DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10151 and CMS–10152]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Data Collection for Medicare Beneficiaries Receiving Implantable Cardioverter-defibrillator for Primary Prevention of Sudden Cardiac Death; *Use:* The Centers for Medicare and Medicaid Services (CMS) provides coverage for implantable cardioverter-defibrillators (ICDs) for secondary prevention of sudden cardiac death based on extensive evidence showing that use of ICDs among patients with a certain set of physiologic conditions are effective. Accordingly, CMS considers coverage for ICDs reasonable and necessary under Section 1862 (a)(1)(A) of the Social Security Act. However, evidence for use of ICDs for primary prevention of sudden cardiac death is less compelling for certain patients.

To encourage responsible and appropriate use of ICDs, CMS issued a Decision Memo for Implantable Defibrillators on January 27, 2005, indicating that ICDs will be covered for primary prevention of sudden cardiac death if the beneficiary is enrolled in either an FDA-approved category B IDE clinical trial (42 DFR § 405.201), a trial under the CMS Clinical Trial Policy (NCD Manual § 310.1) or a qualifying prospective data collection system (either a practical clinical trial or prospective systematic data collection, which is sometimes referred to as a registry). *Form Number:* CMS–10151 (OMB# 0938–0967); *Frequency:* Reporting—Quarterly; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 1,217; *Total Annual Responses:* 50,000; *Total Annual Hours:* 12,500.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Data collection for Medicare Beneficiaries Receiving FDG Positron Emission Tomography (PET) for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and All Other Cancers; *Use:* In the Decision Memo #CAG–00181N issued on January 27, 2005, CMS determined that the evidence is sufficient to conclude that for Medicare beneficiaries receiving FDG positron emission tomography (PET) for brain, cervical, ovarian, pancreatic, small cell lung, and testicular cancers is reasonable and necessary only when the provider is participating in and patients are enrolled in a systematic data collection project. CMS will consider prospective data collection systems to be qualified if they provide assurance that specific hypotheses are addressed and they collect appropriate data elements. The data collection should include baseline patient characteristics; indications for the PET scan; PET scan type and characteristics; FDG PET results; results of all other imaging studies; facility and provider characteristics; cancer type, grade, and stage; long-term patient outcomes; disease management changes; and anti-cancer treatment received. *Form Number:* CMS–10152 (OMB# 0938–0968); *Frequency:* Reporting—On occasion; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 2,000; *Total Annual Responses:* 50,000; *Total Annual Hours:* 4,167.

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 E-mail 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.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on December 15, 2008: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Dated: November 6, 2008.

Michelle Shortt,

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

[FR Doc. E8–27061 Filed 11–13–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2897–FN]

Medicare and Medicaid Programs; Approval of the Accreditation Association for Ambulatory Health Care for Continued Deeming Authority for Ambulatory Surgical Centers

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

ACTION: Final notice.

SUMMARY: This notice announces our decision to approve the Accreditation Association for Ambulatory Health Care (AAAHC) for continued recognition as a national accreditation program for ambulatory surgical centers (ASCs) seeking to participate in the Medicare or Medicaid programs.

DATES: *Effective Date:* This final notice is effective December 20, 2008 through December 20, 2012.

FOR FURTHER INFORMATION CONTACT: Aviva Walker-Sicard, (410)–786–8648. Patricia Chmielewski (410)–786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive selected covered services in an ASC provided certain requirements are met. Sections 1832(a)(2)(f)(i) of the Social Security Act (the Act) authorizes the Secretary to establish distinct criteria for facilities seeking designation as an ASC. Under this authority, the minimum requirements that an ASC must meet to participate in Medicare are set forth in regulations at 42 CFR part 416 which determines the basis and scope of ASC covered services, and the conditions for

Medicare payment for facility services. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488.

Generally, to enter into an agreement, an ASC must first be certified by a State survey agency as complying with conditions or requirements set forth in part 416 of our regulations. Then, the ASC is subject to regular surveys by a State survey agency to determine whether it continues to meet those requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(a)(1) of the Act (as redesignated under section 125(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275)) provides that, if a provider entity demonstrates through accreditation by an approved national accreditation organization that all applicable Medicare conditions are met or exceeded, we may ''deem'' those provider entities as having met the Medicare requirements. (We note that section 125 of MIPPA redesignated subsections (b) through (e) of section 1865 of the Act as (a) through (d), respectively.) Accreditation by an accreditation organization is voluntary and is not required for Medicare participation.

If an accreditation organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, a provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. A national accreditation organization applying for approval of deeming authority under part 488, subpart A must provide us with reasonable assurance that the accreditation organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning reapproval of accrediting organizations are set forth at § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require accreditation organizations to reapply for continued approval of deeming authority every 6 years, or sooner as we determine. The AAAHC's current term of approval as a recognized accreditation program for ASCs expires December 20, 2008.

II. Deeming Applications Approval Process

Section 1865(a)(3)(A) of the Act (formerly section 1865(b)(3)(A) of the Act) provides a statutory timetable to ensure that our review of deeming applications is conducted in a timely manner. The Act provides us with 210 calendar days after the date of receipt of an application to complete our survey activities and application review process. Within 60 days of receiving a completed application, we must publish a notice in the **Federal Register** that identifies the national accreditation body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish an approval or denial of the application.

III. Provisions of the Proposed Notice

In the June 27, 2008 **Federal Register** (73 FR 36520), we published a proposed notice announcing the AAAHC's request for reapproval as a deeming organization for ASCs. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act (formerly section 1865(b)(2) of the Act) and our regulations at § 488.4 (Application and reapplication procedures for accreditation organizations), we conducted a review of the AAAHC application in accordance with the criteria specified by our regulation, which include, but are not limited to the following:

- An onsite administrative review of AAAHC's (1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and (5) survey review and decision-making process for accreditation.
- A comparison of AAAHC's ASC accreditation standards to our current Medicare ASC conditions for coverage.
- A documentation review of AAAHC's survey processes to—

++ Determine the composition of the survey team, survey or qualifications, and the ability of AAAHC to provide continuing surveyor training;

++ Compare AAAHC's processes to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities;

++ Evaluate AAAHC's procedures for monitoring providers or suppliers found to be out of compliance with AAAHC program requirements. The monitoring procedures are used only when AAAHC identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency monitors corrections as specified at § 488.7(d);

++ Assess AAAHC's ability to report deficiencies to a surveyed facility and respond to the facility's plan of correction in a timely manner;

++ Establish AAAHC's ability to provide us with electronic data and reports necessary for effective validation and assessment of AAAHC's survey process;

++ Determine the adequacy of staff and other resources;

++ Review AAAHC's ability to provide adequate funding for performing required surveys;

++ Confirm AAAHC's policies with respect to whether surveys are announced or unannounced; and,

++ Obtain AAAHC's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act (formerly 1865(b)(3)(A) of the Act), the June 27, 2008 proposed notice, also solicited public comments regarding whether AAAHC's requirements met or exceeded the Medicare conditions of coverage for ASCs. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between the AAAHC's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements

We compared the standards contained in AAAHC's accreditation requirements for ASCs and its survey process in AAAHC's application for renewal of deeming authority for ASCs with the Medicare ASC conditions for coverage and our State Operations Manual (SOM). Our review and evaluation of AAAHC's deeming application, which were conducted as described in section III. of this final notice, yielded the following:

- To meet the requirements at § 416.41, AAAHC added language to its standards to ensure that the governing body will provide contracted services in a safe and effective manner.
- To meet the requirements at § 416.42, AAAHC modified its standards to require surgical procedures be performed only by qualified physicians in a safe manner.
- AAAHC modified its standards to ensure the administration of anesthesia meets the requirements at § 416.42.
- To meet the requirements at § 416.44(a)(3), AAAHC amended its standards to ensure that ASC's establish programs for identifying and preventing infections, maintain sanitary environments, and report the results to appropriate authorities.

• To meet the requirements at § 416.44, AAAHC updated the requirements on its Physical Environment Checklist (PEC) and modified its policies to clearly reflect that life safety code (LSC) waivers may only be granted by a CMS regional office.

• To meet the requirements at § 416.44(d), AAAHC revised its standards to require that ASCs train personnel in the use of all types of emergency equipment, not just cardiopulmonary and cardiac emergency equipment.

• To meet the requirements at § 416.45(b), AAAHC revised its standards to require that the scope of procedures performed in the ASC be periodically reviewed and amended as appropriate.

• To meet the requirements at § 416.46(a), AAAHC revised its standards to require a registered nurse be available for emergency treatment whenever there is a patient in the ASC.

• To meet the requirements at § 416.47(b), AAAHC revised its survey procedures to ensure that surveyors use a random selection of medical records for review during an onsite survey.

• To meet the requirements at § 488.4(a)(4), AAAHC revised its policies related to surveyor credentialing and privileging to ensure that surveyor's were appropriately privileged, credentialed and trained.

• AAAHC modified its surveyor training program to strengthen the Physical Environment and Life Safety Code training to ensure that surveyors thoroughly understand Physical Environment and Life Safety Code and can translate the teachings into practice on survey.

• CMS will conduct a survey observation, in 1 year, to validate the implementation of AAAHC's revised surveyor training program for Physical Environment and Life Safety Code and assess the competency of the surveyor's ability to conduct Physical Environment and Life Safety Code surveys in accordance with Medicare requirements.

• AAAHC amended its policies and procedures to address any real or perceived conflict of interest issues between AAAHC's accreditation activities and AAAHC's consultative services.

• To meet the requirements at § 488.4(a)(6) AAAHC amended its policies and procedures for complaints to comply with the Medicare requirements in Chapter 5 of the SOM.

• AAAHC revised its accreditation decision letters to ensure they are accurate and contain all of the required elements necessary for the CMS Regional Office to render a decision regarding deemed status of a provider.

• AAAHC modified its policies regarding condition-level noncompliance identified during an initial certification survey for participation in Medicare in accordance with section 2005A of the SOM.

• To meet the Medicare requirements at § 488.20(a) and § 488.28(a), AAAHC developed a policy regarding CMS requirements for submission of a plan of correction by the ASC and the completion of an onsite follow-up survey to determine compliance with the Medicare conditions for coverage (CFCs) after citing condition level noncompliance during a recertification survey.

• AAAHC modified its policies regarding timeframes for sending and receiving a required plan of correction in accordance with section 2728 of the SOM.

• To meet the Medicare requirements related to unannounced surveys at 2700A of the SOM, AAAHC expanded its survey window in which organizations could receive an accreditation survey for deemed status.

• AAAHC modified the language related to deferred decisions and early survey option in its accreditation handbook to provide clarification and consistency between its policies and the Medicare requirements.

• AAAHC amended its policies regarding subsequent revisions of its Accreditation Handbook and surveyor tools to ensure all documents are consistent in language and reflect CMS's requested changes.

B. Term of Approval

Based on the review and observations described in section III. of this final notice, we have determined that AAAHC's requirements for ASCs meet or exceed our requirements. Therefore, we approve AAAHC as a national accreditation organization for ASCs that request participation in the Medicare program, effective December 20, 2008 through December 20, 2012.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance Program; and Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: October 2, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–27122 Filed 11–13–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2898–FN]

Medicare and Medicaid Programs; Approval of the Joint Commission for Continued Deeming Authority for Ambulatory Surgical Centers

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

ACTION: Final notice.

SUMMARY: This notice announces our decision to approve the Joint Commission for continued recognition as a national accreditation program for ambulatory surgical centers (ASCs) seeking to participate in the Medicare or Medicaid programs.

DATES: *Effective Date:* This final notice is effective December 20, 2008, through December 20, 2014.

FOR FURTHER INFORMATION CONTACT: Laura Weber, (410) 786–0227. Patricia Chmielewski (410) 786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive selected covered services in an ASC provided certain requirements are met. Sections 1832(a)(2)(f)(i) of the Social Security Act (the Act) authorizes the Secretary to establish distinct criteria for facilities seeking designation as an ASC. Under this authority, the minimum requirements that an ASC must meet to participate in Medicare are set forth in regulations at 42 CFR part 416, which determine the basis and scope of ASC covered services, and the conditions for Medicare payment for facility services. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488.

Generally, to enter into an agreement, an ASC must first be certified by a State