

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3211-N]

Medicare Program; Meeting of the Medicare Evidence Development and Coverage Advisory Committee—May 6, 2009

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

ACTION: Notice of meeting.

SUMMARY: This notice announces that a public meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) (“Committee”) will be held on Wednesday, May 6, 2009. The Committee generally provides advice and recommendations concerning the adequacy of scientific evidence needed to determine whether certain medical items and services are reasonable and necessary under the Medicare statute. The Committee may also review and evaluate medical literature and make recommendations concerning items and services that may be eligible for Medicare coverage. This meeting will focus on the requirements for evidence to determine if the use of screening genetic testing of beneficiaries without signs or symptoms of disease improves health outcomes in Medicare beneficiaries. The meeting will discuss the various kinds of evidence that are useful to support requests for Medicare coverage in this field. This meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)).

DATES: Meeting Date: The public meeting will be held 7:30 a.m. until 4:30 p.m., daylight saving time (*d.s.t.*) on Wednesday, May 6, 2009.

Deadline for Submission of Written Comments: Written comments must be received at the address specified in the **ADDRESSES** section of this notice by 5 p.m., *d.s.t.* on Monday, April 6, 2009. Once submitted, comments are final.

Deadlines for Speaker Registration and Presentation Materials: The deadline to register to be a speaker, and to submit materials and writings that will be used in support of an oral presentation, is 5 p.m., *d.s.t.* on Monday, April 6, 2009. Speakers may register by phone or via e-mail by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentation materials must be received at the address specified in the **ADDRESSES** section of this notice.

Deadline for All Other Attendees Registration: Individuals may register by phone or via e-mail by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by 5 p.m., *d.s.t.* on Wednesday, April 29, 2009.

Deadline for Submitting a Request for Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to contact the Executive Secretary as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later than 5 p.m., *d.s.t.* Wednesday, April 29, 2009.

ADDRESSES: Meeting Location: The meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244.

Submission of Presentations and Comments: Presentation materials and written comments that will be presented at the meeting must be submitted via e-mail to MedCACpresentations@cms.hhs.gov or by regular mail to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice.

FOR FURTHER INFORMATION CONTACT: Maria Ellis, Executive Secretary for MEDCAC, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Coverage and Analysis Group, C1-09-06, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Ellis by phone (410-786-0309) or via e-mail at Maria.Ellis@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

MEDCAC, formerly known as the Medicare Coverage Advisory Committee (MCAC), provides advice and recommendations to CMS regarding clinical issues. (For more information on MCAC, see the December 14, 1998 *Federal Register* (63 FR 68780.)) This notice announces the May 6, 2009, public meeting of the Committee. During this meeting, the Committee will discuss the requirements for evidence to determine if the use of screening genetic testing in beneficiaries without signs or symptoms of disease improves health outcomes in Medicare beneficiaries. Background information about this topic, including panel materials, is available at <http://www.cms.hhs.gov/coverage>.

II. Meeting Format

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 30 minutes. The Committee may limit the number and duration of oral presentations to the time available. Your comments should focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the meeting will be available on the following Web site prior to the meeting: http://www.cms.hhs.gov/mcd/index_list.asp?list_type=mcac. We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed.

The Committee will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topics under consideration. At the conclusion of the day, the members will vote and the Committee will make its recommendation(s) to CMS.

III. Registration Instructions

CMS' Coverage and Analysis Group is coordinating the meeting registration. While there is no registration fee, individuals must register to attend. You may register by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your state-issued driver's license), address, organization, telephone, fax number(s), and e-mail address. You will receive a registration confirmation with instructions for your arrival at the CMS complex or you will be notified the seating capacity has been reached.

IV. Security, Building, and Parking Guidelines

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the

Federal Protective Service or Guard Service personnel.

- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.

- Inspection, via metal detector or other applicable means of all persons brought entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting. All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

Authority: 5 U.S.C. App. 2, section 10(a). (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 5, 2009.

Barry M. Straube,

Chief Medical Officer and Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Project

Title: Project LAUNCH Cross-Site Evaluation.

OMB Number: New Collection.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is planning to collect data as part of a cross-site evaluation of a new initiative called Project LAUNCH (Linking Actions for Unmet Needs in Children's Health). Project LAUNCH is intended to promote the healthy development and wellness of children ages birth to eight years. A total of six Project LAUNCH grantees are funded to improve coordination among child-serving systems, build infrastructure, and improve methods for providing services. Grantees will also implement a range of public health strategies to support young child wellness in a designated locality.

Data for the cross-site evaluation of Project LAUNCH will be collected

through: (1) Interviews conducted during annual site-visits to Project LAUNCH grantees, and (2) semi-annual reports that will be submitted electronically on a web-based data-entry system. Information will be collected from all six Project LAUNCH grantees.

During annual site visits, researchers will conduct interviews with Project LAUNCH service providers and collaborators in States/tribes and local communities of focus. Site visitors will ask program administrators questions about all Project LAUNCH activities, including: infrastructure development; collaboration and coordination among partner agencies, organizations, and service providers; and development, implementation, and refinement of service strategies.

As part of the proposed data collection, Project LAUNCH staff will be asked to submit semi-annual electronic reports about the systems development, services that children and families receive, and provider, child and family outcomes. The electronic data report also will collect data about other Project LAUNCH-funded service enhancements, such as trainings, Project LAUNCH systems change activities, and project costs. Information provided in these reports will be tracked on a monthly basis.

Respondents: State/ tribal Child Wellness Coordinator, State/ tribal Wellness Council Members, State ECCS Project Director, Local Child Wellness Coordinator, Local Wellness Council Members, Local Evaluator, and Local Service Providers.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
State/Tribal Level Site Visit Interview Protocol	24	1	.875	21
Local Level Site Visit Interview Protocol	36	1	.75	27
Electronic Data Reporting	150	2	1.5	450

Estimated Total Annual Burden Hours: 498.

In compliance with the requirements of Section 3506(c) (2) (A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant

Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. E-mail address: OPREinfocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c)

the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.