

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

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

(iv) A doctor of podiatric medicine;

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

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

(vii) A supervised trainee in an approved educational program, as described in §§413.85 or 413.86 of this chapter.

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

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

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

mitted 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]

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

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

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

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

(iii) The CAH's health care policies.

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

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

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

(2) Nosocomial infections and medication therapy are evaluated;

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

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

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

(ii) One QIO or equivalent entity; or

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

(5)(i) The CAH staff considers the findings of the evaluations, including

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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]

§ 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;

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(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-hospital 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