DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–8003, CMS–10185 and CMS–10164]

Agency Information Collection Activities: Proposed Collection; 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) 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 functions; (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:* Home and Community Based Waiver Requests and Supporting Regulations in 42 CFR 440.180 and 441.300–310; *Use:* Under a Secretarial waiver, States may offer a wide array of home and community-based services to individuals who would otherwise require institutionalization. States requesting a waiver must provide certain assurances, documentation and cost and utilization estimates which are reviewed, approved and maintained for the purpose of identifying/verifying States' compliance with such statutory and regulatory requirements. CMS has recently revised this data collection tool, as well as the methodology by which the data is collected. *Form Number:* CMS–8003 (OMB # 0938–0449); *Frequency:* Annually; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 49; *Total Annual Responses:* 71; *Total Annual Hours:* 9,059.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Part D Reporting Requirements and Supporting Regulations under 42 CFR 423.505; *Form Number:* CMS–10185 (OMB # 0938–0992); *Use:* Title I, Part 423, § 423.514 describes CMS' regulatory authority to establish requirements for Part D sponsors. It is noted that each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, its enrollees, and the general public, at the times and in the manner that CMS requires, statistics in the following areas: (1) The cost of its operations; (2) The availability of utilization of its services; (3) The availability, accessibility; and acceptability of its services; (4) Information demonstrating that the Part D plan sponsor has a fiscally sound operation; and (5) other matters that CMS may require. Subsection 423.505 of the Medicare Prescription Drug Modernization and Modernization Act establishes as a contract provision that Part D Sponsors must comply with the reporting requirements for submitting drug claims and related information to CMS. Data collected via Medicare Part D Reporting Requirements will be an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. Refer to the ''Crosswalk of Changes between the CY2009 and CY2010 Part D Reporting Requirements'' document to view a list of current changes. *Frequency:* Reporting—yearly, quarterly and semi-annually; *Affected Public:* Business or other for-profit; *Number of Respondents:* 4,526; *Total Annual Responses:* 343,976; *Total Annual Hours:* 154,610.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Electronic Data Interchange (EDI Enrollment Form and Medicare EDI Registration Form; *Form No.:* CMS–10164 (OMB # 0938–983); *Use:* Federal law requires that CMS take precautions to minimize the security risk to Federal information systems. Accordingly, CMS is requiring that trading partners who wish to conduct the Electronic Data Interchange (EDI) transactions provide certain assurances as a condition of receiving access to the Medicare system for the purpose of conducting EDI exchanges. Health care providers, clearinghouses, and health plans that wish to access the Medicare system are required to complete this form. The information will be used to assure that those entities that access the Medicare system are aware of applicable provisions and penalties; *Frequency:* Recordkeeping and Reporting—Other (one-time only); *Affected Public:* Business or other for-profit, not-for-profit institutions; *Number of Respondents:* 240,000; *Total Annual Responses:* 240,000; *Total Annual Hours:* 80,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site 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.

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 *March 17, 2009:*

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: January 8, 2009.

Michelle Shortt,

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

[FR Doc. E9–685 Filed 1–15–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3210–N]

Medicare Program; Meeting of the Medicare Evidence Development & Coverage Advisory Committee—March 18, 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 & Coverage Advisory Committee (MEDCAC) (''Committee'') will be held on Wednesday, March 18, 2009. The Committee generally provides advice and recommendations concerning the adequacy of scientific evidence needed to determine whether certain medical items and services can be covered under the Medicare statute. This meeting will focus on the use of Bayesian statistics to interpret evidence in making coverage decisions. The meeting will introduce Bayesian concepts, contrast Bayesian approaches with frequentist approaches, and provide some examples of using Bayesian techniques for meta-analyses. Bayesian analysis is a statistical technique in which prior evidence is used to update or to newly infer the probability that a hypothesis may be true. 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 on Wednesday, March 18, 2009 from 7:30 a.m. until 4:30 p.m., daylight savings time (d.s.t).

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., eastern standard time (e.s.t) on February 16, 2009. Once submitted, all comments are final.

Deadline for Speaker Registration and Presentation Materials: The deadline to register to be a speaker and to submit Powerpoint presentation materials and writings that will be used in support of an oral presentation, is 5 p.m., e.s.t. on Monday, February 16, 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, March 11, 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. Friday, March 11, 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 March 18, 2009, public meeting of the Committee. During this meeting, the Committee will discuss the use of Bayesian statistics to interpret evidence in making coverage decisions. The meeting will introduce Bayesian concepts, contrast Bayesian approaches with frequentist approaches, and provide some examples of using Bayesian techniques for meta-analyses. Bayesian analysis is a statistical technique in which prior evidence is used to update or to newly infer the probability that a hypothesis may be true. Background information about this topic, including panel materials, is available at *http://www.cms.hhs.gov/coverage.* We encourage the participation of appropriate organizations with expertise in Bayesian statistics, meta-analyses, and clinical trial design and analyses.

II. Meeting Format

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 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's Coverage and Analysis Group is coordinating 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

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: January 9, 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

Statement of Mission, Organization, Functions, and Delegations of Authority

This notice amends Part K of the Statement of Mission, Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF), as follows: Chapter KE, Administration for Native Americans (ANA), as last amended in 60 FR 17084–85, 04/04/95. This notice establishes the Division of Policy, Planning and Evaluation and moves the support staff function to the Office of the Commissioner. The changes are as follows:

I. Chapter KE. Administration for Native Americans

A. Delete KE. 00 Mission in its entirety and replace with the following:

KE. 00 Mission. The mission of the Administration for Native Americans is to promote the goal of self-sufficiency and cultural preservation for Native Americans by providing social and economic development opportunities through financial assistance, training, and technical assistance to eligible Tribes and Native American communities, including American Indians, Alaska Natives, Native Hawaiians, and other Native Pacific Islander organizations. ANA provides funding for community-based projects that are designed to improve the lives of Native children and families and reduce long-term dependency on public assistance. Competitive funding authorized under the Native American Programs Act of 1974, as amended, for community-based projects is provided through three competitive discretionary grant programs to eligible Tribes and non-profit Native American organizations: Social and economic development, language preservation, and environmental regulatory enhancement.

B. Delete KE. 10 Organization in its entirety and replace with the following:

KE.10 Organization. The Administration for Native Americans is headed by a Commissioner who is confirmed by the Senate and reports directly to the Assistant Secretary for Children and Families.

The ANA organization includes the: Office of the Commissioner (KEA); Intra-Departmental Council on Native American Affairs (KEB); Division of Program Operations (KEC); Division of Policy, Planning and Evaluation (KED).

C. Delete KE.20 Functions in its entirety and replace with the following:

KE. 20 Functions

A. The Office of the Commissioner provides executive leadership and management strategies for all components of ANA. As required by statute, the Commissioner is Chair of the Intra-Departmental Council on Native American Affairs and advises the Secretary on all matters affecting Native Americans that involve the Department. The Commissioner serves as an effective and visible advocate on behalf of Native Americans within the Department, and with other departments and agencies of the Federal Government regarding all Federal policies affecting Native Americans. The Commissioner provides policy direction and guidance to ACF Regional Offices with respect to programs for Urban Indians, off-Reservation Indians, and other Native American projects in Hawaii and the Pacific Islands. The Commissioner oversees the Native Hawaiian Revolving Loan Fund administered by the Office of Hawaiian Affairs. In the absence of the Commissioner, the Deputy Commissioner is responsible for all organizational management.

The Management Operations Staff (MOS) is responsible for ANA Budget and Administrative functions. MOS coordinates ANA budget activities, the ANA funding decision memo, data collection, personnel actions, ANA's electronic library, tracking of required grant reports, and oversees contract expenditures. The staff members control the flow of correspondence, including receipt of and response to Freedom of Information Act requests.

B. The Commissioner is the Chair of the Intra-Departmental Council on Native American Affairs (ICNAA) and advises the Secretary on Native American issues. ICNAA staff members provide support to the Commissioner. ICNAA develops and promotes HHS policy to provide greater access and quality services for American Indians, Alaska Natives, and Native Americans (AI/AN/NAs) throughout the Department and where possible, the Federal Government; promotes implementation of HHS policy and agency plans on consultation with AI/AN/NAs and Tribal Governments; identifies and develops legislative, administrative, and regulatory proposals that promotes an effective, meaningful AI/AN/NA policy to improve health and human services for AI/AN/NAs; identifies and develops comprehensive Departmental strategy proposal to promote self-sufficiency and self-determination for all AI/AN/NA people; and promotes the Tribal/Federal government-to-government relationship on a Department-wide basis in accordance with Presidential Executive Order.

C. The Division of Program Operations (DPO) is responsible for the administration of discretionary grant programs to eligible Tribes and non-profit Native American organizations. The responsibilities include (1) Annual grant competitions and coordination of the panel review process, (2) development of ANA's Program Announcements, (3) grant oversight, and (4) grant close-out procedures. The DPO also manages and coordinates activities that support the ACF Native American Affairs Workgroup.

D. The Division of Policy, Planning and Evaluation (DPPE) is responsible for development of organizational policies and planning; community impact evaluation; management of quarterly grantee project assessment; oversight of training and technical contracts; coordination of training and technical assistance activities in Alaska, the Pacific Basin, and the lower forty-eight states; development of organizational and Congressional reports; and completion of special organizational