Conditions of Participation for Hospitals and Critical Access Hospitals Original Requirements and Changes Resulting from Telehealth Final Rule

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Conditions of Participation for Hospitals and Critical Access Hospitals Original Requirements and Changes Resulting from Telehealth Final Rule

*** Please Note: Red = New Provisions Provided Through CMS Final Rule**

TITLE 42--PUBLIC HEALTH

CHAPTER IV--CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF

PART 482_CONDITIONS OF PARTICIPATION FOR HOSPITALS--Table of Contents

Subpart B_Administration

Sec. 482.12 Condition of participation: Governing body.

The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

2. Standard: Medical staff. The governing body must:

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

(b) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;

(c) Assure that the medical staff has bylaws;

(d) Approve medical staff bylaws and other medical staff rules and regulations;

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

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

(g) 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.

(h) Ensure that, when telemedicine services are furnished to the hospital'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 (a)(7) of this section with regard to the distant-site hospital's physicians and practitioners providing telemedicine services. The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with §482.22(a)(3) of this part, grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital.

(i) Ensure that when telemedicine services are furnished to the hospital'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 hospital and as such, in accordance with §482.12(e), furnishes the contracted services in a manner that permits the hospital to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in paragraphs (a)(1) through (a)(7) of this section with regard to the distant-site telemedicine entity's physicians and practitioners providing telemedicine services. The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with §482.22(a)(4) of this part, grant privileges to physicians and practitioners employed by the distant-site telemedicine entity based on such hospital's medical staff recommendations; such staff recommendations may rely on information provided by the distant-site telemedicine entity.

3. Standard: Chief executive officer. The governing body must appoint a chief executive officer who is responsible for managing the hospital.

4. Standard: Care of patients. In accordance with hospital policy, the governing body must ensure that the following requirements are met:

(a) Every Medicare patient is under the care of:

(i) A doctor of medicine or osteopathy (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism.);

(ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license;

(iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;

(iv) A doctor of optometry who is legally authorized to practice optometry by the State in which he or she practices;

(v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist; and

(vi) A clinical psychologist as defined in Sec. 410.71 of this chapter, but only with respect to clinical psychologist services as defined in Sec. 410.71 of this chapter and only to the extent permitted by State law.

(b) Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital. If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, that patient is under the care of a doctor of medicine or osteopathy.

(c) A doctor of medicine or osteopathy is on duty or on call at all times.

(d) A doctor of medicine or osteopathy is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that--

(i) is present on admission or develops during hospitalization; and

(ii) Is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist, as that scope is--

Defined by the medical staff;

Permitted by State law; and

Limited, under paragraph (c)(1)(v) of this section, with respect to chiropractors.

5. Standard: Institutional plan and budget. The institution must have an overall institutional plan that meets the following conditions:

(a) The plan must include an annual operating budget that is prepared according to generally accepted accounting principles.

(b) The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense.

(c) The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of this section is applicable.

(d) The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of $600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act, by the State in which the hospital is located) that relates to any of the following:

(i) Acquisition of land;

(ii) Improvement of land, buildings, and equipment; or

(iii) The replacement, modernization, and expansion of buildings and equipment.

(e) The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Act, or if an agency is not designated, to the appropriate health planning agency in the State. (See part 100 of this title.) A capital expenditure is not subject to section 1122 review if 75 percent of the health care facility's patients who are expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization (HMO) or competitive medical plan (CMP) that meets the requirements of section 1876(b) of the Act, and if the Department determines that the capital expenditure is for services and facilities that are needed by the HMO or CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because--

(i) The facilities do not provide common services at the same site;

(ii) The facilities are not available under a contract of reasonable duration;

(iii) Full and equal medical staff privileges in the facilities are not available;

(iv) Arrangements with these facilities are not administratively feasible; or

(v) The purchase of these services is more costly than if the HMO or CMP provided the services directly.

(f) The plan must be reviewed and updated annually.

(g) The plan must be prepared--

(i) Under the direction of the governing body; and

(ii) By a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.

6. Standard: Contracted services. The governing body must be responsible for services furnished in the hospital 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 hospital to comply with all applicable conditions of participation and standards for the contracted services.

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

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

7. Standard: Emergency services. (1) If emergency services are provided at the hospital, the hospital must comply with the requirements of Sec. 482.55.

(a) If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

(b) If emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff has written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate.

[51 FR 22042, June 17, 1986; 51 FR 27847, Aug. 4, 1986, as amended at 53 FR 6549, Mar. 1, 1988; 53 FR 18987, May 26, 1988; 56 FR 8852, Mar. 1, 1991; 56 FR 23022, May 20, 1991; 59 FR 46514, Sept. 8, 1994; 63 FR 20130, Apr. 23, 1998; 63 FR 33874, June 22, 1998; 68 FR 53262, Sept. 9, 2003]

TITLE 42--PUBLIC HEALTH

CHAPTER IV--CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF

PART 482_CONDITIONS OF PARTICIPATION FOR HOSPITALS--Table of Contents

Subpart C_Basic Hospital Functions

Sec. 482.22 Condition of participation: Medical staff.

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

1. Standard: Composition of the medical staff. The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body.

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

(b) The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.

(c) When telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(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 hospital'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 hospital 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 hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distantsite 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 hospital's patients and all complaints the hospital has received about the distant-site physician or practitioner.

(d) When telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(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 hospital'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 §482.12(e), permit the hospital to comply with all applicable conditions of participation for the contracted services. The hospital'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 CMS-3227-F 73 meet the standards at §482.12(a)(1) through (a)(7) and §482.22(a)(1) through (a)(2).

(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides the hospital 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 hospital 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 hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distantsite 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 hospital's patients, and all complaints the hospital has received about the distant-site physician or practitioner.

2. 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.

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

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

(c) The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy or, when permitted by State law of the State in which the hospital is located, a doctor of dental surgery or dental medicine.

3. Standard: Medical staff bylaws. The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

(a) Be approved by the governing body.

(b) Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.)

(c) Describe the organization of the medical staff.

(d) 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.

(e) Include a requirement that—

(i) A medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(ii) An updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. The updated examination of the patient, including any changes in the patient's condition, must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(f) 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 hospital, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in §482.12(a)(8) and (a)(9), and §482.22(a)(3) and (a)(4).

4. Standard: Autopsies. The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.

[51 FR 22042, June 17, 1986, as amended at 59 FR 64152, Dec. 13, 1994; 71 FR 68694, Nov. 27, 2006; 72 FR 66933, Nov. 27, 2007]

TITLE 42--PUBLIC HEALTH

CHAPTER IV--CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF

PART 485_CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS--Table of Contents

Subpart F_Conditions of Participation: Critical Access Hospitals (CAHs)

Sec. 485.616 Condition of participation: Agreements.

1. Standard: Agreements with network hospitals. In the case of a CAH that is a member of a rural health network as defined in Sec. 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--

(a) Patient referral and transfer;

(b) 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

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

2. 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--

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

(b) One QIO or equivalent entity; or

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

[62 FR 46036, Aug. 29, 1997]

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CHAPTER IV--CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF

PART 485_CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS--Table of Contents

Subpart F_Conditions of Participation: Critical Access Hospitals (CAHs)

Sec. 485.635 Condition of participation: Provision of services.

1. Standard: Patient care policies. (a) The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

(b) The policies are developed with the advice of a group of professional personnel that includes 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 Sec. 485.631(a)(1); at least one member is not a member of the CAH staff.

(c) The policies include the following: (i) A description of the services the CAH furnishes directly and those furnished through agreement or arrangement.

(i) Policies and procedures for emergency medical services.

(ii) 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.

(iii) 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.

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

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

(vi) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of Sec. 483.25(i) is met with respect to inpatients receiving posthospital SNF care.

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

2. Standard: Direct services--(a) General. The CAH staff furnishes, as direct services, 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 direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

(b) Laboratory services. The CAH provides, as direct services, 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:

(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; and

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

(c) Radiology services. Radiology services furnished at the CAH are provided as direct services by staff qualified under State law, and do not expose CAH patients or staff to radiation hazards.

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

3. Standard: Services provided through agreements or arrangements.

(a) 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) Inpatient hospital care;

(ii) Services of doctors of medicine or osteopathy; and

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

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

(b) 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.

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

(d) The person principally responsible for the operation of the CAH under Sec. 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.

4. Standard: Nursing services. Nursing services must meet the needs of patients.

(a) 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.

(b) 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.

(c) 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.

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

5. 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 Sec. 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]

TITLE 42--PUBLIC HEALTH

CHAPTER IV--CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF

PART 485_CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS--Table of Contents

Subpart F_Conditions of Participation: Critical Access Hospitals (CAHs)

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

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

(i) The utilization of CAH services, including at least the number of patients served and the volume of services;

(ii) A representative sample of both active and closed clinical records; and

(iii) The CAH's health care policies.

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

2. Standard: Quality assurance. The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that--

(a) All patient care services and other services affecting patient health and safety, are evaluated;

(b) Nosocomial infections and medication therapy are evaluated;

(c) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;

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

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

(ii) One QIO or equivalent entity; or

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

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

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

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

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