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.

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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