
42 C.F.R. § 414.68

Imaging accreditation.

(a) *Scope and purpose.* Section 1834(e) of the Act requires the Secretary to designate and approve independent accreditation organizations for purposes of accrediting suppliers furnishing the technical component (TC) of advanced diagnostic imaging services and establish procedures to ensure that the criteria used by an accreditation organization is specific to each imaging modality. Suppliers of the TC of advanced diagnostic imaging services for which payment is made under the fee schedule established in section 1848(b) of the Act must become accredited by an accreditation organization designated by the Secretary beginning January 1, 2012.

(b) *Definitions.* As used in this section, the following definitions are applicable:

Accredited supplier means a supplier that has been accredited by a CMS-designated accreditation organization as specified in this part.

Advanced diagnostic imaging service means any of the following diagnostic services:

- (i) Magnetic resonance imaging.
- (ii) Computed tomography.
- (iii) Nuclear medicine.
- (iv) Positron emission tomography.

CMS-approved accreditation organization means an accreditation organization designated by CMS to perform the accreditation functions specified in section 1834(e) of the Act.

(c) *Application and reapplication procedures for accreditation organizations.* An independent accreditation organization applying for approval or reapproval of authority to survey suppliers for purposes of accrediting suppliers furnishing the TC of advanced diagnostic imaging services is required to furnish CMS with all of the following:

(1) A detailed description of how the organization's accreditation criteria satisfy the statutory standards authorized by section 1834(e)(3) of the Act, specifically—

(i) Qualifications of medical personnel who are not physicians and who furnish the TC of advanced diagnostic imaging services;

(ii) Qualifications and responsibilities of medical directors and supervising physicians (who may be the same person), such as their training in advanced diagnostic imaging services in a residency program, expertise obtained through experience, or continuing medical education courses;

- (iii) Procedures to ensure the reliability, clarity, and accuracy of the technical quality of diagnostic images produced by the supplier, including a thorough evaluation of equipment performance and safety;
 - (iv) Procedures to ensure the safety of persons who furnish the TC of advanced diagnostic imaging services and individuals to whom such services are furnished;
 - (v) Procedures to assist the beneficiary in obtaining the beneficiary's imaging records on request; and
 - (vi) Procedures to notify the accreditation organization of any changes to the modalities subsequent to the organization's accreditation decision.
- (2) An agreement to conform accreditation requirements to any changes in Medicare statutory requirements authorized by section 1834(e) of the Act. The accreditation organization must maintain or adopt standards that are equal to, or more stringent than, those of Medicare.
 - (3) Information that demonstrates the accreditation organization's knowledge and experience in the advanced diagnostic imaging arena.
 - (4) The organization's proposed fees for accreditation for each modality in which the organization intends to offer accreditation, including any plans for reducing the burden and cost of accreditation to small and rural suppliers.
 - (5) Any specific documentation requirements and attestations requested by CMS as a condition of designation under this part.
 - (6) A detailed description of the organization's survey process, including the following:

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