

Proposed Project

Colorectal Cancer Control Program Indirect/Non-Medical Cost Study—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Colorectal Cancer (CRC) is the second leading cause of cancer-related deaths in the United States, following lung cancer. Based on scientific evidence which indicates that regular screening with fecal occult blood testing (FOBT), fecal immunochemical testing (FIT), flexible sigmoidoscopy, and/or colonoscopy is effective in reducing CRC incidence and mortality, regular CRC screening is now recommended for average-risk persons. In 2009, by applying lessons learned from a four-year demonstration program, CDC designed and initiated the larger population-based Colorectal Cancer Control Program (CRCCP) at 29 sites with the goals of reducing health disparities in CRC screening, incidence and mortality.

To date there has been no comprehensive assessment of all the costs associated with CRC screening, especially indirect and non-medical costs that may act as barriers to

screening, incurred by the low-income population served by the CRCCP. CDC proposes to address this gap by collecting information from a subset of patients enrolled in the program. CDC plans to conduct the information collection in partnership with providers in five states (Alabama, Arizona, Colorado, New York, and Pennsylvania).

Each provider site will administer the survey to patients who undergo screening by FIT or colonoscopy until it reaches a target number of responses. Targets for each site range between 75 and 150 completed questionnaires, depending on the volume of patients screened. Patients who undergo fecal immunochemical testing will be asked to complete the FIT questionnaire, which is estimated to take about 10 minutes. Patients who undergo colonoscopy will be asked to complete the Colonoscopy questionnaire, which includes additional questions about the preparation and recovery associated with this procedure. The estimated burden per response for the Colonoscopy questionnaire is 25 minutes. Demographic information will be collected from all patients who participate in the study. Participation in the study is voluntary, but patients will be offered an incentive in the form of a gift card. Each participating provider

will make patient navigators available to assist patients with coordinating the screening process and completing the questionnaires. Providers will be reimbursed for patient navigator time and administrative expense associated with data collection.

This information collection will be used to produce estimates of the personal costs incurred by patients who undergo CRC screening by FIT or colonoscopy, and to improve understanding of these costs as potential barriers to participation. Study findings will be disseminated through reports, presentations, and publications. Results will also be used by participating sites, CDC, and other federal agencies to improve delivery of CRC screening services and to increase screening rates among low-income adults over 50 years of age who have no health insurance or inadequate health insurance for CRC screening.

OMB approval is requested for one year. Each respondent will have the option of completing a hardcopy questionnaire (in English or Spanish) or an on-line questionnaire. No identifiable information will be collected by CDC or CDC's data collection contractor. There are no costs to respondents other than their time. The total estimated annualized burden hours are 181.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)
Patients Served by the Colorectal Cancer Control Program.	FIT Questionnaire	300	1	10/60
	Colonoscopy Questionnaire	315	1	25/60

Dated: November 19, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), 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-3265-FN]

Medicare and Medicaid Programs; Approval of the Accreditation Association for Ambulatory Health Care (AAAHC) Application for Continuing CMS Approval of Its Ambulatory Surgical Center Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the Accreditation Association for Ambulatory Health Care (AAAHC) for

continued recognition as a national accrediting organization for ambulatory surgical centers (ASCs) that wish to participate in the Medicare and/or Medicaid programs.

DATES: *Effective Date:* This notice is effective December 20, 2012 through December 20, 2018.

FOR FURTHER INFORMATION CONTACT: Lillian Williams, (410) 786-8636. Cindy Melanson, (410) 786-0310. Patricia Chmielewski, (410) 786-6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in an ambulatory surgical center (ASC) provided certain requirements are met. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) requires ASCs to meet

health, safety, and other standards specified by the Secretary. 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. The regulations at 42 CFR part 416 specify the conditions that an ASC must meet to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for ASCs.

Generally, to enter into an agreement, an ASC must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 416. Thereafter, the ASC is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. However, there is an alternative to surveys by State agencies.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, CMS will deem those provider entities as having met the Medicare requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting 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 would be deemed to meet the Medicare conditions. A national accrediting organization applying for approval of its accreditation program under part 488, subpart A, must provide us with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require accrediting organizations to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS.

The Ambulatory Health Care's (AAAHC) current term of approval for their ASC accreditation program expires on December 20, 2012.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the

request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish a notice of approval or denial of the application.

III. Provisions of the Proposed Notice

On June 22, 2012, we published a proposed notice in the **Federal Register** (77 FR 37678) entitled, "Application from the Accreditation Association for Ambulatory Health Care for Continued Approval of Its Ambulatory Surgical Centers Accreditation Program" announcing the AAAHC's request for continued approval of its ASC accreditation program.

Under section 1865(a)(2) of the Act and in our regulations at § 488.4 and § 488.8, we conducted a review of AAAHC's application in accordance with the criteria specified by our regulations, 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.

- The comparison of AAAHC's accreditation to CMS's current Medicare ASC conditions for coverage.

- A documentation review of AAAHC's survey process to—
 - + Determine the composition of the survey team, surveyor qualifications, and AAAHC's ability 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 ASC's found to be out of compliance with AAAHC's 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 the surveyed facilities and respond to the facility's plan of correction in a timely manner.

- Establish AAAHC's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

- Determine the adequacy of staff and other resources.

- + Confirm AAAHC's ability to provide adequate funding for performing required surveys.

- + Confirm AAAHC's policies with respect to whether surveys are announced or unannounced.

- + Obtain AAAHC's agreement to provide CMS 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, the June 22, 2012 proposed notice also solicited public comments regarding whether AAAHC's requirements met or exceeded the Medicare conditions for coverage for ASCs. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

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

We compared AAAHC's ASC requirements and survey process with the Medicare conditions for certification and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of AAAHC's ASC application, which were conducted as described in section III of this final notice, yielded the following:

- To meet the requirements at § 416.41(a), AAAHC revised its standards to address all contracts.

- To meet the requirements at § 416.41(c)(1), AAAHC revised its standards to address "the emergency care of patients."

- To meet the requirements at § 416.44, AAAHC revised its standards to address the Life Safety Code (LSC) survey and created a policy to ensure all ASCs receive a complete and comprehensive LSC survey.

- To meet the requirements at § 416.47(a), AAAHC revised its standards to address the use of patients records.

- To meet the requirements at § 416.47(b), AAAHC revised its standards to address the requirement that every record must be accurate, legible, and promptly completed.

- To meet the requirements at § 416.50(b)(1)(ii), AAAHC revised its standards to ensure patients have the right to "voice grievances regarding treatment or care that is (or fails to be) provided."

- To meet the requirements at § 488.4(a)(5), AAAHC modified its policies to improve the accuracy and consistency of data submissions to CMS.

- To meet the requirements at § 488.4(a)(6), AAAHC modified its

policies to ensure that all compliant investigations are conducted in accordance with the requirements in the SOM, chapter 5.

- To meet the requirements at § 488.28(a) and Section 2726 of the SOM, AAAHC amended its policies to require a Plan of Correction (PoC) for all deficiencies cited.

- To meet the requirements at section 2728A of the SOM, AAAHC modified its policies to include all of the required elements in an acceptable PoC.

- To meet the requirements at 2728B of the SOM, AAAHC modified its policies regarding timeframes for requesting PoCs.

- To meet the requirements at section 2728B of the SOM, AAAHC modified its policies to ensure that accepted PoCs contain all elements specified in the SOM.

- To meet the Medicare requirements at section 3012 of the SOM related to focused and follow-up surveys, AAAHC amended its policies to include the 45-day response timeframe.

- To meet the requirements at Appendix L of the SOM— Sampling for Initial Surveys, Recertification Surveys, or Representative Sample Validation Surveys, AAAHC revised its policies to ensure surveyors review at least the required minimum number of medical records during a survey.

- To meet the requirements at Appendix L of the SOM— Use of the Infection Control Tool, AAAHC revised its survey protocol to ensure consistency, completeness and proper implementation of the Infection Control Tool.

- To verify AAAHC's continued compliance with the provisions of the LSC, CMS will conduct a follow-up survey observation within 1 year of the date of publication of this final notice.

B. Term of Approval

Based on our 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, 2012 through December 20, 2018.

V. Collection of Information Requirements

This document does not impose any reporting, recordkeeping or third-party disclosure 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. 35).

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

Dated: November 20, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012-28728 Filed 11-23-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-7026-N]

Medicare, Medicaid, and Children's Health Insurance Programs; Meeting of the Advisory Panel on Outreach and Education (APOE), December 18, 2012

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a meeting of the Advisory Panel on Outreach and Education (APOE) (the Panel) in accordance with the Federal Advisory Committee Act. The Panel advises and makes recommendations to the Secretary of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services on opportunities to enhance the effectiveness of consumer education strategies concerning Medicare, Medicaid and the Children's Health Insurance Program (CHIP). This meeting is open to the public.

DATES: *Meeting Date:* Tuesday, December 18, 2012, 8:30 a.m. to 4:00 p.m. Eastern Standard Time (EST).

Deadline for Meeting Registration, Presentations and Comments: Tuesday, December 4, 2012, 5:00 p.m., EST.

Deadline for Requesting Special Accommodations: Tuesday, December 4, 2012, 5:00 p.m., EST.

ADDRESSES: *Meeting Location:* The Liaison Capitol Hill, 415 New Jersey Avenue NW., Washington, DC 20001.

Presentations and Written Comments: Jennifer Kordonski, Designated Federal Official (DFO), Division of Forum and Conference Development, Office of Communications, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop S1-13-05, Baltimore, MD 21244-1850 or contact Ms. Kordonski via email at Jennifer.Kordonski@cms.hhs.gov.

Registration: The meeting is open to the public, but attendance is limited to

the space available. Persons wishing to attend this meeting must register at the Web site <http://events.SignUp4.com/APOEDECMTG> or by contacting the DFO at the address listed in the

ADDRESSES section of this notice or by telephone at number listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice, by the date listed in the **DATES** section of this notice. Individuals requiring sign language interpretation or other special accommodations should contact the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

FOR FURTHER INFORMATION CONTACT:

Jennifer Kordonski, (410) 786-1840. Additional information about the APOE is available on the Internet at http://www.cms.gov/FACA/04_APOE.asp. Press inquiries are handled through the CMS Press Office at (202) 690-6145.

SUPPLEMENTARY INFORMATION: In accordance with section 10(a) of the Federal Advisory Committee Act (FACA), this notice announces a meeting of the Advisory Panel on Outreach and Education (APOE) (the Panel). Section 9(a)(2) of the Federal Advisory Committee Act authorizes the Secretary of Health and Human Services (the Secretary) to establish an advisory panel if the Secretary determines that the panel is "in the public interest in connection with the performance of duties imposed * * * by law." Such duties are imposed by section 1804 of the Social Security Act (the Act), requiring the Secretary to provide informational materials to Medicare beneficiaries about the Medicare program, and section 1851(d) of the Act, requiring the Secretary to provide for "activities * * * to broadly disseminate information to [M]edicare beneficiaries * * * on the coverage options provided under [Medicare Advantage] in order to promote an active, informed selection among such options."

The Panel is also authorized by section 1114(f) of the Act (42 U.S.C. 1314(f)) and section 222 of the Public Health Service Act (42 U.S.C. 217a). The Secretary signed the charter establishing this Panel on January 21, 1999 (64 FR 7899, February 17, 1999) and approved the renewal of the charter on January 21, 2011 (76 FR 11782, March 3, 2011).

Pursuant to the amended charter, the Panel advises and makes recommendations to the Secretary of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services (CMS) concerning optimal strategies for the following: