partners in the discharge planning for post-discharge care. The discharge planning process and the discharge plan must be consistent with the patient's goals for care and their treatment preferences, ensure an effective transition of the patient from the REH to post-discharge care, and reduce the factors leading to preventable hospital admissions or readmissions.

(a) *Standard: Discharge planning process.* The REH's discharge planning process must identify, at an early stage of the provision of services, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning and must provide a discharge planning evaluation for those patients so identified as well as for other patients upon the request of the patient, patient's representative, or patient's physician.

(1) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-REH care will be made before discharge and to avoid unnecessary delays in discharge.

(2) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate services following those furnished by the REH, including, but not limited to, hospice care services, post-REH extended care services, home health services, and non-health care services and community-based care providers, and must also include a determination of the availability of the appropriate services as well as of the patient's access to those services.

(3) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

(4) Upon the request of a patient's physician, the REH must arrange for the development and initial implementation of a discharge plan for the patient.

(5) Any discharge planning evaluation or discharge plan required under this paragraph (a) must be developed by, or under the supervision of, a registered nurse, social worker, or other appropriately qualified personnel.

(6) The REH's discharge planning process must require regular re-evaluation of the patient's condition to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.

(7) The REH must assess its discharge planning process on a regular basis. The assessment must include ongoing periodic review of a representative sample of discharge plans.

(8) The REH must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, home health agency (HHA), skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), or long term care hospital (LTCH) data on quality measures and data on resource use measures. The REH must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

(b) *Standard: Discharge of the patient and provision and transmission of the patient's necessary medical information.* The REH must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.

§ 485.534 Condition of participation: Patient's rights.

An REH must protect and promote each patient's rights.

(a) *Standard: Notice of rights.* (1) An REH must inform each patient, or when appropriate, the patient's representative (as allowed under state law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(2) The REH must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The REH's governing body or responsible individual must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

(i) The REH must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the REH.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance, the REH must provide the patient with written notice of its decision that contains the name of the REH contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(b) *Standard: Exercise of rights.* The patient has the right to—

(1) Participate in the development and implementation of their plan of care.

(2) Make informed decisions regarding their care, including being informed of their health status, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) Formulate advance directives and to have REH staff and practitioners who provide care in the REH comply with these directives, in accordance with §§ 489.100, 489.102, and 489.104 of this chapter.

(c) *Standard: Privacy and safety.* The patient has the right to—

(1) Personal privacy.

(2) Receive care in a safe setting.

(3) Be free from all forms of abuse or harassment.

(d) *Standard: Confidentiality of patient records.* (1) The patient has the right to the confidentiality of their medical records.

(2) The patient has the right to access their medical records, including current medical records, upon an oral or written request.

(i) The records must be provided in the form and format requested by the individual, if it is readily producible in such form and format. This includes in an electronic form or format when such medical records are maintained electronically or if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual.

(ii) The records must be provided within a reasonable time frame. The REH must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

(e) *Standard: Restraint or seclusion.* All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(1)(i) A *restraint is*—

(A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move their arms, legs, body, or head freely; or

(B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

(C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, off of a stretcher, or out of a chair, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

(ii) *Seclusion* is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

(2) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member or others from harm.

(3) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

(4) The REH must have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice.

(f) *Standard: Restraint or seclusion: Staff training requirements.* The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) The REH must provide patient-centered competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the use of restraint and seclusion.

(2) The training must include alternatives to the use of restraint/seclusion.

(g) *Standard: Death reporting requirements.* REHs must report deaths associated with the use of seclusion or restraint.

(1) With the exception of deaths described under paragraph (g)(2) of this section, the REH must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death:

(i) Each death that occurs while a patient is in restraint or seclusion.

(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the REH that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. ''Reasonable to assume'' in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, nonrigid, cloth-like materials, the REH staff must record in an internal log or other system, the following information:

(i) Any death that occurs while a patient is in such restraints.

(ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.

(3) The staff must document in the patient's medical record the date and time the death was:

(i) Reported to CMS for deaths described in paragraph (g)(1) of this section; or

(ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section.

(4) For deaths described in paragraph (g)(2) of this section, entries into the internal log or other system must be documented as follows:

(i) Each entry must be made not later than seven days after the date of death of the patient.

(ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is responsible for the care of the patient, medical record number, and primary diagnosis(es).

(iii) The information must be made available in either written or electronic form to CMS immediately upon request.

(h) *Standard: Patient visitation rights.* An REH 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 REH may need to place on such rights and the reasons for the clinical restriction or limitation. An REH must meet the following requirements:

(1) Inform each patient (or support person, where appropriate) of their visitation rights, including any clinical restriction or limitation on such rights, when they are informed of their other rights under this section.

(2) Inform each patient (or support person, where appropriate) of the right, subject to their consent, to receive the visitors whom they designate, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and their 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.

§ 485.536 Condition of participation: Quality assessment and performance improvement program.

The REH must develop, implement, and maintain an effective, ongoing, REH-wide, data-driven quality assessment and performance improvement (QAPI) program. The REH's governing body must ensure that the program reflects the complexity of the REH's organization and services; involves all REH departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The REH must maintain and demonstrate evidence of its QAPI program for review by CMS.

(a) *Standard: Program scope.* (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.

(2) The REH must measure, analyze, and track quality indicators, including adverse patient events, staffing, and other aspects of performance that assess processes of care including REH service and operations.

(b) *Standard: Program data collection and analysis.* The program must incorporate quality indicator data including patient care data, and other relevant data, in order to achieve the goals of the QAPI program.

(c) *Standard: Program activities.* (1) The REH must set priorities for its performance improvement activities that—

(i) Focus on high-risk, high-volume, or problem-prone areas;

(ii) Consider the incidence, prevalence, and severity of problems in those areas; and

(iii) Affect health outcomes, patient safety, and quality of care.

(2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the REH. An adverse patient event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. Medical error means an error that occurs in the delivery of health care services.

(3) The REH must take actions aimed at performance improvement and, after implementing those actions, the REH must measure its success, and track performance to ensure that improvements are sustained.

(d) *Standard: Executive responsibilities.* The REH's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the REH), medical staff, and administrative officials are responsible and accountable for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.

(2) That the REH-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.

(3) That clear expectations for safety are established.

(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the REH's performance and reducing risk to patients.

(e) *Standard: Unified and integrated QAPI program for an REH in a multi-facility system.* If an REH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have a unified and integrated QAPI program for all of its member facilities after determining that such a decision is in accordance with all applicable state and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified REHs meets all of the requirements of this section. Each separately certified REH subject to the system governing body must demonstrate that—

(1) The unified and integrated QAPI program is established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each REH; and

(2) The unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified REHs, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular REHs are duly considered and addressed.

§ 485.538 Condition of participation: Agreements.

The REH must have in effect an agreement with at least one certified hospital that is a level I or level II trauma center for the referral and transfer of patients requiring emergency medical care beyond the capabilities of the REH that is—

(a) Licensed as a hospital in a state that provides for the licensing of hospitals under state or applicable local law or approved by the agency of such state or locality responsible for licensing hospitals, as meeting standards established for licensing established by the agency of the state; and

(b) Licensed or designated by the state or local government authority as level I or level II trauma center or is verified by the American College of Surgeons as a level I or level II trauma center.

§ 485.540 Condition of participation: Medical records.

(a) *Standard: Records system.* (1) The REH must maintain a medical records system in accordance with written policies and procedures.

(2) The records must be 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 REH must maintain 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 patient'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 REH must maintain the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

(2) The REH must have written policies and procedures that govern the use and removal of records from the REH 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 must be retained for at least 5 years from date of last entry, and longer if required by state statute, or if the records may be needed in any pending proceeding.

(d) *Standard: Electronic notifications.* If the REH utilizes an electronic medical records system or other electronic administrative system, which is conformant with the content exchange standard at 45 CFR 170.205(d)(2), then the REH must demonstrate that—

(1) The system's notification capacity is fully operational and the REH uses it in accordance with all state and Federal statutes and regulations applicable to the REH's exchange of patient health information.

(2) The system sends notifications that must include at least patient name, treating practitioner name, and sending institution name.

(3) To the extent permissible under applicable Federal and state law and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, at the time of the patient's registration in the REH's emergency department.

(4) To the extent permissible under applicable Federal and state law and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, either immediately prior to, or at the time the patient's discharge or transfer from the REH's emergency department.

(5) The REH has made a reasonable effort to ensure that the system sends the notifications to all applicable post-acute care services providers and suppliers, as well as to any of the following practitioners and entities, which need to receive notification of the patient's status for treatment, care coordination, or quality improvement purposes:

(i) The patient's established primary care practitioner;

(ii) The patient's established primary care practice group or entity; or

(iii) Other practitioner, or other practice group or entity, identified by the patient as the practitioner, or practice group or entity, primarily responsible for their care.

§ 485.542 Condition of participation: Emergency preparedness.

The REH must comply with all applicable Federal, state, and local emergency preparedness requirements. The REH must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The REH must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do 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, the type of services the REH 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.

(b) *Policies and procedures.* The REH 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 every 2 years. 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 REH's care during an emergency. If on-duty staff or sheltered patients are relocated during the emergency, the REH must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the REH, which includes the following:

(i) Consideration of care and treatment needs of evacuees.

(ii) Staff responsibilities.

(iii) Transportation.

(iv) Identification of evacuation location(s).

(v) 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 REH.

(5) A system of medical documentation that does the following:

(i) Preserves patient information.

(ii) Protects confidentiality of patient information.

(iii) Secures and maintains the availability of records.

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

(7) The role of the REH 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 REH 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 every 2 years. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) 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) REH'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 REH'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 REH's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The REH 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 every 2 years.

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

(i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least every 2 years.

(iii) Maintain documentation of all emergency preparedness training.

(iv) Demonstrate staff knowledge of emergency procedures.

(v) If the emergency preparedness policies and procedures are significantly updated, the REH must conduct training on the updated policies and procedures.

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

(i) Participate in a full-scale exercise that is community-based every 2 years.

(A) When a community-based exercise is not accessible, conduct a facility-based functional exercise every 2 years; or

(B) If the REH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the REH is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

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

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion 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 REH's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the REH's emergency plan, as needed.

(e) *Emergency and standby power systems.* The REH 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 REH 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.* REHs 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 an REH 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 REH may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must—

(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.

(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 the following:

(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) *Incorporation by reference.* The material listed in this paragraph (g) is incorporated by reference into this section with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, CMS must publish a document in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at CMS and the National Archives and Records Administration (NARA). Contact CMS at: CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD, email: *scott.cooper@cms.hhs.gov* or call (410) 786–9465. For information on the availability of this material at NARA, email: *fr.inspection@nara.gov*, or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html*. The material may be obtained from the following source(s) in this paragraph (g):

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

(2) [Reserved]

[87 FR 72293, Nov. 23, 2022; 88 FR 299, Jan. 4, 2023]

§ 485.544 Condition of participation: Physical environment.

The REH must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special services appropriate to the needs of the community.

(a) *Standard: Buildings.* The condition of the physical plant and the overall REH environment must be developed and maintained in such a manner that the safety and well-being of patients are ensured.

(1) There must be emergency power and lighting in at least the operating, recovery, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

(2) There must be facilities for emergency gas and water supply.

(3) The REH must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.

(b) *Standard: Facilities.* The REH must maintain adequate facilities for its services.

(1) Diagnostic and therapeutic facilities must be located for the safety of patients.

(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

(3) The extent and complexity of facilities must be determined by the services offered.

(4) There must be proper ventilation, light, and temperature controls in patient care, pharmaceutical, food preparation, and other appropriate areas.

(c) *Standard: Safety from fire.* (1) Except as otherwise provided in this section, the REH must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served, 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).

(2) In consideration of a recommendation by the state survey agency or accrediting organization or at the discretion of the Secretary, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon an REH, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a state if CMS finds that a fire and safety code imposed by state law adequately protects patients in an REH.

(4) An REH may place alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

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

(d) *Standard: Building safety.* Except as otherwise provided in this section, the REH must meet the applicable provisions and must proceed in accordance with the 2012 edition of 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 an REH.

(2) If application of the Health Care Facilities Code required under paragraph (d) of this section would result in unreasonable hardship for the REH, 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.

(e) *Incorporation by reference.* The material listed in this paragraph (e) is incorporated by reference into this section with the approval the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, CMS must publish a document in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at CMS and the National Archives and Records Administration (NARA). Contact CMS at: CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD, email *scott.cooper@cms.hhs.gov* or call (410) 786–9465. For information on the availability of this material at NARA, email *fr.inspection@nara.gov* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html*. The material may be obtained from the following source(s) in this paragraph (e).

(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.
(2) [Reserved]

§ 485.546 Condition of participation: Skilled nursing facility distinct part unit.

If the REH provides skilled nursing facility services in a distinct part unit, the services furnished by the distinct part unit must be separately licensed and certified and comply with the requirements of participation for long-term care facilities specified in part 483, subpart B, of this chapter.

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
(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.* (1) The CAH is located more than a 35-mile drive on primary roads

(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.

(2) Primary roads of travel for determining the driving distance of a CAH and its proximity to other providers is defined as:

(i) A numbered Federal highway, including interstates, intrastates, expressways, or any other numbered Federal highway with 2 or more lanes each way; or

(ii) A numbered State highway with 2 or more lanes each way.

(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 on primary roads, as defined in paragraph (c)(2) of this section (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; 87 FR 72307, Nov. 23, 2022; 88 FR 299, Jan. 4, 2023]

§ 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]

§ 485.614 Condition of participation: Patient's rights.

A CAH must protect and promote each patient's rights.

(a) *Standard: Notice of rights.* (1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under state law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(b) *Standard: Exercise of rights.* (1) The patient has the right to participate in the development and implementation of their plan of care.

(2) The patient or their representative (as allowed under state law) has the right to make informed decisions regarding their care. The patient's rights include being informed of their health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with §§ 489.100, 489.102, and 489.104 of this chapter.

(4) The patient has the right to have a family member or representative of their choice and their own physician notified promptly of their admission to the hospital.

(c) *Standard: Privacy and safety.* (1) The patient has the right to personal privacy.

(2) The patient has the right to receive care in a safe setting.

(3) The patient has the right to be free from all forms of abuse or harassment.

(d) *Standard: Confidentiality of patient records.* (1) The patient has the right to the confidentiality of their clinical records.

(2) The patient has the right to access their medical records, including current medical records, upon an oral or written request, in the form and format requested by the individual, if it is readily producible in such form and

format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, and within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

(e) *Standard: Restraint or seclusion.* All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(1)(i) A restraint is—

(A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move their arms, legs, body, or head freely; or

(B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

(C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

(ii) *Seclusion* is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

(2) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient a staff member or others from harm.

(3) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

(4) The CAH must have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice.

(f) *Standard: Restraint or seclusion: Staff training requirements.* The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) The CAH must provide patient-centered, trauma informed competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAH, on the use of restraint and seclusion.

(2) The training must include alternatives to the use of restraint/seclusion.

(g) *Standard: Death reporting requirements.* Hospitals must report deaths associated with the use of seclusion or restraint.

(1) With the exception of deaths described under paragraph (g)(2) of this section, the hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death:

(i) Each death that occurs while a patient is in restraint or seclusion.

(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. ''Reasonable to assume'' in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or

death related to chest compression, restriction of breathing, or asphyxiation.

(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, nonrigid, cloth-like materials, the hospital staff must record in an internal log or other system, the following information:

(i) Any death that occurs while a patient is in such restraints.

(ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.

(3) The staff must document in the patient's medical record the date and time the death was:

(i) Reported to CMS for deaths described in paragraph (g)(1) of this section; or

(ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section.

(4) For deaths described in paragraph (g)(2) of this section, entries into the internal log or other system must be documented as follows:

(i) Each entry must be made not later than seven days after the date of death of the patient.

(ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is responsible for the care of the patient, medical record number, and primary diagnosis(es).

(iii) The information must be made available in either written or electronic form to CMS immediately upon request.

(h) *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.

[87 FR 72307, 72309, Nov. 23, 2022]

§ 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 recommendations 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, antiarrythmics, 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: 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 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.

(d) *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.

(e) 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; 81 FR 64036, Sept. 16, 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 every 2 years. 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.

(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 every 2 years. 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 every 2 years. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(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 every 2 years.

(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 every 2 years.

(iii) Maintain documentation of the training.

(iv) Demonstrate staff knowledge of emergency procedures.

(v) If the emergency preparedness policies and procedures are significantly updated, the CAH must conduct training on the updated policies and procedures.

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

(i) Participate in an annual full-scale exercise that is community-based; or

(A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or.

(B) 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 its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.

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

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

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, 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) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

(2) [Reserved]

[81 FR 64036, Sept. 16, 2016; 81 FR 80594, Nov. 16, 2016, as amended at 84 FR 51826, Sept. 30, 2019]

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

(2) The person responsible for medical direction.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 84 FR 51827, Sept. 30, 2019]

§ 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—

(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.

(d) *Standard: Periodic review of clinical privileges and performance.* The CAH requires that—

(1) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialist, 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.

(2) 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 Quality Improvement Organization (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 patient under an 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 (d)(2)(i) through (iii) of this section.

(3) The CAH staff consider the findings of the evaluation and make the necessary changes as specified in paragraphs (b) through (d) of this section.

(e) *Standard: Unified and integrated medical staff for a CAH in a multi-facility system.* If a CAH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs, and the system elects to have a unified and integrated medical staff for its member hospitals, CAHs, and/or REHs after determining that such a decision is in accordance with all applicable state and local laws, each separately certified CAH must demonstrate that:

(1) The medical staff members of each separately certified CAH in the system (that is, all medical staff members who hold specific privileges to practice at that CAH) have voted by majority, in accordance with medical

staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective CAH;

(2) The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified CAH (that is, all medical staff members who hold specific privileges to practice at that CAH) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their CAH;

(3) The unified and integrated medical staff is established in a manner that takes into account each member CAH's unique circumstances and any significant differences in patient populations and services offered in each hospital, CAH, and REH; and

(4) The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, CAHs, and REHs, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals, CAHs, and REHs are duly considered and addressed.

[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; 84 FR 51827, Sept. 30, 2019; 87 FR 72308, Nov. 23, 2022]

§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) Procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices. All patient diets, including therapeutic diets, must be ordered by the practitioner responsible for the care of the patients or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff in accordance with State law governing dietitians and nutrition professionals and that the requirement of §483.25(i) of this chapter is met with respect to inpatients receiving post CAH SNF care.

(vii) [Reserved]

(viii) Policies and procedures that address the post-acute care needs of patients receiving CAH services.

(4) These policies are reviewed at least biennially by the group of professional personnel required under paragraph (a)(2) of this section and updated 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. 263a). (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.

(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.

[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; 81 FR 68871, Oct. 4, 2016; 82 FR 32260, July 13, 2017; 84 FR 51827, 51883, Sept. 30, 2019; 87 FR 72309, Nov. 23, 2022]

§ 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 patient'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.

(d) *Standard: Electronic notifications*. If the CAH utilizes an electronic medical records system or other electronic administrative system, which is conformant with the content exchange standard at 45 CFR 170.205(d)(2), then the CAH must demonstrate that—

(1) The system's notification capacity is fully operational and the CAH uses it in accordance with all State and Federal statutes and regulations applicable to the CAH's exchange of patient health information.

(2) The system sends notifications that must include at least patient name, treating practitioner name, and sending institution name.

(3) To the extent permissible under applicable federal and state law and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, at the time of:

(i) The patient's registration in the CAH's emergency department (if applicable).

(ii) The patient's admission to the CAH's inpatient services (if applicable).

(4) To the extent permissible under applicable federal and state law and regulations, and not inconsistent with

the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, either immediately prior to, or at the time of:

(i) The patient's discharge or transfer from the CAH's emergency department (if applicable).

(ii) The patient's discharge or transfer from the CAH's inpatient services (if applicable).

(5) The CAH has made a reasonable effort to ensure that the system sends the notifications to all applicable post-acute care services providers and suppliers, as well as to any of the following practitioners and entities, which need to receive notification of the patient's status for treatment, care coordination, or quality improvement purposes:

(i) The patient's established primary care practitioner;

(ii) The patient's established primary care practice group or entity; or

(iii) Other practitioner, or other practice group or entity, identified by the patient as the practitioner, or practice group or entity, primarily responsible for his or her care.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 85 FR 25638, May 1, 2020]

§ 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.

(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 §§ 413.76 through 413.83 of this chapter.

(2) In those cases in which a CRNA administers the anesthesia, the anesthetist 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 exemption 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; 85 FR 72910, Nov. 16, 2020]

§ 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

The CAH must have active facility-wide programs, for the surveillance, prevention, and control of HAIs and other infectious diseases and for the optimization of antibiotic use through stewardship. The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in coordination with the facility-wide quality assessment and performance improvement (QAPI) program.

(a) *Standard: Infection prevention and control program organization and policies.* The CAH must demonstrate that:

(1) An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is appointed by the governing body, or responsible individual, as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership;

(2) The infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the CAH and between the CAH and other healthcare settings;

(3) The infection prevention and control includes surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and that the program also addresses any infection control issues identified by public health authorities; and

(4) The infection prevention and control program reflects the scope and complexity of the CAH services provided.

(b) *Standard: Antibiotic stewardship program organization and policies.* The CAH must demonstrate that:

(1) An individual (or individuals), who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body, or responsible individual, as the leader(s) of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership;

(2) The facility-wide antibiotic stewardship program:

(i) Demonstrates coordination among all components of the CAH responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services;

(ii) Documents the evidence-based use of antibiotics in all departments and services of the CAH; and

(iii) Documents any improvements, including sustained improvements, in proper antibiotic use;

(3) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use; and

(4) The antibiotic stewardship program reflects the scope and complexity of the CAH services provided.

(c) *Standard: Leadership responsibilities.* (1) The governing body, or responsible individual, must ensure all of the following:

(i) Systems are in place and operational for the tracking of all infection surveillance, prevention and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities.

(ii) All HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with the CAH's QAPI leadership.

(2) The infection prevention and control professional(s) is responsible for:

(i) The development and implementation of facility-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.

(ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.

(iii) Communication and collaboration with the CAH's QAPI program on infection prevention and control issues.

(iv) Competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAH, on the practical applications of infection prevention and control guidelines, policies and procedures.

(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by CAH personnel.

(vi) Communication and collaboration with the antibiotic stewardship program.

(3) The leader(s) of the antibiotic stewardship program is responsible for:

(i) The development and implementation of a facility-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.

(ii) All documentation, written or electronic, of antibiotic stewardship program activities.

(iii) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as the CAH's infection prevention and control and QAPI programs, on antibiotic use issues.

(iv) Competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAHs, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

(d) *COVID–19 reporting.* (1) During the Public Health Emergency, as defined in § 400.200 of this chapter, the CAH must report information in accordance with a frequency as specified by the Secretary on COVID–19 in a standardized format specified by the Secretary. This report must include, but not be limited to, the following data elements:

(i) The CAH's current inventory supplies of any COVID–19-related therapeutics that have been distributed and delivered to the CAH under the authority and direction of the Secretary; and

(ii) The CAH's current usage rate for any COVID–19-related therapeutics that have been distributed and delivered to the CAH under the authority and direction of the Secretary.

(2) Beginning at the conclusion of the COVID–19 Public Health Emergency, as defined in § 400.200 of this chapter, and continuing until April 30, 2024, except when the Secretary specifies an earlier end date for the requirements of this paragraph (d)(2), the CAH must electronically report information about COVID–19 in a standardized format specified by the Secretary. To the extent as required by the Secretary, this report must include the following data elements:

(i) Confirmed COVID–19 infections among patients.

(ii) Total deaths among patients.

(iii) Personal protective equipment and testing supplies.

(iv) Ventilator use, capacity, and supplies.

(v) Total bed and intensive care unit bed census and capacity.

(vi) Staffing shortages.

(vii) COVID–19 vaccine administration data of patients and staff.

(viii) Relevant therapeutic inventories or usage, or both.

(e) *Standard: Reporting of acute respiratory illness, including seasonal influenza virus, influenza-like illness, and severe acute respiratory infection.* (1) During the Public Health Emergency, as defined in §400.200 of this chapter, the CAH must report information, in accordance with a frequency as specified by the Secretary, on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) in a standardized format specified by the Secretary.

(2) Beginning at the conclusion of the COVID–19 Public Health Emergency, as defined in §400.200 of this chapter, and continuing until April 30, 2024, except when the Secretary specifies an earlier end date for the requirements of this paragraph (e)(2), the CAH must electronically report information about seasonal influenza in a standardized format specified by the Secretary. To the extent as required by the Secretary, this report must include the following data elements:

(i) Confirmed influenza infections among patients.

(ii) Total deaths among patients.

(iii) Confirmed co-morbid influenza and COVID–19 infections among patients.

(f) [Reserved]

(g) *Standard: Unified and integrated infection prevention and control and antibiotic stewardship programs for a CAH in a multi-facility system.* If a CAH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities after determining that such a decision is in accordance with all applicable state and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified CAHs meets all of the requirements of this section. Each separately certified CAH subject to the system governing body must demonstrate that:

(1) The unified and integrated infection prevention and control and antibiotic stewardship programs are established in a manner that takes into account each member CAH's unique circumstances and any significant differences in patient populations and services offered in each CAH;

(2) The unified and integrated infection prevention and control and antibiotic stewardship programs establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified CAHs, regardless of practice or location, are given due consideration;

(3) The unified and integrated infection prevention and control and antibiotic stewardship programs have mechanisms in place to ensure that issues localized to particular CAHs are duly considered and addressed; and

(4) A qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship has been designated at the CAH as responsible for communicating with the unified infection prevention and control and antibiotic stewardship programs, for implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs, and for providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to CAH staff.

[84 FR 51827, Sept. 30, 2019, as amended at 85 FR 54873, Sept. 2, 2020; 85 FR 86304, Dec. 29, 2020; 86 FR 61623, Nov. 5, 2021; 87 FR 49410, Aug. 10, 2022; 87 FR 72309, Nov. 23, 2022; 88 FR 36510, June 5, 2023]

EDITORIAL NOTE: At 85 FR 86304, Dec. 29, 2020, this section was amended, effective Dec. 4, 2020; however, due to a publication error, the amendments were codified at 86 FR 33902, June 28, 2021.

§ 485.641 Condition of participation: Quality assessment and performance improvement program.

The CAH must develop, implement, and maintain an effective, ongoing, CAH-wide, data-driven quality assessment and performance improvement (QAPI) program. The CAH must maintain and demonstrate evidence of the effectiveness of its QAPI program.

(a) *Definitions.* For the purposes of this section—

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof.

Error means the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems; and

Medical error means an error that occurs in the delivery of healthcare services.

(b) *Standard: QAPI Program Design and scope.* The CAH's QAPI program must:

(1) Be appropriate for the complexity of the CAH's organization and services provided.

(2) Be ongoing and comprehensive.

(3) Involve all departments of the CAH and services (including those services furnished under contract or arrangement).

(4) Use objective measures to evaluate its organizational processes, functions and services.

(5) Address outcome indicators related to improved health outcomes and the prevention and reduction of medical errors, adverse events, CAH-acquired conditions, and transitions of care, including readmissions.

(c) *Standard: Governance and leadership.* The CAH's governing body or responsible individual is ultimately responsible for the CAH's QAPI program and is responsible and accountable for ensuring that the QAPI program meets the requirements of paragraph (b) of this section.

(d) *Standard: Program activities.* For each of the areas listed in paragraph (b) of this section, the CAH must:

(1) Focus on measures related to improved health outcomes that are shown to be predictive of desired patient outcomes.

(2) Use the measures to analyze and track its performance.

(3) Set priorities for performance improvement, considering either high-volume, high-risk services, or problem-prone areas.

(e) *Standard: Program data collection and analysis.* The program must incorporate quality indicator data including patient care data, and other relevant data, in order to achieve the goals of the QAPI program.

(f) *Standard: Unified and integrated QAPI program for a CAH in a multi-facility system.* If a CAH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have a unified and integrated QAPI program for all of its member facilities after determining that such a decision is in accordance with all applicable state and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified CAHs meets all of the requirements of this section. Each separately certified CAH subject to the system governing body must demonstrate that:

(1) The unified and integrated QAPI program is established in a manner that takes into account each member CAH's unique circumstances and any significant differences in patient populations and services offered in each CAH; and

(2) The unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified CAHs, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular CAHs are duly considered and addressed.

[84 FR 51828, Sept. 30, 2019, as amended at 87 FR 72309, Nov. 23, 2022]

§ 485.642 Condition of participation: Discharge planning.

A Critical Access Hospital (CAH) must have an effective discharge planning process that focuses on the patient's goals and treatment preferences and includes the patient and his or her caregivers/support person(s) as active partners in the discharge planning for post-discharge care. The discharge planning process and the discharge plan must be consistent with the patient's goals for care and his or her treatment preferences, ensure an effective transition of the patient from the CAH to post-discharge care, and reduce the factors leading to preventable CAH and hospital readmissions.

(a) *Standard: Discharge planning process.* The CAH's discharge planning process must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning and must provide a discharge planning evaluation for those patients so identified as well as for other patients upon the request of the patient, patient's representative, or patient's physician.

(1) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-CAH care will be made before discharge and to avoid unnecessary delays in discharge.

(2) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-CAH services, including, but not limited to, hospice care services, post-CAH extended care services, home health services, and non-health care services and community based care providers, and must also include a determination of the availability of the appropriate services as well as of the patient's access to those services.

(3) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

(4) Upon the request of a patient's physician, the CAH must arrange for the development and initial implementation of a discharge plan for the patient.

(5) Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered nurse, social worker, or other appropriately qualified personnel.

(6) The CAH's discharge planning process must require regular re-evaluation of the patient's condition to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.

(7) The CAH must assess its discharge planning process on a regular basis. The assessment must include ongoing, periodic review of a representative sample of discharge plans, including those patients who were readmitted within 30 days of a previous admission, to ensure that the plans are responsive to patient post-discharge needs.

(8) The CAH must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The CAH must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

(b) *Standard: Discharge of the patient and provision and transmission of the patient's necessary medical information.* The CAH must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.

[84 FR 51883, Sept. 30, 2019]

§ 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 definition 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 provide post-CAH SNF care, as specified in § 409.30 of this chapter, and to be paid 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) Resident rights (§ 483.10(b)(7), (c)(1), (c)(2)(iii), (c)(6), (d), (e)(2) and (4), (f)(4)(ii) and (iii), (g)(8) and (17), (g)(18) introductory text, and (h) of this chapter).

(2) Admission, transfer, and discharge rights (§ 483.5 definition of transfer & discharge, § 483.15(c)(1), (c)(2), (c)(3), (c)(4), (c)(5), (c)(7), (c)(8), and (c)(9) of this chapter).

(3) Freedom from abuse, neglect and exploitation (§ 483.12(a)(1), (a)(2), (a)(3)(i), (a)(3)(ii), (a)(4), (b)(1), (b)(2), (c)(1), (c)(2), (c)(3), and (c)(4) of this chapter).

(4) Social services (§ 483.40(d) of this chapter).

(5) Comprehensive assessment, comprehensive care plan, and discharge planning (§ 483.20(b), and § 483.21(b) and (c)(2) 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).

(6) Specialized rehabilitative services (§ 483.65 of this chapter).

(7) Dental services (§ 483.55(a)(2), (3), (4), and (5) and (b) of this chapter).

(8) Nutrition (§ 483.25(g)(1) and (g)(2) 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; 81 FR 68871, Oct. 4, 2016; 82 FR 32260, July 13, 2017; 84 FR 51828, Sept. 30, 2019]

§ 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

(ii) Who (unless otherwise provided in this subpart) is on the premises if the person performing the function or activity does not meet the assistant-level practitioner qualifications specified in § 485.705.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988; 54 FR 38679, Sept. 20, 1989. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995; 73 FR 69941, Nov. 19, 2008]

§ 485.705 Personnel qualifications.

(a) *General qualification requirements.* Except as specified in paragraphs (b) and (c) of this section, all personnel who are involved in the furnishing of outpatient physical therapy, occupational therapy, and speech-language pathology services directly by or under arrangements with an organization must be legally authorized (licensed or, if applicable, certified or registered) to practice by the State in which they perform the functions or actions, and must act only within the scope of their State license or State certification or registration.

(b) *Exception for Federally defined qualifications.* The following Federally defined qualifications must be met:

(1) For a physician, the qualifications and conditions as defined in section 1861(r) of the Act and the requirements in part 484 of this chapter.

(2) *For a speech-language pathologist,* the qualifications specified in section 1861(11)(1) of the Act and the requirements in part 484 of this chapter.

(c) *Exceptions when no State Licensing laws or State certification or registration requirements exist.* If no State licensing laws or State certification or registration requirements exist for the profession, the following requirements must be met—

(1) An *administrator* is a person who has a bachelor's degree and:

(i) Has experience or specialized training in the administration of health institutions or agencies; or

(ii) Is qualified and has experience in one of the professional health disciplines.

(2) An *occupational therapist* must meet the requirements in part 484 of this chapter.

(3) *An occupational therapy assistant* must meet the requirements in part 484 of this chapter.

(4) A *physical therapist* must meet the requirements in part 484 of this chapter.

(5) A *physical therapist assistant* must meet the requirements in part 484 of this chapter.

(6) A *social worker* must meet the requirements in part 484 of this chapter.

(7) A *vocational specialist* is a person who has a baccalaureate degree and—

(i) Two years experience in vocational counseling in a rehabilitation setting such as a sheltered workshop, State employment service agency, etc.; or

(ii) At least 18 semester hours in vocational rehabilitation, educational or vocational guidance, psychology, social work, special education or personnel administration, and 1 year of experience in vocational counseling in a rehabilitation setting; or

(iii) A master's degree in vocational counseling.

(8) A nurse practitioner is a person who must:

(i) Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law; *and*

(ii) Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners; *or*

(iii) Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law and have been granted a Medicare billing number as a nurse practitioner by December 31, 2000; *or*

(iv) Be a nurse practitioner who on or after January 1, 2001, applies for a Medicare billing number for the first time and meets the standards for nurse practitioners in paragraphs (c)(8)(i) and (c)(8)(ii) of this section; *or*

(v) Be a nurse practitioner who on or after January 1, 2003, applies for a Medicare billing number for the first time and possesses a master's degree in nursing and meets the standards for nurse practitioners in paragraphs (b)(1)(i) and (b)(1)(ii) of this section.

(9) *A clinical nurse specialist* is a person who must:

(i) Be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to perform the services of a clinical nurse specialist in accordance with State law;

(ii) Have a master's degree in a defined clinical area of nursing from an accredited educational institution; and,

(iii) Be certified as a clinical nurse specialist by the American Nurses Credentialing Center.

(10) *A physician assistant* is a person who:

(i) Has graduated from a physician assistant educational program that is accredited by the Commission on Accreditation of Allied Health Education Programs; or

(ii) Has passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants; and

(iii) Is licensed by the State to practice as a physician assistant.

[63 FR 58912, Nov. 2, 1998; 64 FR 25457, May 12, 1999; 64 FR 59442, Nov. 2, 1999]

§ 485.707 Condition of participation: Compliance with Federal, State, and local laws.

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

(a) *Standard: Licensure of organization.* In any State in which State or applicable local law provides for the licensing of organizations, a clinic, rehabilitation agency, or public health agency is licensed in accordance with applicable laws.

(b) *Standard: Licensure or registration of personnel.* Staff of the organization

are licensed or registered in accordance with applicable laws.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995]

§ 485.709 Condition of participation: Administrative management.

The clinic or rehabilitation agency has an effective governing body that is legally responsible for the conduct of the clinic or rehabilitation agency. The governing body designates an administrator, and establishes administrative policies.

(a) *Standard: Governing body.* There is a governing body (or designated person(s) so functioning) which assumes full legal responsibility for the overall conduct of the clinic or rehabilitation agency and for compliance with applicable laws and regulations. The name of the owner(s) of the clinic or rehabilitation agency is fully disclosed to the State agency. In the case of corporations, the names of the corporate officers are made known.

(b) *Standard: Administrator.* The governing body—

(1) Appoints a qualified full-time administrator;

(2) Delegates to the administrator the internal operation of the clinic or rehabilitation agency in accordance with written policies;

(3) Defines clearly the administrator's responsibilities for procurement and direction of personnel; and

(4) Designates a competent individual to act during temporary absence of the administrator.

(c) *Standard: Personnel policies.* Personnel practices are supported by appropriate written personnel policies that are kept current. Personnel records include the qualifications of all professional and assistant level personnel, as well as evidence of State licensure if applicable.

(d) *Standard: Patient care policies.* Patient care practices and procedures are supported by written policies established by a group of professional personnel including one or more physicians associated with the clinic or rehabilitation agency, one or more qualified physical therapists (if physical therapy services are provided), and one or more qualified speech pathologists (if speech pathology services are provided). The policies govern the outpatient physical therapy and/or speech pathology services and related services that are provided. These policies are evaluated at least annually by the group of professional personnel, and revised as necessary based upon this evaluation.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.711 Condition of participation: Plan of care and physician involvement.

For each patient in need of outpatient physical therapy or speech pathology services, there is a written plan of care established and periodically reviewed by a physician, or by a physical therapist or speech pathologist respectively.

(a) *Standard: Medical history and prior treatment.* The following are obtained by the organization before or at the time of initiation of treatment:

(1) The patient's significant past history.

(2) Current medical findings, if any.

(3) Diagnosis(es), if established.

(4) Physician's orders, if any.

(5) Rehabilitation goals, if determined.

(6) Contraindications, if any.

(7) The extent to which the patient is aware of the diagnosis(es) and prognosis.

(8) If appropriate, the summary of treatment furnished and results achieved during previous periods of rehabilitation services or institutionalization.

(b) *Standard: Plan of care.* (1) For each patient there is a written plan of care established by the physician or by the physical therapist or speech-language pathologist who furnishes the services.

(2) The plan of care for physical therapy or speech pathology services indicates anticipated goals and specifies for those services the—

(i) Type;

(ii) Amount;

(iii) Frequency; and

(iv) Duration.

(3) The plan of care and results of treatment are reviewed by the physician or by the individual who established the plan at least as often as the patient's condition requires, and the indicated action is taken.

(4) Changes in the plan of care are noted in the clinical record. If the patient has an attending physician, the therapist or speech-language pathologist who furnishes the services promptly notifies him or her of any change in the patient's condition or in the plan of care.

(c) *Standard: Emergency care.* The rehabilitation agency must establish procedures to be followed by personnel in an emergency, which cover immediate care of the patient, persons to be notified, and reports to be prepared.

[54 FR 38679, Sept. 20, 1989. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 63 FR 58913, Nov. 2, 1998; 73 FR 69941, Nov. 19, 2008]

§ 485.713 Condition of participation: Physical therapy services.

If the organization offers physical therapy services, it provides an adequate program of physical therapy and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

(a) *Standard: Adequate program.* (1) The organization is considered to have an adequate outpatient physical therapy program if it can:

(i) Provide services using therapeutic exercise and the modalities of heat, cold, water, and electricity;

(ii) Conduct patient evaluations; and

(iii) Administer tests and measurements of strength, balance, endurance, range of motion, and activities of daily living.

(2) A qualified physical therapist is present or readily available to offer supervision when a physical therapist assistant furnishes services.

(i) If a qualified physical therapist is not on the premises during all hours of operation, patients are scheduled so as to ensure that the therapist is present when special skills are needed, for example, for evaluation and reevaluation.

(ii) When a physical therapist assistant furnishes services off the organization's premises, those services are supervised by a qualified physical therapist who makes an onsite supervisory visit at least once every 30 days.

(b) *Standard: Facilities and equipment.* The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of disabilities it accepts for service.

(c) *Standard: Personnel qualified to provide physical therapy services.* Physical therapy services are provided by, or under the supervision of, a qualified physical therapist. The number of qualified physical therapists and qualified physical therapist assistants is adequate for the volume and diversity of physical therapy services offered. A qualified physical therapist is on the premises or readily available during the operating hours of the organization.

(d) *Standard: Supportive personnel.* If personnel are available to assist qualified physical therapists by performing services incident to physical therapy that do not require professional knowledge and skill, these personnel are instructed in appropriate patient care services by qualified physical therapists who retain responsibility for the treatment prescribed by the attending physician.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.715 Condition of participation: Speech pathology services.

If speech pathology services are offered, the organization provides an adequate program of speech pathology and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

(a) *Standard: Adequate program.* The organization is considered to have an adequate outpatient speech pathology program if it can provide the diagnostic and treatment services to effectively treat speech disorders.

(b) *Standard: Facilities and equipment.* The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of speech disorders it accepts for service.

(c) *Standard: Personnel qualified to provide speech pathology services.* Speech pathology services are given or supervised by a qualified speech pathologist and the number of qualified speech pathologists is adequate for the volume and diversity of speech pathology services offered. At least one qualified speech pathologist is present at all times when speech pathology services are furnished.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995]

§ 485.717 Condition of participation: Rehabilitation program.

This condition and standards apply only to a rehabilitation agency's own patients, not to patients of hospitals, skilled nursing facilities (SNFs), or Medicaid nursing facilities (NFs) to which the agency furnishes services. The hospital, SNF, or NF is responsible for ensuring that qualified staff furnish services for which they arrange or contract for their patients. The rehabilitation agency provides physical therapy and speech-language pathology services to all of its patients who need them.

(a) *Standard: Qualification of staff.* The agency's therapy services are furnished by qualified individuals as direct services and/or services provided under contract.

(b) *Standard: Arrangements for services.* If services are provided under contract, the contract must specify the term of the contract, the manner of termination or renewal and provide that the agency retains responsibility for the control and supervision of the services.

[73 FR 69942, Nov. 19, 2008]

§ 485.719 Condition of participation: Arrangements for physical therapy and speech pathology services to be performed by other than salaried organization personnel.

(a) *Conditions.* If an organization provides outpatient physical therapy or speech pathology services under an arrangement with others, the services are to be furnished in accordance with the terms of a written contract, which provides that the organization retains of professional and administrative responsibility for, and control and supervision of, the services.

(b) *Standard: Contract provisions.* The contract—

(1) Specifies the term of the contract and the manner of termination or renewal;

(2) Requires that personnel who furnish the services meet the requirements that are set forth in this subpart for salaried personnel; and

(3) Provides that the contracting outside resource may not bill the patient or Medicare for the services. This limitation is based on section 1861(w)(1) of the Act, which provides that—

(i) Only the provider may bill the beneficiary for covered services furnished under arrangements; and

(ii) Receipt of Medicare payment by the provider, on behalf of an entitled individual, discharges the liability of the individual or any other person to pay for those services.

[56 FR 46562, Sept. 13, 1991. Redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.721 Condition of participation: Clinical records.

The organization maintains clinical records on all patients in accordance with accepted professional standards, and practices. The clinical records are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.

(a) *Standard: Protection of clinical record information.* The organization recognizes the confidentiality of clinical record information and provides safeguards against loss, destruction, or unauthorized use. Written procedures govern the use and removal of records and the conditions for release of information. The patient's written consent is required for release of information not authorized by law.

(b) *Standard: Content.* The clinical record contains sufficient information to identify the patient clearly, to justify the diagnosis(es) and treatment, and to document the results accurately. All clinical records contain the following general categories of data:

(1) Documented evidence of the assessment of the needs of the patient, of

an appropriate plan of care, and of the care and services furnished.

(2) Identification data and consent forms.

(3) Medical history.

(4) Report of physical examinations, if any.

(5) Observations and progress notes.

(6) Reports of treatments and clinical findings.

(7) Discharge summary including final diagnosis(es) and prognosis.

(c) *Standard: Completion of records and centralization of reports.* Current clinical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's clinical record. Each physician signs the entries that he or she makes in the clinical record.

(d) *Standard: Retention and preservation.* Clinical records are retained for at least:

(1) The period determined by the respective State statute, or the statute of limitations in the State; or

(2) In the absence of a State statute—

(i) Five years after the date of discharge; or

(ii) In the case of a minor, 3 years after the patient becomes of age under State law or 5 years after the date of discharge, whichever is longer.

(e) *Standard: Indexes.* Clinical records are indexed at least according to name of patient to facilitate acquisition of statistical medical information and retrieval of records for research or administrative action.

(f) *Standard: Location and facilities.* The organization maintains adequate facilities and equipment, conveniently located, to provide efficient processing of clinical records (reviewing, indexing, filing, and prompt retrieval).

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995]

§ 485.723 Condition of participation: Physical environment.

The building housing the organization is constructed, equipped, and maintained to protect the health and safety of patients, personnel, and the public and provides a functional, sanitary, and comfortable environment.

(a) *Standard: Safety of patients.* The organization satisfies the following requirements:

(1) It complies with all applicable State and local building, fire, and safety codes.

(2) Permanently attached automatic fire-extinguishing systems of adequate capacity are installed in all areas of the premises considered to have special fire hazards. Fire extinguishers are conveniently located on each floor of the premises. Fire regulations are prominently posted.

(3) Doorways, passageways and stairwells negotiated by patients are:

(i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs), (ii) free from obstruction at all times, and (iii) in the case of stairwells, equipped with firmly attached handrails on at least one side.

(4) Lights are placed at exits and in corridors used by patients and are supported by an emergency power source.

(5) A fire alarm system with local alarm capability and, where applicable, an emergency power source, is functional.

(6) At least two persons are on duty on the premises of the organization whenever a patient is being treated.

(7) No occupancies or activities undesirable or injurious to the health and safety of patients are located in the building.

(b) *Standard: Maintenance of equipment, building, and grounds.* The organization establishes a written preventive-maintenance program to ensure that—

(1) The equipment is operative, and is properly calibrated; and

(2) The interior and exterior of the building are clean and orderly and maintained free of any defects that are a potential hazard to patients, personnel, and the public.

(c) *Standard: Other environmental considerations.* The organization provides a functional, sanitary, and comfortable environment for patients, personnel, and the public.

(1) Provision is made for adequate and comfortable lighting levels in all areas; limitation of sounds at comfort levels; a comfortable room temperature; and adequate ventilation through

windows, mechanical means, or a combination of both.

(2) Toilet rooms, toilet stalls, and lavatories are accessible and constructed so as to allow use by nonambulatory and semiambulatory individuals.

(3) Whatever the size of the building, there is an adequate amount of space for the services provided and disabilities treated, including reception area, staff space, examining room, treatment areas, and storage.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995]

§ 485.725 Condition of participation: Infection control.

The organization that provides outpatient physical therapy services establishes an infection-control committee of representative professional staff with responsibility for overall infection control. All necessary housekeeping and maintenance services are provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.

(a) *Standard: Infection-control committee.* The infection-control committee establishes policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure that the policies and procedures are executed.

(b) All personnel follow written procedures for effective aseptic techniques. The procedures are reviewed annually and revised if necessary to improve them.

(c) *Standard: Housekeeping.* (1) The organization employs sufficient housekeeping personnel and provides all necessary equipment to maintain a safe, clean, and orderly interior. A full-time employee is designated as the one responsible for the housekeeping services and for supervision and training of housekeeping personnel.

(2) An organization that has a contract with an outside resource for housekeeping services may be found to be in compliance with this standard provided the organization or outside resource or both meet the requirements of the standard.

(d) *Standard: Linen.* The organization has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

(e) *Standard: Pest control.* The organization's premises are maintained free from insects and rodents through operation of a pest-control program.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995; 86 FR 61623, Nov. 5, 2021; 88 FR 36510, June 5, 2023]

§ 485.727 Condition of participation: Emergency preparedness.

The Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (''Organizations'') must comply with all applicable Federal, State, and local emergency preparedness requirements. The Organizations must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The Organizations must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. 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, the type of services the Organizations have the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Address the location and use of alarm systems and signals; and methods of containing fire.

(5) 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.

(6) Be developed and maintained with assistance from fire, safety, and other appropriate experts.

(b) *Policies and procedures.* The Organizations 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 every 2 years. At a minimum, the policies and procedures must address the following:

(1) Safe evacuation from the Organizations, which includes staff responsibilities, and needs of the patients.

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

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

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

(c) *Communication plan.* The Organizations 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 every 2 years. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other Organizations.

(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) Organizations' staff.

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

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

(5) A means of providing information about the Organizations' needs, and their ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) *Training and testing.* The Organizations 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 every 2 years.

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

(i) Initial training in emergency preparedness policies and procedures 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 every 2 years.

(iii) Maintain documentation of the training.

(iv) Demonstrate staff knowledge of emergency procedures.

(v) If the emergency preparedness policies and procedures are significantly updated, the Organizations must conduct training on the updated policies and procedures.

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

(i) Participate in a full-scale exercise that is community-based every 2 years; or

(A) When a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years; or.

(B) If the Organizations experience an actual natural or man-made emergency that requires activation of the emergency plan, the organization is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional exercise every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

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

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, 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 Organization's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise their emergency plan, as needed.

(e) *Integrated healthcare systems.* If the Organizations are part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the Organizations 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.

(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 all of the following:

(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.

[81 FR 64037, Sept. 16, 2016, as amended by 84 FR 51829, Sept. 30, 2019]

§ 485.729 Condition of participation: Program evaluation.

The organization has procedures that provide for a systematic evaluation of its total program to ensure appropriate utilization of services and to determine whether the organization's policies are followed in providing services to patients through employees or under arrangements with others.

(a) *Standard: Clinical-record review.* A sample of active and closed clinical records is reviewed quarterly by the appropriate health professionals to ensure that established policies are followed in providing services.

(b) *Standard: Annual statistical evaluation.* An evaluation is conducted annually of statistical data such as number of different patients treated, number of patient visits, condition on admission and discharge, number of new patients, number of patients by diagnosis(es), sources of referral, number and cost of units of service by treatment given,

and total staff days or work hours by discipline.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2329, Jan. 9, 1995]

Subpart I [Reserved]

Subpart J—Conditions of Participation: Community Mental Health Centers (CMHCs)

SOURCE: 78 FR 64630, Oct. 29, 2013, unless otherwise noted.

§ 485.900 Basis and scope.

(a) *Basis.* This subpart is based on the following sections of the Social Security Act:

(1) Section 1832(a)(2)(J) of the Act specifies that payments may be made under Medicare Part B for partial hospitalization services furnished by a community mental health center (CMHC) as described in section 1861(ff)(3)(B) of the Act.

(2) Section 1861(ff) of the Act describes the items and services that are covered under Medicare Part B as ''partial hospitalization services'' and the conditions under which the items and services must be provided. In addition, section 1861(ff) of the Act specifies that the entities authorized to provide partial hospitalization services under Medicare Part B include CMHCs and defines that term.

(3) Section 1866(e)(2) of the Act specifies that a provider of services for purposes of provider agreement requirements includes a CMHC as defined in section 1861(ff)(3)(B) of the Act, but only with respect to providing partial hospitalization services.

(b) *Scope.* The provisions of this subpart serve as the basis of survey activities for the purpose of determining whether a CMHC meets the specified requirements that are considered necessary to ensure the health and safety of clients; and for the purpose of determining whether a CMHC qualifies for a provider agreement under Medicare.

§ 485.902 Definitions.

As used in this subpart, unless the context indicates otherwise—

Active treatment plan means an individualized client plan that focuses on the provision of care and treatment services that address the client's physical, psychological, psychosocial, emotional, and therapeutic needs and goals as identified in the comprehensive assessment.

Community mental health center (CMHC) means an entity as defined in § 410.2 of this chapter.

Comprehensive assessment means a thorough evaluation of the client's physical, psychological, psychosocial, emotional, and therapeutic needs related to the diagnosis under which care is being furnished by the CMHC.

Employee of a CMHC means an individual—

(1) Who works for the CMHC and for whom the CMHC is required to issue a W–2 form on his or her behalf; or

(2) For whom an agency or organization issues a W–2 form, and who is assigned to such CMHC if the CMHC is a subdivision of an agency or organization.

Initial evaluation means an immediate care and support assessment of the client's physical, psychosocial (including a screen for harm to self or others), and therapeutic needs related to the psychiatric illness and related conditions for which care is being furnished by the CMHC.

Representative means an individual who has the authority under State law to authorize or terminate medical care on behalf of a client who is mentally or physically incapacitated. This includes a legal guardian.

Restraint means—

(1) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a client to move his or her arms, legs, body, or head freely, not including devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a client for the purpose of conducting routine physical examinations or tests, or to protect the client from falling out of bed, or to permit the client to participate in activities without the risk of physical harm (this does not include a client being physically escorted); or

(2) A drug or medication when it is used as a restriction to manage the client's behavior or restrict the client's freedom of movement, and which is not a standard treatment or dosage for the client's condition.

Seclusion means the involuntary confinement of a client alone in a room or an area from which the client is physically prevented from leaving.

Volunteer means an individual who is an unpaid worker of the CMHC; or if the CMHC is a subdivision of an agency or organization, is an unpaid worker of the agency or organization and is assigned to the CMHC. All volunteers must meet the standard training requirements under § 485.918(d).

§ 485.904 Condition of participation: Personnel qualifications.

(a) *Standard: General qualification requirements.* All professionals who furnish services directly, under an individual contract, or under arrangements with a CMHC, must be legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and must act only within the scope of their State licenses, certifications, or registrations. All personnel qualifications must be kept current at all times.

(b) *Standard: Personnel qualifications for certain disciplines.* The following qualifications must be met:

(1) *Administrator of a CMHC.* A CMHC employee who meets the education and experience requirements established by the CMHC's governing body for that position and who is responsible for the day-to-day operation of the CMHC.

(2) *Clinical psychologist.* An individual who meets the qualifications at § 410.71(d) of this chapter.

(3) *Clinical Social worker.* An individual who meets the qualifications at § 410.73 of this chapter.

(4) *Social worker.* An individual who—

(i) Has a baccalaureate degree in social work from an institution accredited by the Council on Social Work Education, or a baccalaureate degree in psychology or sociology, and is supervised by a clinical social worker, as described in paragraph (b)(3) of this section; and

(ii) Has 1 year of social work experience in a psychiatric healthcare setting.

(5) *Mental health counselor.* A professional counselor who is certified and/or licensed by the State in which he or she practices, and has the skills and knowledge to provide a range of behavioral health services to clients. The mental health counselor conducts assessments and provides services in areas such as psychotherapy, substance abuse, crisis management, psychoeducation, and prevention programs.

(6) *Occupational therapist.* A person who meets the requirements for the definition of ''occupational therapist'' at § 484.4 of this chapter.

(7) *Physician.* An individual who meets the qualifications and conditions as defined in section 1861(r) of the Act, and provides the services at § 410.20 of this chapter, and has experience providing mental health services to clients.

(8) *Physician assistant.* An individual who meets the qualifications and conditions as defined in section 1861(s)(2)(K)(i) of the Act and provides the services, in accordance with State law, at § 410.74 of this chapter.

(9) *Advanced practice nurse.* An individual who meets the following qualifications:

(i) Is a nurse practitioner who meets the qualifications at § 410.75 of this chapter; or

(ii) Is a clinical nurse specialist who meets the qualifications at § 410.76 of this chapter.

(10) *Psychiatric registered nurse.* A registered nurse, who is a graduate of an approved school of professional nursing, is licensed as a registered nurse by the State in which he or she is practicing, and has at least 1 year of education and/or training in psychiatric nursing.

(11) *Psychiatrist.* An individual who specializes in assessing and treating persons having psychiatric disorders; is board certified, or is eligible to be board certified by the American Board of Psychiatry and Neurology, or has documented equivalent education,

training or experience, and is fully licensed to practice medicine in the State in which he or she practices.

[78 FR 64630, Oct. 29, 2013, as amended at 86 FR 61624, Nov. 5, 2021; 88 FR 36510, June 5, 2023]

§ 485.910 Condition of participation: Client rights.

The client has the right to be informed of his or her rights. The CMHC must protect and promote the exercise of these client rights.

(a) *Standard: Notice of rights and responsibilities.* (1) During the initial evaluation, the CMHC must provide the client, the client's representative (if appropriate) or surrogate with verbal and written notice of the client's rights and responsibilities. The verbal notice must be in a language and manner that the client or client's representative or surrogate understands. Written notice must be understandable to persons who have limited English proficiency.

(2) During the initial evaluation, the CMHC must inform and distribute written information to the client concerning its policies on filing a grievance.

(3) The CMHC must obtain the client's and/or the client representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities.

(b) *Standard: Exercise of rights and respect for property and person.* (1) The client has the right to—

(i) Exercise his or her rights as a client of the CMHC.

(ii) Have his or her property and person treated with respect.

(iii) Voice grievances and understand the CMHC grievance process; including but not limited to grievances regarding mistreatment and treatment or care that is (or fails to be) furnished.

(iv) Not be subjected to discrimination or reprisal for exercising his or her rights.

(2) If a client has been adjudged incompetent under State law by a court of proper jurisdiction, the rights of the client are exercised by the person appointed in accordance with State law to act on the client's behalf.

(3) If a State court has not adjudged a client incompetent, any legal representative designated by the client in accordance with State law may exercise the client's rights to the extent allowed under State law.

(c) *Standard: Rights of the client.* The client has a right to—

(1) Be involved in developing his or her active treatment plan.

(2) Refuse care or treatment.

(3) Have a confidential clinical record. Access to or release of client information and the clinical record client information is permitted only in accordance with 45 CFR parts 160 and 164.

(4) Be free from mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of client property.

(5) Receive information about specific limitations on services that he or she will be furnished.

(6) Not be compelled to perform services for the CMHC, and to be compensated by the CMHC for any work performed for the CMHC at prevailing wages and commensurate with the client's abilities.

(d) *Standard: Addressing violations of client rights.* The CMHC must adhere to the following requirements:

(1) Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of client property by anyone, including those furnishing services on behalf of the CMHC, are reported immediately to the CMHC's administrator by CMHC employees, volunteers and contracted staff.

(2) Immediately investigate all alleged violations involving anyone furnishing services on behalf of the CMHC and immediately take action to prevent further potential violations while the alleged violation is being verified. Investigations and documentation of all alleged violations must be conducted in accordance with procedures established by the CMHC.

(3) Take appropriate corrective action in accordance with State law if the alleged violation is investigated by the CMHC's administration or verified

by an outside entity having jurisdiction, such as the State survey and certification agency or the local law enforcement agency; and

(4) Ensure that, within 5 working days of becoming aware of the violation, all violations are reported to the State survey and certification agency, and verified violations are reported to State and local entities having jurisdiction.

(e) *Standard: Restraint and seclusion.* (1) All clients have the right to be free from physical or mental abuse, and corporal punishment. All clients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion, defined in § 485.902, may only be imposed to ensure the immediate physical safety of the client, staff, or other individuals.

(2) The use of restraint or seclusion must be in accordance with the written order of a physician or other licensed independent practitioner who is authorized to order restraint or seclusion in accordance with State law and must not exceed one 1-hour duration per order.

(3) The CMHC must obtain a corresponding order for the client's immediate transfer to a hospital when restraint or seclusion is ordered.

(4) Orders for the use of restraint or seclusion must never be written as a standing order or on an as-needed basis.

(5) When a client becomes an immediate threat to the physical safety of himself or herself, staff or other individuals, the CMHC must adhere to the following requirements:

(i) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the client or other individuals from harm.

(ii) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the client or other individuals from harm.

(iii) The use of restraint or seclusion must be implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by State law.

(iv) The condition of the client who is restrained or secluded must be continuously monitored by a physician or by trained staff who have completed the training criteria specified in paragraph (f) of this section.

(v) When restraint or seclusion is used, there must be documentation in the client's clinical record of the following:

(A) A description of the client's behavior and the intervention used.

(B) Alternatives or other less restrictive interventions attempted (as applicable).

(C) The client's condition or symptom(s) that warranted the use of the restraint or seclusion.

(D) The client's response to the intervention(s) used, including the rationale for continued use of the intervention.

(E) The name of the hospital to which the client was transferred.

(f) *Standard: Restraint or seclusion: Staff training requirements.* The client has the right to safe implementation of restraint or seclusion by trained staff. Application of restraint or seclusion in a CMHC must only be imposed when a client becomes an immediate physical threat to himself or herself, staff or other individuals and only in facilities where restraint and seclusion are permitted.

(1) *Training intervals.* In facilities where restraint and seclusion are permitted, all appropriate client care staff working in the CMHC must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a client in restraint or seclusion and use of alternative methods to restraint and seclusion. In facilities where restraint and seclusion are not permitted, appropriate client care staff working in CMHC must be trained in the use of alternative methods to restraint and seclusion. Training will occur as follows:

(i) Before performing any of the actions specified in this paragraph (f).

(ii) As part of orientation.

(iii) Subsequently on a periodic basis, consistent with the CMHC's policy.

(2) *Training content.* The CMHC must require all appropriate staff caring for clients to have appropriate education, training, and demonstrated knowledge

based on the specific needs of the client population in at least the following:

(i) Techniques to identify staff and client behaviors, events, and environmental factors that may trigger circumstances that could require the use of restraint or seclusion.

(ii) The use of nonphysical intervention skills.

(iii) In facilities where restraint and seclusion are permitted, choosing the least restrictive intervention based on an individualized assessment of the client's medical and behavioral status or condition.

(iv) The safe application and use of all types of restraint or seclusion that are permitted in the CMHC, including training in how to recognize and respond to signs of physical and psychological distress.

(v) In facilities where restraint and seclusion are permitted, clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

(vi) In facilities where restraint and seclusion are permitted, monitoring the physical and psychological well-being of the client who is restrained or secluded, including, but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by the CMHC's policy.

(3) *Trainer requirements.* Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address clients' behaviors.

(4) *Training documentation.* The CMHC must document in the staff personnel records that the training and demonstration of competency were successfully completed.

(g) *Standard: Death reporting requirements.* The CMHC must report deaths associated with the use of seclusion or restraint.

(1) The CMHC must report to CMS each death that occurs while a client is in restraint or seclusion awaiting transfer to a hospital.

(2) Each death referenced in paragraph (g)(1) of this section must be reported to the CMS Regional Office by telephone no later than the close of business the next business day following knowledge of the client's death.

(3) Staff must document in the client's clinical record the date and time the death was reported to CMS.

§ 485.914 Condition of participation: Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client.

The CMHC must ensure that all clients admitted into its program are appropriate for the services the CMHC furnishes in its facility.

(a) *Standard: Admission.* (1) The CMHC must determine that each client is appropriate for the services it provides as specified in § 410.2 of this chapter.

(2) For clients assessed and admitted to receive partial hospitalization services, the CMHC must also meet separate requirements as specified in § 485.918(f).

(b) *Standard: Initial evaluation.* (1) A licensed mental health professional employed by the CMHC and acting within his or her state scope of practice requirements must complete the initial evaluation within 24 hours of the client's admission to the CMHC.

(2) The initial evaluation, at a minimum, must include the following:

(i) The admitting diagnosis as well as other diagnoses.

(ii) The source of referral.

(iii) The reason for admission as stated by the client or other individuals who are significantly involved.

(iv) Identification of the client's immediate clinical care needs related to the psychiatric diagnosis.

(v) A list of current prescriptions and over-the-counter medications, as well as other substances that the client may be taking.

(vi) For partial hospitalization services only, include an explanation as to why the client would be at risk for hospitalization if the partial hospitalization services were not provided.

(3) Based on the findings of the initial evaluation, the CMHC must determine the appropriate members of each client's interdisciplinary treatment team.

(c) *Standard: Comprehensive assessment.* (1) The comprehensive assessment must be completed by licensed mental health professionals who are members of the interdisciplinary treatment team, performing within their State's scope of practice.

(2) The comprehensive assessment must be completed in a timely manner, consistent with the client's immediate needs, but no later than 4 working days after admission to the CMHC.

(3) The comprehensive assessment must identify the physical, psychological, psychosocial, emotional, therapeutic, and other needs related to the client's psychiatric illness. The CMHC's interdisciplinary treatment team must ensure that the active treatment plan is consistent with the findings of the comprehensive assessment.

(4) The comprehensive assessment, at a minimum, must include the following:

(i) The reasons for the admission.

(ii) A psychiatric evaluation, completed by a psychiatrist, non-physician practitioner or psychologist practicing within the scope of State licensure that includes the medical history and severity of symptoms. Information may be gathered from the client's primary health care provider (if any), contingent upon the client's consent.

(iii) Information concerning previous and current mental status, including but not limited to, previous therapeutic interventions and hospitalizations.

(iv) Information regarding the onset of symptoms of the illness and circumstances leading to the admission.

(v) A description of attitudes and behaviors, including cultural and environmental factors that may affect the client's treatment plan.

(vi) An assessment of intellectual functioning, memory functioning, and orientation.

(vii) Complications and risk factors that may affect the care planning.

(viii) Functional status, including the client's ability to understand and participate in his or her own care, and the client's strengths and goals.

(ix) Factors affecting client safety or the safety of others, including behavioral and physical factors, as well as suicide risk factors.

(x) A drug profile that includes a review of all of the client's prescription and over-the-counter medications; herbal remedies; and other alternative treatments or substances that could affect drug therapy.

(xi) The need for referrals and further evaluation by appropriate health care professionals, including the client's primary health care provider (if any), when warranted.

(xii) Factors to be considered in discharge planning.

(xiii) Identification of the client's current social and health care support systems.

(xiv) For pediatric clients, the CMHC must assess the social service needs of the client, and make referrals to social services and child welfare agencies as appropriate.

(d) *Standard: Update of the comprehensive assessment.* (1) The CMHC must update each client's comprehensive assessment via the CMHC interdisciplinary treatment team, in consultation with the client's primary health care provider (if any), when changes in the client's status, responses to treatment, or goal achievement have occurred and in accordance with current standards of practice.

(2) For clients that receive PHP services, the assessment must be updated no less frequently than every 30 days.

(3) The update must include information on the client's progress toward desired outcomes, a reassessment of the client's response to care and therapies, and the client's goals.

(e) *Standard: Discharge or transfer of the client.* (1) If the client is transferred to another entity, the CMHC must, within 2 working days, forward to the entity, a copy of—

(i) The CMHC discharge summary.

(ii) The client's clinical record, if requested.

(2) If a client refuses the services of a CMHC, or is discharged from a CMHC due to noncompliance with the treatment plan, the CMHC must forward to the primary health care provider (if any) a copy of—

(i) The CMHC discharge summary.

(ii) The client's clinical record, if requested.

(3) The CMHC discharge summary must include—

(i) A summary of the services provided, including the client's symptoms, treatment and recovery goals and preferences, treatments, and therapies.

(ii) The client's current active treatment plan at time of discharge.

(iii) The client's most recent physician orders.

(iv) Any other documentation that will assist in post-discharge continuity of care.

(4) The CMHC must adhere to all Federal and State-related requirements pertaining to the medical privacy and the release of client information.

[78 FR 64630, Oct. 29, 2013, as amended at 84 FR 51829, Sept. 30, 2019]

§485.916 Condition of participation: Treatment team, person-centered active treatment plan, and coordination of services.

The CMHC must designate an interdisciplinary treatment team that is responsible, with the client, for directing, coordinating, and managing the care and services furnished for each client. The interdisciplinary treatment team is composed of individuals who work together to meet the physical, medical, psychosocial, emotional, and therapeutic needs of CMHC clients.

(a) *Standard: Delivery of services.* (1) An interdisciplinary treatment team, led by a physician, NP, PA, CNS, clinical psychologist, or clinical social worker, must provide the care and services offered by the CMHC.

(2) Based on the findings of the comprehensive assessment, the CMHC must determine the appropriate licensed mental health professional, who is a member of the client's interdisciplinary treatment team, to coordinate care and treatment decisions with each client, to ensure that each client's needs are assessed, and to ensure that the active treatment plan is implemented as indicated.

(3) The interdisciplinary treatment team may include:

(i) A doctor of medicine, osteopathy or psychiatry (who is an employee of or under contract with the CMHC).

(ii) A psychiatric registered nurse.

(iii) A clinical social worker.

(iv) A clinical psychologist.

(v) An occupational therapist.

(vi) Other licensed mental health professionals, as necessary.

(vii) Other CMHC staff or volunteers, as necessary.

(4) If the CMHC has more than one interdisciplinary team, it must designate the treatment team responsible for establishing policies and procedures governing the coordination of services and the day-to-day provision of CMHC care and services.

(b) *Standard: Person-centered active treatment plan.* All CMHC care and services furnished to clients must be consistent with an individualized, written, active treatment plan that is established by the CMHC interdisciplinary treatment team, the client, and the client's primary caregiver(s), in accordance with the client's recovery goals and preferences, within 7 working days of admission to the CMHC. The CMHC must ensure that each client and the client's primary caregiver(s), as applicable, receive education and training provided by the CMHC that are consistent with the client's and caregiver's responsibilities as identified in the active treatment plan.

(c) *Standard: Content of the person-centered active treatment plan.* The CMHC must develop a person-centered individualized active treatment plan for each client. The active treatment plan must take into consideration client recovery goals and the issues identified in the comprehensive assessment. The active treatment plan must include all services necessary to assist the client in meeting his or her recovery goals, including the following:

(1) Client diagnoses.

(2) Treatment goals.

(3) Interventions.

(4) A detailed statement of the type, duration, and frequency of services, including social work, psychiatric nursing, counseling, and therapy services, necessary to meet the client's specific needs.

(5) Drugs, treatments, and individual and/or group therapies.

(6) Family psychotherapy with the primary focus on treatment of the client's conditions.

(7) The interdisciplinary treatment team's documentation of the client's or representative's and primary caregiver's (if any) understanding, involvement, and agreement with the plan of care, in accordance with the CMHC's policies.

(d) *Standard: Review of the person-centered active treatment plan.* The CMHC interdisciplinary treatment team must

review, revise, and document the individualized active treatment plan as frequently as the client's condition requires, but no less frequently than every 30 calendar days. A revised active treatment plan must include information from the client's initial evaluation and comprehensive assessments, the client's progress toward outcomes and goals specified in the active treatment plan, and changes in the client's goals. The CMHC must also meet partial hospitalization program requirements specified under § 424.24(e) of this chapter if such services are included in the active treatment plan.

(e) *Standard: Coordination of services.* The CMHC must develop and maintain a system of communication that assures the integration of services in accordance with its policies and procedures and, at a minimum, would do the following:

(1) Ensure that the interdisciplinary treatment team maintains responsibility for directing, coordinating, and supervising the care and services provided.

(2) Ensure that care and services are provided in accordance with the active treatment plan.

(3) Ensure that the care and services provided are based on all assessments of the client.

(4) Provide for and ensure the ongoing sharing of information among all disciplines providing care and services, whether the care and services are provided by employees or those under contract with the CMHC.

(5) Provide for ongoing sharing of information with other health care and non-medical providers, including the primary health care provider, furnishing services to a client for conditions unrelated to the psychiatric condition for which the client has been admitted, and non-medical supports addressing environmental factors such as housing and employment.

§ 485.917 Condition of participation: Quality assessment and performance improvement.

The CMHC must develop, implement, and maintain an effective, ongoing, CMHC-wide data-driven quality assessment and performance improvement program (QAPI). The CMHC's governing body must ensure that the program reflects the complexity of its organization and services, involves all CMHC services (including those services furnished under contract or arrangement), focuses on indicators related to improved behavioral health or other healthcare outcomes, and takes actions to demonstrate improvement in CMHC performance. The CMHC must maintain documentary evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS.

(a) *Standard: Program scope.* (1) The CMHC program must be able to demonstrate measurable improvement in indicators related to improving behavioral health outcomes and CMHC services.

(2) The CMHC must measure, analyze, and track quality indicators; adverse client events, including the use of restraint and seclusion; and other aspects of performance that enable the CMHC to assess processes of care, CMHC services, and operations.

(b) *Standard: Program data.* (1) The program must use quality indicator data, including client care, and other relevant data, in the design of its program.

(2) The CMHC must use the data collected to do the following:

(i) Monitor the effectiveness and safety of services and quality of care.

(ii) Identify opportunities and priorities for improvement.

(3) The frequency and detail of the data collection must be approved by the CMHC's governing body.

(c) *Standard: Program activities.* (1) The CMHC's performance improvement activities must:

(i) Focus on high risk, high volume, or problem-prone areas.

(ii) Consider incidence, prevalence, and severity of problems.

(iii) Give priority to improvements that affect behavioral outcomes, client safety, and person-centered quality of care.

(2) Performance improvement activities must track adverse client events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the CMHC.

(3) The CMHC must take actions aimed at performance improvement and, after implementing those actions, the CMHC must measure its success and track performance to ensure that improvements are sustained.

(d) *Standard: Performance improvement projects.* CMHCs must develop, implement and evaluate performance improvement projects.

(1) The number and scope of distinct performance improvement projects conducted annually, based on the needs of the CMHC's population and internal organizational needs, must reflect the scope, complexity, and past performance of the CMHC's services and operations.

(2) The CMHC must document what performance improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(e) *Standard: Executive responsibilities.* The CMHC's governing body is responsible for ensuring the following:

(1) That an ongoing QAPI program for quality improvement and client safety is defined, implemented, maintained, and evaluated annually.

(2) That the CMHC-wide quality assessment and performance improvement efforts address priorities for improved quality of care and client safety, and that all improvement actions are evaluated for effectiveness.

(3) That one or more individual(s) who are responsible for operating the QAPI program are designated.

§485.918 Condition of participation: Organization, governance, administration of services, and partial hospitalization services.

The CMHC must organize, manage, and administer its resources to provide CMHC services, including specialized services for children, elderly individuals, individuals with serious mental illness, and residents of its mental health service area who have been discharged from an inpatient mental health facility.

(a) *Standard: Governing body and administrator.* (1) A CMHC must have a designated governing body made up of two or more designated persons, one of which may be the administrator, that assumes full legal authority and responsibility for the management of the CMHC, the services it furnishes, its fiscal operations, and continuous quality improvement. One member of the governing body must possess knowledge and experience as a mental health clinician.

(2) The CMHC's governing body must appoint an administrator who reports to the governing body and is responsible for the day-to-day operation of the CMHC. The administrator must be a CMHC employee and meet the education and experience requirements established by the CMHC's governing body.

(b) *Standard: Provision of services.* (1) A CMHC must be primarily engaged in providing the following care and services to all clients served by the CMHC regardless of payer type, and must do so in a manner that is consistent with the following accepted standards of practice:

(i) Provides outpatient services, including specialized outpatient services for children, elderly individuals, individuals with serious mental illness, and residents of its mental health service area who have been discharged from inpatient mental health facilities.

(ii) Provides 24-hour-a-day emergency care services.

(iii) Provides day treatment, partial hospitalization services other than in an individual's home or in an inpatient or residential setting, or psychosocial rehabilitation services.

(iv) Provides screening for clients being considered for admission to State mental health facilities to determine the appropriateness of such services, unless otherwise directed by State law.

(v) Provides at least 40 percent of its items and services to individuals who are not eligible for benefits under title XVIII of the Act, as measured by the total number of CMHC clients treated by the CMHC for whom services are not paid for by Medicare, divided by the total number of clients treated by the CMHC for each 12-month period of enrollment.

(A) A CMHC is required to submit to CMS a certification statement provided by an independent entity that

certifies that the CMHC's client population meets the 40 percent requirement specified at this paragraph (b)(1)(v).

(B) The certification statement described in paragraph (b)(1)(v)(A) of this section is required upon initial application to enroll in Medicare, and as a part of revalidation, including any off cycle revalidation, thereafter carried out pursuant to § 424.530 of this chapter. Medicare enrollment will be denied or revoked in instances where the CMHC fails to provide the certification statement as required. Medicare enrollment will also be denied or revoked if the 40 percent requirement as specified in this paragraph (b)(1)(v) is not met.

(vi) Provides individual and group psychotherapy utilizing a psychiatrist, psychologist, or other licensed mental health counselor, to the extent authorized under State law.

(vii) Provides physician services.

(viii) Provides psychiatric nursing services.

(ix) Provides clinical social work services.

(x) Provides family counseling services, with the primary purpose of treating the individual's condition.

(xi) Provides occupational therapy services.

(xii) Provides services of other staff trained to work with psychiatric clients.

(xiii) Provides drugs and biologicals furnished for therapeutic purposes that cannot be self-administered.

(xiv) Provides client training and education as related to the individual's care and active treatment.

(xv) Provides individualized therapeutic activity services that are not primarily recreational or diversionary.

(xvi) Provides diagnostic services.

(2) The CMHC and individuals furnishing services on its behalf must meet applicable State licensing and certification requirements.

(c) *Standard: Professional management responsibility.* A CMHC that has a written agreement with another agency, individual, or organization to furnish any services under arrangement must retain administrative and financial management and oversight of staff and services for all arranged services. As part of retaining financial management responsibility, the CMHC must retain all payment responsibility for services furnished under arrangement on its behalf. Arranged services must be supported by a written agreement which requires that all services be as follows:

(1) Authorized by the CMHC.

(2) Furnished in a safe and effective manner.

(3) Delivered in accordance with established professional standards, the policies of the CMHC, and the client's active treatment plan.

(d) *Standard: Staff training.* (1) A CMHC must provide education about CMHC care and services, and person-centered care to all employees, volunteers, and staff under contract who have contact with clients and their families.

(2) A CMHC must provide an initial orientation for each individual furnishing services that addresses the specific duties of his or her job.

(3) A CMHC must assess the skills and competence of all individuals furnishing care and, as necessary, provide in-service training and education programs where indicated. The CMHC must have written policies and procedures describing its method(s) of assessing competency and must maintain a written description of the in-service training provided during the previous 12 months.

(e) *Standard: Physical environment*—(1) *Environmental conditions.* The CMHC must provide a safe, functional, sanitary, and comfortable environment for clients and staff that is conducive to the provision of services that are identified in paragraph (b) of this section.

(2) *Building.* The CMHC services must be provided in a location that meets Federal, State, and local health and safety standards and State health care occupancy regulations.

(3) *Infection control.* There must be policies, procedures, and monitoring for the prevention, control, and investigation of infection and communicable diseases with the goal of avoiding sources and transmission of infection.

(4) *Therapy sessions.* The CMHC must ensure that individual or group therapy sessions are conducted in a manner that maintains client privacy and ensures client dignity.

(f) *Standard: Partial hospitalization services.* A CMHC providing partial hospitalization services must—

(1) Provide services as defined in § 410.2 of this chapter.

(2) Provide the services and meet the requirements specified in § 410.43 of this chapter.

(3) Meet the requirements for coverage as described in § 410.110 of this chapter.

(4) Meet the content of certification and plan of treatment requirements as described in § 424.24(e) of this chapter.

(g) *Standard: Compliance with Federal, State, and local laws and regulations related to the health and safety of clients.* The CMHC and its staff must operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations related to the health and safety of clients. If State or local law provides for licensing of CMHCs, the CMHC must be licensed. The CMHC staff must follow the CMHC's policies and procedures.

§ 485.920 Condition of participation: Emergency preparedness.

The Community Mental Health Center (CMHC) must comply with all applicable Federal, State, and local emergency preparedness requirements. The CMHC must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The CMHC must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. 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 client population, including, but not limited to, the type of services the CMHC 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.

(b) *Policies and procedures.* The CMHC 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 every 2 years. At a minimum, the policies and procedures must address the following:

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

(2) Safe evacuation from the CMHC, 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.

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

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

(5) 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.

(6) The development of arrangements with other CMHCs or other providers to receive clients in the event of limitations or cessation of operations to maintain the continuity of services to CMHC clients.

(7) The role of the CMHC under a waiver declared by the Secretary of

Health and Human Services, in accordance with section 1135 of the Social Security Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The CMHC 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 every 2 years. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Clients' physicians.

(iv) Other CMHCs.

(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) CMHC's staff.

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

(4) A method for sharing information and medical documentation for clients under the CMHC'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 client information as permitted under 45 CFR 164.510(b)(1)(ii).

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

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

(d) *Training and testing.* The CMHC 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 every 2 years. If the emergency preparedness policies and procedures are significantly updated, the CMHC must conduct training on the updated policies and procedures.

(1) *Training.* The CMHC must provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. The CMHC must demonstrate staff knowledge of emergency procedures. Thereafter, the CMHC must provide emergency preparedness training at least every 2 years.

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

(i) Participate in a full-scale exercise that is community-based every 2 years; or

(A) When a community-based exercise is not accessible, conduct an individual, facility-based every 2 years; or.

(B) If the CMHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CMHC is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional exercise every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to following:

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

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, 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 CMHC's response to and maintain documentation of all

drills, tabletop exercises, and emergency events, and revise the CMHC's emergency plan, as needed.

(e) *Integrated healthcare systems.* If a CMHC 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 CMHC 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.

(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 all of the following:

(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.

[81 FR 64039, Sept. 16, 2016, as amended at 84 FR 51829, Sept. 30, 2019]

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

Subpart A—General Provisions

Sec.

Subpart B [Reserved]

Subpart C—Conditions for Coverage: Portable X-Ray Services

Subparts D–F [Reserved]

Subpart G—Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations

REQUIREMENTS FOR CERTIFICATION AND DESIGNATION

RE-CERTIFICATION AND DE-CERTIFICATION

ORGAN PROCUREMENT ORGANIZATION OUTCOME REQUIREMENTS