DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6023–N]

Medicare Program; Solicitation of Independent Accrediting Organizations To Participate in the Advanced Diagnostic Imaging Supplier Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces to independent accreditation organizations an opportunity to submit applications to participate in the advanced diagnostic imaging supplier accreditation program as a designated accreditation organization. Advanced diagnostic imaging accreditation is required for suppliers furnishing the technical component (TC) of advanced diagnostic imaging services. This notice contains information on accreditation application guidelines for CMS approval of suppliers who furnish the TC of advanced diagnostic imaging services.

DATES: Applications will be considered for the January 1, 2010 designation deadline if received at the address, provided in the **ADDRESSES** section of this notice, no later than 5 p.m. eastern standard time (e.s.t.) on December 1, 2009.

ADDRESSES: Applications should be sent to the following: Attention: Sandra Bastinelli, Office of Financial Management, Mail stop C3–02–16, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244.

FOR FURTHER INFORMATION CONTACT: Sandra Bastinelli, (410) 786–3630.

SUPPLEMENTARY INFORMATION:

I. Background

Section 135(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) added section 1834(e) of the Social Security Act (the Act) that requires the Secretary to designate organizations in order to accredit suppliers furnishing the technical component (TC) of advanced diagnostic imaging service and establish procedures to ensure that the criteria used by an accreditation organization is specific to each imaging modality. Section 1834 (e)(1)(B) of the Act defines advanced diagnostic imaging services as—

(i) Diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine—including positron emission tomography, and

(ii) Such other diagnostic imaging services, including services described in section 1848(b)(4)(B) (excluding x-ray, ultrasound, and fluoroscopy, as specified by the Secretary in consultation with physician specialty organizations and other stakeholders.

Section 1848(b)(4)(B) of the Act defines imaging services as ''imaging and computer-assisted imaging services, including x-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography.'' Suppliers of the TC of advanced diagnostic imaging services for which payment is made under the fee schedule established under section 1848(b) of the Act, must become accredited by an accreditation organization designated by the Secretary beginning January 1, 2012.

II. Provisions of the Notice

This notice solicits applications from accreditation organizations with the ability to accredit the TC of at least one of the categories of advanced diagnostic imaging services.

A. Eligible Organizations

An accreditation organization that can show evidence of the ability to accredit at least one of the categories of advanced diagnostic imaging services as defined in sections 1834(e)(1)(B) and 1848 (b)(4)(B) of the Act is eligible to apply for approval as a designated accreditation organization.

B. Application Requirements

To be considered for approval as a designated accreditation organization for Medicare requirements under 42 CFR 414.68, an accreditation organization must furnish to us all of the following information:

- A list of the categories of advanced diagnostic imaging services for which the organization is requesting approval.
- A description of the accrediting organization's duration of accreditation (annual, biannual, and triennial), to include a summary of activities that occur at each cycle.
- A detailed description of how the organization's accreditation criteria satisfy the statutory standards at section 1834(e)(3) of the Act, including the following:

++ Qualifications of medical personnel who are not physicians and who furnish the TC of advanced diagnostic imaging services.

++ Qualifications and responsibilities of medical directors and supervising physicians, such as training in advanced diagnostic imaging services in a residency program, expertise obtained through experience or continuing medical education courses.

++ Procedures to ensure the safety of persons who furnish the TC of advanced diagnostic imaging services and individuals to whom such services are furnished.

++ Procedures to ensure the reliability, clarity, and accuracy of the technical quality of diagnostic images produced by the supplier.

- A detailed description of the organization's survey process, to include the following:

++ Type and frequency of the surveys performed.

++ The ability of the organization to conduct timely reviews of accreditation applications, to include a projection of the organization's national capacity for processing new applications before the January 1, 2012 accreditation deadline.

++ Description of the organization's audit procedures, including—random site visits; site audits or other strategies for ensuring suppliers accredited by the organization maintain compliance throughout the period of accreditation.

++ Procedures for performing unannounced site surveys.

++ Copies of the organization's survey forms.

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

++ Procedures for coordinating surveys with another accrediting organization (when the organization does not accredit all modalities) provided by an applicant for accreditation which the supplier provided.

++ Comprehensive information about the individuals who perform evaluations for the accreditation organization, including all of the following information:

—Detailed information about the size and composition of accreditation teams for each category of advanced medical imaging service supplier accredited.

—The number of professional and technical staff that are available for survey.

—The education, current employment and experience requirements surveyors must meet.

—The content and length of any orientation program.

—The frequency and types of in-service training provided to survey personnel.
—The evaluation systems used to monitor the performance of individual surveyors and survey teams.
—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.

++ Policies and procedures used when an organization has a dispute regarding survey findings or an adverse decision.

• A description of the organization's data management and analysis capabilities in support of its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

• The organization's procedures for investigating and responding to complaints against accredited facilities, including policies and procedures regarding coordination of these activities with relevant licensing bodies and CMS.

• A description of the organization's policies and procedures for withholding or removal of accreditation status for facilities that fail to meet the organization's accreditation standards and other actions taken by the organization in response to noncompliance with its accreditation criteria. These policies and procedures must include notifying CMS of facilities that fail to meet the requirements of the accrediting organization as required by CMS.

• The information submitted for notification of these organizations includes—

++ A list of all accredited suppliers that the accrediting organization has accredited to include the type and category of accreditation currently held by each supplier, and the expiration date of each supplier's current accreditation;

++ A list of all accreditation surveys scheduled to be performed by the organization;

++ A plan for reducing the burden and cost of accreditation to small and rural suppliers;

++ Information to demonstrate the accreditation organization's knowledge and experience in the advanced medical imaging arena;

++ The organization's proposed fees for accreditation for each modality in which the organization intends to offer accreditation; and

++ Any specific documentation requirements and attestations requested by CMS as a condition of designation.

• The accreditation organization must also submit the following supporting documentation:

++ A written presentation that demonstrates the organization's ability to furnish us with electronic data in ASCII comparable code.

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

++ A statement acknowledging that, as a condition for approval the organization will agree to the following:

—Provide a statement agreeing to notify us, in writing, of any 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.
—Notify all accredited suppliers within 10 calendar days of our withdrawal of the organization's approval of deeming authority.
—Notify us, in writing, at least 30 calendar days in advance of the effective date of any proposed changes in accreditation requirements.
—Permit its surveyors to serve as witnesses if we take an adverse action based on accreditation findings.
—Notify us, in writing, within 2 calendar days of a deficiency identified in any accreditation entity where the deficiency poses an immediate jeopardy to the supplier's beneficiaries or a hazard to the general public.
—Provide, on an annual basis, summary data specified by us that relates to the past years' accreditations and trends.
—Attest that the organization will not perform any accreditation surveys of Medicare participating suppliers with which it has a financial relationship with or interest.

If, after review of an accreditation organization's submission of information we determine that additional information is necessary to make a determination for approval or denial of the accreditation organization's application, the organization will be notified and afforded an opportunity to provide additional information. We may visit the organization's office(s) to verify representations made in the organization's accreditation application. The site visit may include, but is not limited to, review of documents and interviews with the organization's staff. The accreditation organization will receive a formal notice from us stating whether the request for designation has been approved or denied, the rationale for any denial and reconsideration, and reapplication procedures.

We will make every effort to issue a final decision within 30 days from the time we receive the completed accreditation reapplication. An accreditation organization may withdraw its application for designation under section 1834(e) of the Act at any time prior to the formal notice of approval or denial is received. An accreditation organization notified of a denial of request for designation may request a reconsideration in accordance with 42 CFR 488.201 through 488.211. Any accreditation organization whose request for approval of designation has been denied may resubmit the application if the organization—

• Revises its accreditation program to address the rationale for denial of its previous request;

• Provides reasonable assurance that its accredited companies meet applicable Medicare requirements; and

• Resubmits the application in its entirety. If an accreditation organization is denied reconsideration determination (as designated under section 1834(e) of the Act), the organization may not submit a new application as a designated accreditation organization for the type of modality that is at issue in the reconsideration until the reconsideration is final.

C. Application Deadline

The deadline for the submission of applications is the date specified in the **DATES** section of this notice.

D. Evaluation of Applications

A panel will evaluate all applications from accreditation organizations seeking designation under section 1834(e) of the Act using the existing survey and certification process as established in 42 CFR part 488.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

We detailed the burden associated with the submission of advanced diagnostic imaging provider accreditation applications from independent accrediting bodies in the CY 2010 Physician Fee Schedule final rule that published elsewhere in this **Federal Register**. We are reprinting the discussion of the information collection requirements in this notice.

Section 414.68(b) contains the application and reapplication procedures for accreditation organizations. Specifically, an independent accreditation organization applying for approval or reapproval of authority to survey suppliers for purposes of accrediting suppliers furnishing the technical component (TC) of advanced diagnostic imaging services must furnish CMS with all of the information listed in proposed § 414.68(b)(1) through (14). The requirements include but are not limited to reporting, notification, documentation, and survey requirements.

The burden associated with the collection requirements in § 414.68(b) is the time and effort necessary to develop, compile and submit the information listed in § 414.68(b)(1) through (14). We believe all 3 entities will choose to comply with these requirements. We estimate that it will take each of the 3 entities, 80 hours to submit a complete application for approval or reapproval authority to become an accrediting organization approved by CMS.

Section 414.68(c) contains the information collection requirements pertaining to CMS approved accrediting organizations. An accrediting organization approved by CMS must undertake all of the activities listed in § 414.68(c)(1) through (6). The burden associated with the collection requirements in § 414.68(c) is the time and effort necessary to develop, compile and submit the information listed in § 414.68(c)(1) through (6). We believe that 3 entities will choose to comply with these requirements. We estimate that it will take each of the 3 entities, 80 hours to submit the required information on an ongoing basis.

Section 414.68(d)(1) states that CMS or its contractor may conduct an audit of an accredited supplier, examine the results of a CMS approved accreditation organization's survey of a supplier, or observe a CMS approved accreditation organization's onsite survey of a supplier, in order to validate the CMS approved accreditation organizations accreditation process. The burden associated with this requirement is the time and effort necessary for an accrediting organization to comply with the components of the validation audit. While this requirement is subject to the PRA, we believe the associated burden is exempt as stated in 5 CFR 1320.3(h)(6). The burden associated with a request for facts addressed to a single person, as defined in 5 CFR 1320.3(j), is not subject to the PRA.

As stated in § 414.68(e)(1), 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 organization meet the applicable quality standards is entitled to a reconsideration. CMS reconsiders any determination to deny, remove, or not to renew the approval of deeming authority to an accreditation organization if the accrediting organization files a written request for reconsideration by its authorized officials or through its legal representative. The written request must be filed within 30 calendar days of the receipt of CMS' notice of an adverse determination or nonrenewal. In addition, the request must also specify the findings or issues with which the accreditation organization disagrees and the reasons for the disagreement.

The burden associated with this requirement is the time and effort necessary for an accrediting organization to develop and file a written request for reconsideration. While this requirement is subject to the PRA, the associated burden is exempt under 5 CFR 1320.4. The information in question is being collected as a result of an administrative action; accrediting organizations are submitting requests for reconsideration after receiving a notice of an adverse decision.

Authority: Section 1834(e) of the Act.

Dated: October 13, 2009.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare-Supplementary Medical Insurance Program)

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

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