

CMS Proposes Rules Regarding Implementation of Accreditation Standards

By Adrienne Dresevic, Esq. and Carey F. Kalmowitz, Esq., The Health Law Partners, P.C.

Pursuant to Section 135 (a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), January 1, 2012 will be a turning point for providers of the technical component (TC) of advanced diagnostic imaging services payable under the Medicare Physician Fee Schedule (the "fee schedule") (eg, mobile units, physician offices, and independent diagnostic testing facilities), as Medicare payment will only be made for the TC of advanced imaging services to a supplier who is accredited by a CMS-designated accreditation organization (AO). The 2010 Medicare Proposed Physician Fee Schedule (2010 PPFs), released in July of 2009, addresses aspects of the implementation of MIPAA's upcoming accreditation standards. This article summarizes CMS' proposals.

Accreditation Requirement

In the 2010 PPFs, CMS set forth criteria for AOs to accredit suppliers furnishing the TC of advanced diagnostic imaging services and promulgated proposed procedures to ensure that the criteria used by an AO meets the minimum standards for each imaging modality. CMS defines "advanced diagnostic imaging services" as "diagnostic magnetic resonance imaging (MRI), computed tomography (CT), nuclear medicine, and positron emission tomography (PET)."

The AO would apply standards that prescribed qualifications for non-physician personnel who furnish the TC. These standards set forth qualifications and responsibilities for medical directors and supervising physicians including the following:

- whether a medical director or supervising physician received training in advanced imaging services in a residency program;
- whether a medical director or supervising physician has attained, through experience, the necessary expertise to be a medical director or supervising physician;
- whether a medical director or supervising physician

has completed any continuing medical education courses related to advanced imaging services; and

- whether a medical director or supervising physician has met any other standards the Secretary deems important or necessary.

In addition, the standards would require suppliers to meet certain requirements designed to ensure and maintain the quality and the safety of the furnished advanced diagnostic imaging services. More specifically, CMS proposes mandating suppliers to: (1) establish and maintain a quality control program that ensures the technical quality of the diagnostic images produced by the supplier; (2) ensure that the equipment meets performance specifications; and (3) ensure the safety of the personnel involved in furnishing the services.

On or before November 1, 2009, CMS expects to publish a notice to solicit applications from entities that want to become an AO. CMS is required to designate AOs by 2010.

Accreditation for Suppliers

With the goal of ensuring consistency in accrediting providers and suppliers throughout the Medicare program generally, CMS proposes to use existing procedures for the application, selection, and oversight of AOs and apply them to the suppliers of the TC of advanced diagnostic imaging services. CMS also proposes modifications to the existing procedures in order to meet the specialized needs of the advanced imaging industry. These additional modifications will require an organization applying for approval as an AO to include the following in their application:

- a detailed description of how the organization meets the current accreditation standards, specifically:
- qualifications of medical personnel (non-physicians) who furnish the TC of the advanced diagnostic imag-

... continued on next page

CMS Proposes Rules Regarding Implementation of Accreditation Standards

... from previous page
ing services;

- qualifications and responsibilities of medical directors and supervising physicians;
- procedures to ensure safety of personnel and patients; and
- procedures to ensure reliability, clarity, and accuracy of the technical quality of the services.
- an agreement to conform accreditation requirements to any changes in Medicare statutory requirements;
- information to demonstrate the organization's knowledge and experience in the advanced imaging industry;
- the organization's proposed accreditation fees for each modality in which the organization intends to offer accreditation and any plans for reducing the burden and accreditation cost to small and rural suppliers; and
- any specific documentation requirements and attestations requested by CMS.

Once submitted, the organization will receive a formal notice from CMS stating whether the request to become an AO has been approved or denied. To those applicants that are denied, the notice will include the basis for the denial, and will outline the reconsideration procedures available to that organization.

Payment Rules for Suppliers

CMS proposes to specify in Section 414.68 that all suppliers of the TC of advanced diagnostic imaging services be accredited by an AO by January 1, 2012 for payments made under the fee schedule. CMS also notes that advanced diagnostic imaging services include MRI, CT, nuclear medicine, and PET, and that at this time it is not proposing to include other diagnostic imaging services under the definition.

Ongoing Responsibilities of AOs

After an organization has been approved and designated as an AO, CMS proposes requiring the organization to, on a regular and continual basis, perform and submit, in writing, the following:

copies of all accreditation surveys of specific suppliers;

- notice of all accreditation decisions;
- notice of complaints related to the TC of advanced diagnostic imaging services; information about any suppliers of the TC of advanced diagnostic imaging services for which the accrediting organization has denied the supplier's accreditation status;
- notice of any proposed changes in its accreditation standards;
- permit its surveyors to serve as witnesses if CMS takes any adverse action based on accreditation findings;
- provide CMS with written notice of any deficiencies and adverse actions implemented by the CMS-approved AO against an accredited supplier of the TC of advanced diagnostic imaging services within two days of identifying the deficiencies, if the deficiencies pose an immediate jeopardy to a beneficiary or to the general public;
- provide written notice of withdrawal to all accredited suppliers within 10 days of CMS' notice to withdraw approval of the AO; and
- annually provide summary data specified by CMS that is related to the past year's accreditation activities and trends.

Continuing CMS Oversight of AOs

CMS Validation Audits

... continued on next page

CMS Proposes Rules Regarding Implementation of Accreditation Standards

... from previous page

While CMS proposes mandating designated AOs to submit the aforementioned materials, CMS proposes to audit AOs to validate the survey accreditation process. These validation audits will be comprehensive and will be conducted on a representative sample of suppliers who have been accredited by a particular AO, or in response to allegations of supplier non-compliance with the standards. If a supplier selected for a validation audit fails the audit, its accreditation will be revoked, and it will no longer be eligible to receive Medicare payment for the TC of advanced diagnostic imaging services furnished to beneficiaries.

Results of the Validation Audits

Of all of the audited AOs, CMS proposes to identify any AOs in which their accreditation programs indicate any of the following:

- a 10% rate of disparity between findings by the AO and findings by CMS on standards that did not constitute immediate jeopardy to patient health and safety if not met;
- any disparity between findings by the AO and findings by CMS on standards that constituted immediate jeopardy to patient health and safety if not met; or
- there were widespread or systematic problems in

the organization's accreditation process such that the accreditation no longer provides assurance that suppliers meet or exceeded the Medicare requirements, irrespective of the rate of disparity.

CMS further proposes that if a validation audit, onsite observation, or other ethical concerns of an AO suggest that the AO is not meeting its requirements, CMS will provide the AO with notice of its intent to withdraw its approval. CMS proposes withdrawing approval of those organizations that fail to provide sufficient assurance that suppliers no longer meet Medicare's requirements, putting the beneficiary's health in jeopardy; that constitute a significant hazard to the public's health; or that failed to meet its obligations. AOs would be entitled to reconsideration of CMS' proposal to withdraw approval.

RAs and RPAs

Finally, in the 2010 PPFs, CMS is soliciting information on the role of radiology assistants (RA) and radiology practitioner assistants (RPA), including the level of physician supervision that would be appropriate when RAs and RPAs are involved in the performance of the TC of advanced diagnostic imaging, whether the role varies by State, and any related information. CMS is soliciting specific clinical scenarios with associated CPT codes that would represent such services involving RAs and RPAs.