Section 1311 for planning and establishment of an Exchange within one year of the enactment of the Affordable Care Act, by Statute, it will not be eligible for Section 1311 Exchange planning and establishment money in the future. Section 1311 of the Affordable Care Act provides for grants to States for the planning and establishment of these Exchanges. Given the innovative nature of Exchanges and the statutorily prescribed relationship between the Secretary and States in their development and operation, it is critical that the Secretary work closely with States to provide necessary guidance and technical assistance to ensure that States can meet the prescribed timelines, federal requirements, and goals of the statute.

In order to provide appropriate and timely guidance and technical assistance, the Secretary must have access to timely, periodic information regarding State progress. Consequently, the information collection associated with these grants is essential to facilitating reasonable and appropriate federal monitoring of funds, providing statutorily mandated assistance to States to implement Exchanges in accordance with Federal requirements, and to ensure that States have all necessary information required to proceed, such that retrospective corrective action can be minimized.

There are two levels of awards for States to apply for the Establishment grants. Grants are open to States that received federal funding for Exchange Planning activities, awardees of the Cooperative Agreements to Support Innovative Exchange Information Technology Systems, and awardees under the Cooperative Agreement to Support Establishment of State-Operated Health Insurance Exchanges. Level One Establishment cooperative agreements provide one year of funding to States that are ready to initiate establishment activities having made progress under their Exchange Planning grant. Level Two Establishment cooperative agreements are designed to provide funding to applicants for the establishment of a State-based Exchange and that can demonstrate specific eligibility criteria. Level One Establishment grantees may apply for additional funding under Level Two Establishment grants once they have achieved the benchmarks identified in the Level Two Establishment review criteria.

HHS anticipates releasing this funding opportunity on June 15, 2012. There will be four opportunities for applicants to apply for funding. HHS anticipates Level One Establishment and Level Two Establishment applications will be due: August 1, 2012; November 1, 2012; February 1, 2013; May 1, 2013; August 1, 2013; November 1, 2013; February 3, 2014; May 1, 2014; August 1, 2014; and November 3, 2014. The Period of Performance for Level One Establishment grants is up to one year after date of award. The Period of Performance for Level Two Establishment grants is up to three years after date of award. *Form Number:* CMS–10424 (OCN: 0938–NEW); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Governments. *Number of Respondents:* 50. *Number of Responses:* 325. *Total Annual Hours:* 49,175. (For policy questions regarding this collection contact Katherine Harkins at 301–492–4445. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by May 1, 2012:

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: February 27, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–5011 Filed 2–27–12; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6043–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 invites independent accreditation organizations who have not previously submitted applications to participate in the advanced diagnostic imaging supplier accreditation program as a designated accreditation organization, for the purpose of accrediting suppliers furnishing the technical component (TC) of advanced diagnostic imaging services. It also sets forth the application guidelines for approval of organizations wishing to accredit suppliers furnishing the TC of advanced diagnostic imaging services.

DATES: Applications will be considered if received at the address provided in the **ADDRESSES** section of this notice, no later than 5 p.m. daylight savings time (d.s.t.) on May 1, 2012.

ADDRESSES: Applications should be sent to the following: Attention: Sandra Bastinelli, Mail stop AR–18–50, 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) to the Social Security Act (Act). Section 1834(e) of the Act requires the Secretary to designate organizations to accredit suppliers furnishing the technical component (TC) of advanced diagnostic imaging services (section 1834(e)(2)(B) of the Act), and to establish procedures to ensure that the criteria used by such accrediting organizations to accredit TC suppliers are specific to each imaging modality and meet the requirements of the statute (section 1834(e)(3)). 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 (that is, the Physician Fee Schedule (FFS)), must become accredited by an accreditation organization designated by the Secretary (for the TC of the defined advanced diagnostic imaging services) on or after January 1, 2012 in order to receive payment from Medicare.

We implemented these statutory provisions via the CY 2010 PFS final rule which appeared in the November 25, 2009 **Federal Register** (''Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010'' (74 FR 61738). This final rule set out criteria for designating organizations to accredit suppliers furnishing the TC of advanced diagnostic imaging services, as specified in section 1834(e) of the Act. In addition, 45 CFR 414.68(h) specifies our procedures for ensuring that accreditation organizations correctly apply the criteria to ensure that suppliers are meeting minimum standards for each imaging modality.

In the same issue of the **Federal Register**, we published a notice soliciting applicants for participation in the advanced diagnostic imaging supplier accreditation program as designated accreditation organizations (''Medicare Program; Solicitation of Independent Accrediting Organizations To Participate in the Advanced Diagnostic Imaging Supplier Accreditation Program'', (74 FR 62189), November 25, 2009). As a result of this solicitation, we published a second **Federal Register** notice (Medicare Program; Approval of Independent Accrediting Organizations To Participate in the Advanced Diagnostic Imaging Supplier Accreditation Program'' (January 26, 2010 (75 FR 4088)) announcing approval of three national accreditation organizations to accredit suppliers seeking to furnish the TC of advanced diagnostic imaging services under the Medicare program: the American College of Radiology (ACR); the Intersocietal Accreditation Commission (IAC); and The Joint Commission (TJC).

II. Provisions of the Notice

This notice solicits additional applications from accreditation organizations with the ability to accredit the TC of at least one of the categories of advanced diagnostic imaging services as defined at 42 CFR 414.68(b).

A. Eligible Organizations

Any 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 imaging services accreditation organization. As previously noted, this notice solicits applications from accrediting organizations that have not previously applied; the three existing designated accreditation organizations and current applicants are not required to reapply.

B. Application Requirements

To be considered for approval as a designated accreditation organization for Medicare requirements under 42 CFR 414.68 and as defined by sections 1834(e)(1)(B) and 1848 (b)(4)(B) of the Act an accreditation organization must furnish us with the following, as specified in 42 CFR 414.68(c):

- A detailed description of how the organization's accreditation criteria satisfy the statutory standards at section 1834(e)(3)of the Act, including—

++ 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 (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.

++ 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;

++ 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 assist the beneficiary in obtaining the beneficiary's imaging record on request; and

++ Procedure to notify the accreditation organization of any changes to the modalities subsequent to the organizations' accreditation decision.

- 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.
- Information that demonstrates the accreditation organization's knowledge and experience in the advanced diagnostic imaging arena.
- 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.
- Any specific documentation requirements and attestations requested by CMS as a condition of designation under this part.
- A detailed description of the organization's survey process, including the following:

++ Type and frequency of the surveys performed.

++ The ability of the organization to conduct timely reviews of accreditation applications, to include the organizations national capacity.

++ 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.

++ Procedures for performing unannounced site surveys.

++ Copies of the organizations survey forms.

++ A description of the accreditation survey review process and the accreditation status decision-making process, including the process for addressing deficiencies identified what 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 if the organization does not accredit all products the supplier provides.

++ Detailed information about the individuals who perform evaluations for the accreditation organization,

including all of the following information:

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

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

—The content and length of the 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.

++ 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.

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

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

• 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.

• 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.

• The organization's policies and procedures for the withholding or removal accreditation status for facilities that fail to meet the accreditation organization's standards or requirement, 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.

• 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.

• A written presentation that demonstrates the organization's ability to furnish CMS 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 of designation, the organization agrees to:

++ 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.

++ Notify all accredited supplier within 10 calendar days of the organizations' removal for the list of designated accreditation organizations.

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

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

++ 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.

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

++ 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.

++ Conform accreditation requirements to changes in Medicare requirements.

++ 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.

C. Application Deadline and Notification of Receipt

The deadline for the submission of applications is the date specified in the **DATES** section of this notice. We will acknowledge receipt of applications via email.

D. Evaluation of Application

A professional and medical panel will evaluate all applications from accreditation organizations seeking designation under section 1834(e) of the Act.

If we determine that additional information is necessary to make a determination for approval or denial of the accreditation organization's application for designation, we will notify the organization and afford it an opportunity to provide the additional information. We may also 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.

E. Approval of Application

The accreditation organization will receive a formal notice via mail from CMS approving or denying the request for consideration. If denied, the notice will state the basis for denial, and include information about seeking reconsideration and reapplication procedures. 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 reconsideration in accordance with 42 CFR 414.68(i). Any accreditation organization whose request for approval of designation has been denied may also resubmit the application to us 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.

An organization may not submit a new application for the same type of modality as that initially applied for, until any reconsideration proceedings under § 414.68(i) with respect to the previous application are completed.

We will publish a **Federal Register** document notifying the public of the approved applicants.

F. Term of Approval of Designation of Accreditation Organizations

Under section 1834(e)(2)(C)(i) of the Act, the Secretary shall review the list of accreditation organizations designated, taking into account the performance of such organizations, and may, by regulation, modify the list of accreditation organizations designated. Our regulations at § 414.68(h) set out the specific criteria and procedures for continuing CMS oversight of approved accreditation organizations, and for withdrawing approval of a CMS approved accreditation organization. There is no stated period of performance related to this accreditation designation.

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 detailed the burden associated with the submission of advanced diagnostic imaging provider accreditation applications from independent accrediting bodies in the CY 2010 PFS final rule that published November 25, 2009 (74 FR 61738). We are summarizing 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 estimate that it will take an entity 80 hours to submit a complete application for approval or reapproval authority to become an accrediting organization approved by CMS. Three entities complied with these requirements during the initial round of submissions. Currently, we are only aware of one other entity that is eligible to submit an application. In addition, the three currently approved accrediting organizations are not required to resubmit applications. Furthermore, we are not able to accurately quantify the total number of entities that are eligible to comply with these requirements beyond those previously identified. While these requirements are subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(c)(4). This collection will impact less than 10 entities in a 12-month period. We cannot estimate the number of expected submissions from entities seeking to become accrediting organizations. We will review each submission on a case-by-case basis. If we determine that the number of submissions may exceed the threshold of 10 or more persons in a 12-month period, as defined in 5 CFR 1320.3(c)(4), we will develop an information collection request as part of the formal OMB approval process.

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 estimate that it will take the applicant entity 80 hours to submit the required information on an ongoing basis. As stated earlier, there are 3 currently approved accrediting organizations that have already complied with this requirement. In addition, we are only aware of one other entity that is eligible to submit an application; we are not able to accurately quantify the total number of entities that are eligible to comply with these requirements beyond those previously identified. While these requirements are subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(c)(4). This collection will impact less than 10 entities in a 12-month period. Because we cannot estimate the number of expected submissions from new CMS approved accrediting organizations, we will review each submission on a case-by-case basis. If we determine that the number of submissions may exceed the threshold of 10 or more persons in a 12-month period, as defined in 5 CFR 1320.3(c)(4), we will develop an information collection request as part of the formal OMB approval process.

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. We reconsider 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 our 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 file, develop and file 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 determination.

Authority: Section 1834(e) of the Act.

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

Dated: February 24, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012–5013 Filed 3–1–12; 8:45 am]

BILLING CODE 4120–01–P