Kimberly S. Lane,

Deputy Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6023–N3]

Medicare Program; Approval of Accrediting Organization for Suppliers of Advanced Diagnostic Imaging Supplier Accreditation Program

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

ACTION: Notice.

SUMMARY: This notice announces our approval of RadSite™, a national accreditation organization to accredit suppliers seeking to furnish the technical component (TC) of advanced diagnostic imaging services under the Medicare program.

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) to the Social Security Act (the Act) requiring the Secretary to designate organizations that accredit suppliers furnishing the technical component (TC) of advanced diagnostic imaging (ADI) service and establish procedures to ensure that the criteria used by an accreditation organization are specific to each imaging modality. Section 1834(e)(1)(B) of the Act defines advanced diagnostic imaging services as—

(i) [D]iagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and

(ii) [S]uch 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, which include physicians, non-physician practitioners and physician and non-physician organizations, 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, were required to be accredited by an accreditation organization designated by the Secretary beginning January 1, 2012.

The application requirements for accrediting organizations were finalized in the Calendar Year 2010 Physician Fee Schedule final rule published on November 25, 2009 (74 FR 61738), as corrected in the November 30, 2009 correcting document (74 FR 62579) and set forth as application criteria in a November 25, 2009 **Federal Register** notice (74 FR 62189), as corrected in the November 30, 2009 correction notice (74 FR 62579).

In the January 26, 2010, **Federal Register** (75 FR 4088), we announced the approval of the American College of Radiology (ACR), the Intersocietal Accreditation Commission (IAC), and The Joint Commission (TJC) as designated accreditation organizations to accredit suppliers furnishing the technical component of the following advanced diagnostic imaging modalities: Computerized tomography, nuclear medicine, positron emission tomography, and magnetic resonance imaging.

II. Application Requirements, Review, and Approval

We received the completed application from RadSite™ to be considered as a designated accreditation organization for advanced diagnostic imaging services on January 18, 2011. An internal professional panel reviewed and compared the standards contained in the application with our requirements in 42 CFR 414.68. Accordingly, to be considered for approval as a designated accreditation organization, the accreditation organization had to furnish the following information specified in 42 CFR 414.68(c):

- 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.

++ Procedures to assist the beneficiary in obtaining the beneficiary's imaging records on request.

++ Procedures to notify CMS of any changes to the modalities subsequent to the organization's accreditation decision.

- An agreement to conform accreditation requirements to any changes in Medicare statutory requirements authorized by 1834(e) of the Act.
- An agreement to maintain or adopt standards that are equal to, or more stringent than, those of Medicare.
- Information that demonstrates the accreditation organization's knowledge and experience in the advanced diagnostic imaging arena.
- A plan for reducing the burden and cost of accreditation to small and rural suppliers that include—

++ 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.

- 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.

++ 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 include—

++ 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; and

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

• 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 designation 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.

(For further information regarding the application requirements see the November 25, 2009 (74 FR 62189) and November 30, 2009 (74 FR 62579) notices.)

We have complete our review and believe that RadSite™ has provided us with demonstrated evidence of their qualifications and ability to accredit the categories of advanced diagnostic imaging services to include computerized tomography, nuclear medicine, positron emission tomography, and magnetic resonance imaging as defined in sections 1834(e)(1)(B) and 1848(b)(4)(B) of the Act. Therefore this notice announces our approval of RadSite™ to accredit suppliers furnishing the TC of all advanced imaging modalities (that is, computerized tomography, nuclear medicine, positron emission tomography, and magnetic resonance imaging) on or after September 27, 2013.

Authority: Section 1834(e) of the Act.

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

Dated: September 19, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4167–N]

Medicare Program; Medicare Appeals: Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2014

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

ACTION: Notice.

SUMMARY: This notice announces the annual adjustment in the amount in controversy (AIC) threshold amounts for Administrative Law Judge (ALJ) hearings and judicial review under the Medicare appeals process. The adjustment to the AIC threshold amounts will be effective for requests for ALJ hearings and judicial review filed on or after January 1, 2014. The calendar year 2014 AIC threshold