

email 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, Center for Clinical Standards and Quality, Coverage and Analysis Group, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Ellis by phone (410-786-0309) or via email 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 Wednesday, January 30, 2013, public meeting of the Committee. During this meeting, the Committee will discuss beta amyloid positron emission tomography in dementia and neurodegenerative disease. Background information about this topic, including panel materials, is available at <http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAAA&>. CMS will no longer be providing paper copies of the handouts for the meeting. Electronic copies of all the meeting materials will be on the CMS Web site no later than 2 business days before the meeting. We encourage the participation of appropriate organizations with expertise in beta amyloid positron emission tomography in dementia and neurodegenerative disease.

II. Meeting Format

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, CMS may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 20, 2012. 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.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAAA&>. 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 meeting registration. While there is no registration fee, individuals must register to attend. You may register online at <http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3> or by phone 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 email address. You will receive a registration confirmation with instructions for your arrival at the CMS complex or you will be notified that 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: October 17, 2012.

Patrick Conway,

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

[FR Doc. 2012-26124 Filed 10-23-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Native Employment Works (NEW) Program Plan Guidance and Report Requirements.

OMB No.: 0970-0174.

Description: The Native Employment Works (NEW) program plan is the application for NEW program funding. As approved by the Department of Health and Human Services (HHS), it documents how the grantee will carry out its NEW program. The NEW program plan guidance provides instructions for preparing a NEW program plan and explains the process for plan submission every third year. The NEW program report provides information on the activities and accomplishments of grantees' NEW programs. The NEW program report and instructions specify the program data that NEW grantees report annually.

Respondents: Federally recognized Indian Tribes and Tribal organizations that are NEW program grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
NEW program plan guidance	* 26	1	29	754
NEW program report	** 48	1	15	720

Estimated Total Annual Burden Hours: 1,474.

* 79 grantees divided by 3 (because grantees submit the NEW plan once every 3 years) = 26.

** We estimate that 48 of the 79 NEW grantees will not include their NEW programs in P.L. 102-477 projects and therefore will submit the NEW program report to HHS.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV. Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012-26197 Filed 10-23-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0585]

Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled "Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories." FDA has developed this guidance in response to amendments made by the FDA Food Safety Modernization Act (FSMA) to the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance contains FDA's determination that information about food product categories in food facility registrations is necessary for a quick, accurate, and focused response to a food safety related issue or incident, an actual or potential bioterrorist incident, or other food-related emergency. The guidance also identifies the additional food product categories included as mandatory fields in food facility registrations, as determined appropriate by FDA.

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to Office of Compliance, Division of Field Programs and Guidance, Center for Food Safety and Applied Nutrition (HFS-615), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amy Barringer, Center for Food Safety

and Applied Nutrition (HFS-615), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1988.

SUPPLEMENTARY INFORMATION:**I. Background**

We are announcing the availability of a guidance for industry entitled "Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories." FDA has developed this guidance in response to amendments made by section 102 of FSMA (Pub. L. 111-353) to section 415(a)(2) of the FD&C Act (21 U.S.C. 350d(a)(2)).

FSMA, enacted on January 4, 2011, amended the food facility registration requirements of section 415 of the FD&C Act. Section 415(a)(2) of the FD&C Act, as amended by section 102 of FSMA, provides in relevant part that, when determined necessary by FDA through guidance, a registrant is required to submit a registration to FDA containing information necessary to notify FDA of the general food category (as identified in § 170.3 (21 CFR 170.3) or any other food categories, as determined appropriate by FDA, including by guidance) of any food manufactured, processed, packed, or held at such facility. This guidance contains FDA's determination that information about food product categories as identified in § 170.3 and the other food product categories is necessary for a quick, accurate, and focused response to a food safety related issue or incident, an actual or potential bioterrorist incident, or other food-related emergency. The guidance also identifies the additional food product categories included as mandatory fields in food facility registrations, as determined appropriate by FDA under section 102 of FSMA.

In the **Federal Register** of August 15, 2012 (77 FR 48990), we made available a draft guidance entitled "Guidance for Industry: Necessity of the Use of Food