

§ 485.635

42 CFR Ch. IV (10–1–20 Edition)

(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.

[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]

§ 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 in-

clude 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. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include the following:

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

(ii) Hemoglobin or hematocrit.

(iii) Blood glucose.

(iv) Examination of stool specimens for occult blood.

(v) Pregnancy tests.

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

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

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

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

(i) Services of doctors of medicine or osteopathy;

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

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

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

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

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

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

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

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

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

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

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

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

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

(e) *Standard: Rehabilitation Therapy Services.* Physical therapy, occupational therapy, and speech-language pathology services furnished at the CAH, if provided, are provided by staff

qualified under State law, and consistent with the requirements for therapy services in § 409.17 of this subpart.

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

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

(2) Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.

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

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

[58 FR 30671, May 26, 1993; 58 FR 49935, Sept. 24, 1993, as amended at 59 FR 45403, Sept. 1, 1994; 62 FR 46037, Aug. 29, 1997; 72 FR 66408, Nov. 27, 2007; 73 FR 69941, Nov. 19, 2008; 75 FR 70844, Nov. 19, 2010; 76 FR 25564, May 5, 2011; 77 FR 29076, May 16, 2012; 78 FR 50970, Aug. 19, 2013; 79 FR 27156, May 12, 2014; 81 FR 68871, Oct. 4, 2016; 82 FR 32260, July 13, 2017; 84 FR 51827, 51883, Sept. 30, 2019]

§ 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