

## § 414.68

year but not included on the published list of zip codes for which automated HPSA bonus payments are made should use the AQ modifier to receive the HPSA bonus payment.

[69 FR 66424, Nov. 15, 2004, as amended at 73 FR 69936, Nov. 19, 2008]

### § 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 author-

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ized 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:

(i) Type and frequency of the surveys performed.

(ii) The ability of the organization to conduct timely reviews of accreditation applications, to include the organization's national capacity.

(iii) Description of the organization's audit procedures, including random site visits, site audits, or other strategies for ensuring suppliers maintain compliance for the duration of accreditation.

(iv) Procedures for performing unannounced site surveys.

(v) Copies of the organization's survey forms.

(vi) A description of the accreditation survey review process and the accreditation status decision-making process, including the process for addressing deficiencies identified with the accreditation requirements, and the procedures used to monitor the correction of deficiencies found during an accreditation survey.

(vii) Procedures for coordinating surveys with another accrediting organization if the organization does not accredit all products the supplier provides.

(viii) Detailed information about the individuals who perform evaluations for the accreditation organization, including all of the following information:

(A) The number of professional and technical staff that are available for surveys.

(B) The education, employment, and experience requirements surveyors must meet.

(C) The content and length of the orientation program.

(ix) The frequency and types of in-service training provided to survey personnel.

(x) The evaluation systems used to monitor the performance of individual surveyors and survey teams.

(xi) The policies and procedures regarding an individual's participation in the survey or accreditation decision process of any organization with which the individual is professionally or financially affiliated.

(xii) The policies and procedures used when an organization has a dispute regarding survey findings or an adverse decision.

(7) Detailed information about the size and composition of survey teams

for each category of advanced medical imaging service supplier accredited.

(8) A description of the organization's data management and analysis system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(9) The organization's procedures for responding to and for the investigation of complaints against accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and CMS.

(10) The organization's policies and procedures for the withholding or removal of accreditation status for facilities that fail to meet the accreditation organization's standards or requirements, and other actions taken by the organization in response to noncompliance with its standards and requirements. These policies and procedures must include notifying CMS of Medicare facilities that fail to meet the requirements of the accrediting organization.

(11) A list of all currently accredited suppliers, the type and category of accreditation currently held by each supplier, and the expiration date of each supplier's current accreditation.

(12) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data in ASCII comparable code.

(13) A resource analysis that demonstrates that the organization's staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(14) A statement acknowledging that, as a condition for approval of designation, the organization agrees to carry out the following activities:

(i) Prioritize surveys for those suppliers needing to be accredited by January 1, 2012.

(ii) Notify CMS, in writing, of any Medicare supplier that had its accreditation revoked, withdrawn, revised, or any other remedial or adverse action taken against it by the accreditation organization within 30 calendar days of any such action taken.

(iii) Notify all accredited suppliers within 10 calendar days of the organization's removal from the list of designated accreditation organizations.

(iv) Notify CMS, in writing, at least 30 calendar days in advance of the effective date of any significant proposed changes in its accreditation requirements.

(v) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(vi) Notify CMS, in writing (electronically or hard copy), within 2 business days of a deficiency identified in any accreditation supplier from any source where the deficiency poses an immediate jeopardy to the supplier's beneficiaries or a hazard to the general public.

(vii) Provide, on an annual basis, summary data specified by CMS that relates to the past year's accreditations and trends.

(viii) Attest that the organization will not perform any accreditation surveys of Medicare-participating suppliers with which it has a financial relationship in which it has an interest.

(ix) Conform accreditation requirements to changes in Medicare requirements.

(x) If CMS withdraws an accreditation organization's approved status, work collaboratively with CMS to direct suppliers to the remaining accreditation organizations within a reasonable period of time.

(d) *Determination of whether additional information is needed.* If CMS determines that additional information is necessary to make a determination for approval or denial of the accreditation organization's application for designation, the organization must be notified and afforded an opportunity to provide the additional information.

(e) *Visits to the organization's office.* CMS may visit the organization's offices to verify representations made by the organization in its application, including, but not limited to, reviewing documents and interviewing the organization's staff.

(f) *Formal notice from CMS.* The accreditation organization will receive a formal notice from CMS stating whether the request for designation has been approved or denied. If approval was de-

nied the notice includes the basis for denial and reconsideration and re-application procedures.

(g) *Ongoing responsibilities of a CMS-approved accreditation organization.* An accreditation organization approved by CMS must carry out the following activities on an ongoing basis:

(1) Provide CMS with all of the following in written format (either electronic or hard copy):

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to suppliers.

(iv) Information about all accredited suppliers against which the accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the supplier's accreditation.

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS' approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 calendar days after a change in CMS requirements, the accreditation organization must submit an acknowledgment of receipt of CMS' notification to CMS.

(3) The accreditation organization must permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 2 business days of identifying a deficiency of an accredited supplier that poses immediate jeopardy to a beneficiary or to the general public, the accreditation organization must provide CMS with written notice of the deficiency and any adverse action implemented by the accreditation organization.

(5) Within 10 calendar days after CMS' notice to a CMS-approved accreditation organization that CMS intends to withdraw approval of the accreditation organization, the accreditation organization must provide written notice

of the withdrawal to all of the organization's accredited suppliers.

(6) The organization must provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(h) *Continuing Federal oversight of approved accreditation organizations.* This paragraph establishes specific criteria and procedures for continuing oversight and for withdrawing approval of a CMS-approved accreditation organization.

(1) *Validation audits.* (i) CMS or its contractor may conduct an audit of an accredited supplier to validate the survey accreditation process of approved accreditation organizations for the TC of advanced diagnostic imaging services.

(ii) The audits must be conducted on a representative sample of suppliers who have been accredited by a particular accrediting organization or in response to allegations of supplier non-compliance with the standards.

(A) When conducted on a representative sample basis, the audit is comprehensive and addresses all of the standards, or may focus on a specific standard in issue.

(B) When conducted in response to an allegation, CMS audits any standards that CMS determines are related to the allegations.

(2) *Notice of intent to withdraw approval.* (i) If, during the audit specified in paragraph (h)(1) of this section, CMS identifies any accreditation programs for which validation audit results indicate—

(A) A 10 percent or greater rate of disparity between findings by the accreditation organization and findings by CMS on standards that do not constitute immediate jeopardy to patient health and safety if unmet; or

(B) Any disparity between findings by the accreditation organization and findings by CMS on standards that constitute immediate jeopardy to patient health and safety if unmet; or,

(C) Irrespective of the rate of disparity, widespread or systemic problems in an organization's accreditation process such that accreditation by that accreditation organization no longer provides CMS with adequate assurance

that suppliers meet or exceed the Medicare requirements; then CMS will give the organization written notice of its intent to withdraw approval as specified in paragraph (h)(3) of this section.

(ii) CMS may also provide the organization written notice of its intent to withdraw approval if an equivalency review, onsite observation, or CMS' daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this section.

(3) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Accreditation by the organization no longer adequately assures that the suppliers furnishing the technical component of advanced diagnostic imaging service are meeting the established industry standards for each modality and that failure to meet those requirements could jeopardize the health or safety of Medicare beneficiaries and could constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations with respect to application or reapplication procedures.

(1) *Reconsideration.* An accreditation organization dissatisfied with a determination that its accreditation requirements do not provide or do not continue to provide reasonable assurance that the suppliers accredited by the accreditation organization meet the applicable quality standards is entitled to a reconsideration. CMS reconsiders any determination to deny, remove, or not renew the approval of designation to accreditation organizations if the accreditation organization files a written request for reconsideration by its authorized officials or through its legal representative.

(1) *Filing requirements.* (i) The request must be filed within 30 calendar days of the receipt of CMS notice of an adverse determination or non-renewal.

(ii) The request for reconsideration must specify the findings or issues with which the accreditation organization disagrees and the reasons for the disagreement.

(iii) A requestor may withdraw its request for reconsideration at any time

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before the issuance of a reconsideration determination.

(2) *CMS response to a filing request.* In response to a request for reconsideration, CMS provides the accreditation organization with—

(i) The opportunity for an informal hearing to be conducted by a hearing officer appointed by the Administrator of CMS and provide the accreditation organization the opportunity to present, in writing and in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew designation; and

(ii) Written notice of the time and place of the informal hearing at least 10 business days before the scheduled date.

(3) *Hearing requirements and rules.* (i) The informal reconsideration hearing is open to all of the following:

(A) CMS.

(B) The organization requesting the reconsideration including—

(1) Authorized representatives;

(2) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts); and

(3) Legal counsel.

(ii) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action.

(iii) Testimony and other evidence may be accepted by the hearing officer even though such evidence may be inadmissible under the Federal Rules of Civil Procedure.

(iv) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(v) Within 45 calendar days of the close of the hearing, the hearing officer presents the findings and recommendations to the accreditation organization that requested the reconsideration.

(vi) The written report of the hearing officer includes separate numbered findings of fact and the legal conclusions of the hearing officer.

(vii) The hearing officer's decision is final.

[74 FR 62006, Nov. 25, 2009]

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### Subpart C—Fee Schedules for Parenteral and Enteral Nutrition (PEN) Nutrients, Equipment and Supplies

SOURCE: 66 FR 45176, Aug. 28, 2001, unless otherwise noted.

#### § 414.100 Purpose.

This subpart implements fee schedules for PEN items and services as authorized by section 1842(s) of the Act.

#### § 414.102 General payment rules.

(a) *General rule.* For items and services furnished on or after January 1, 2002, Medicare pays for the items and services as described in paragraph (b) of this section on the basis of 80 percent of the lesser of—

(1) The actual charge for the item or service; or

(2) The fee schedule amount for the item or service, as determined in accordance with § 414.104.

(b) *Payment classification.* (1) CMS or the carrier determines fee schedules for Parenteral and enteral nutrition (PEN) nutrients, equipment, and supplies, as specified in § 414.104.

(2) CMS designates the specific items and services in each category through program instructions.

(c) *Updating the fee schedule amounts.* For each year subsequent to 2002, the fee schedule amounts of the preceding year are updated by the percentage increase in the CPI-U for the 12-month period ending with June of the preceding year.

#### § 414.104 PEN Items and Services.

(a) *Payment rules.* Payment for PEN items and services is made in a lump sum for nutrients and supplies that are purchased and on a monthly basis for equipment that is rented.

(b) *Fee schedule amount.* The fee schedule amount for payment for an item or service furnished in 2002 is the lesser of—

(i) The reasonable charge from 1995; or

(ii) The reasonable charge that would have been used in determining payment for 2002.