

**SUMMARY:** This notice announces a request for applications for organizations to participate in the Pioneer Accountable Care Organization Model for a period beginning in 2011 and ending December 2016.

**DATES:** *Letter of Intent Submission Deadline:* Interested organizations must submit a nonbinding letter of intent by June 10, 2011 as described on the Innovation Center Web site <http://innovations.cms.gov/areas-of-focus/seamless-and-coordinated-care-models/pioneer-aco>.

*Application Submission Deadline:* Applications must be received on or before July 19, 2011.

**ADDRESSES:** Applications should be submitted by mail to the following address by the date specified in the **DATES** section of this notice: Pioneer ACO Model, *Attention:* Maria Alexander, Center for Medicare and Medicaid Innovation, Centers for Medicare and Medicaid Services, Mail Stop S3-13-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

**FOR FURTHER INFORMATION CONTACT:** *PioneerACO@cms.hhs.gov* for questions regarding the aspects of the Pioneer Accountable Care Organization Model or the application process.

#### **SUPPLEMENTARY INFORMATION:**

#### **I. Background**

We are committed to achieving the three-part aim of better health, better health care, and lower per-capita costs for Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. One potential mechanism for achieving this goal is for CMS to partner with groups of health care providers of services and suppliers with a mechanism for shared governance that have formed an Accountable Care Organization (ACO) through which they work together to manage and coordinate care for a specified group of patients. We will pursue such partnerships through two complementary efforts—the Medicare Shared Savings Program and initiatives undertaken by the Center for Medicare and Medicaid Innovation (Innovation Center). The Pioneer ACO Model is an Innovation Center initiative targeted at organizations that can demonstrate the improvements in financial and clinical performance with respect to the care of Medicare beneficiaries that are possible in a mature ACO. To be eligible to participate in the Pioneer ACO Model, organizations would ideally already be coordinating care for a significant portion of patients under financial risk sharing contracts and be positioned to transform both their care and financial

models from fee-for-service to a three-part aim, value based model. This notice provides a general overview of the Pioneer ACO Model. For more details see the request for application which is available on the Innovation Center Web site at <http://innovations.cms.gov/areas-of-focus/seamless-and-coordinated-care-models/pioneer-aco>.

#### **II. Provisions of the Notice**

Consistent with its authority under section 1115A of the Social Security Act (of the Act), as added by section 3021 of the Affordable Care Act, to test innovative payment and service delivery models that reduce spending under Medicare, Medicaid, or CHIP, while preserving or enhancing the quality of care, the Innovation Center aims to achieve the following goals through implementation of the Pioneer ACO Model:

- Test a more rapid transition for providers from volume based FFS payments to payment for coordination and outcomes.
- Promote a diversity of successful ACOs, including physician-led ACOs and those serving indigent or rural populations.

This Model will test the effectiveness of a combination of the following:

- Payment arrangements that place a group of providers at joint risk for quality performance and financial performance for the majority of their patients and revenues (including non-Medicare patients and revenues). Such payment arrangements will require participants to transition from fee-for-service to population-based payment by the third performance year. We believe the payment arrangements being tested will provide more opportunities for rapid escalation of shared savings and risk compared to the Medicare Shared Savings Program.
- Technical support in the form of rapid data feedback and shared learning activities.
- Size and scope of testing: We expect to partner with approximately 30 organizations in the Model, with a minimum of 15,000 Medicare beneficiaries each (5,000 for rural ACOs). The application process and selection criteria are described in Section IV of the Request for Applications but in general, applications will be prioritized based on the strength of their care improvement plans, leadership, and commitment to outcomes-based contracts with non-Medicare purchasers. Final selection will be based on the strength of the application and interviews of finalists, together with other factors to promote representation of diverse geographic

areas, types of organizations, and types of Medicare populations served.

- Population: ACOs will be accountable for all fee-for-service Medicare beneficiaries that CMS determines are aligned with them, and who have continuous enrollment in Parts A and B during baseline and performance periods, with emphasis on encouraging care of underserved populations and dual eligibles.
- Duration: Between 5 and 6 years (start third or fourth quarter of 2011 and end December 2016, which includes two 1-year optional periods).

#### **III. Collection of Information Requirements**

Section 1115A(d) of the Act waives the requirements of the Paperwork Reduction Act of 1995 for the Innovation Center for purposes of testing new payment and service delivery models.

**Authority:** Section 1115A of the Social Security Act.

Dated: March 10, 2011.

**Donald M. Berwick,**  
*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2011-12383 Filed 5-17-11; 8:45 am]

**BILLING CODE 4120-01-P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

#### **Administration for Children and Families**

#### **President's Committee for People With Intellectual Disabilities; Notice of Meeting**

**AGENCY:** President's Committee for People with Intellectual Disabilities (PCPID), HHS.

**ACTION:** Notice of Quarterly Meeting.

**DATES:** Thursday, June 16, 2011, from 9:30 a.m. to 4 p.m. EST; and Friday, June 17, 2011, from 9 a.m. to 5 p.m. EST. The meeting will be open to the public.

**ADDRESSES:** The meeting will be held in Room 800 on the Penthouse Level of the Hubert H. Humphrey Building, U.S. Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201. Individuals who would like to participate via conference call may do so by dialing 888-323-9869, pass code: PCPID. Individuals who will need accommodations for a disability in order to attend the meeting (e.g., sign language interpreting services, assistive listening devices, materials in alternative format

such as large print or Braille) should notify Genevieve Swift, PCPID Executive Administrative Assistant, via e-mail at [Edith.Swift@acf.hhs.gov](mailto:Edith.Swift@acf.hhs.gov), or via telephone at 202-619-0634, no later than June 10, 2011. PCPID will attempt to meet requests for accommodations made after that date, but cannot guarantee ability to grant requests received after this deadline. All meeting sites are barrier free.

**Agenda:** PCPID will meet to swear-in the new members of the Committee and set the agenda for the coming year.

**Additional Information:** For further information, please contact Laverdia Taylor Roach, Director, President's Committee for People with Intellectual Disabilities, The Aerospace Center, Second Floor West, 370 L'Enfant Promenade, SW., Washington, DC 20447. Telephone: 202-619-0634. Fax: 202-205-9519. E-mail: [LRoach@acf.hhs.gov](mailto:LRoach@acf.hhs.gov).

**SUPPLEMENTARY INFORMATION:** PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services, through the Administration on Developmental Disabilities, on a broad range of topics relating to programs, services and supports for persons with intellectual disabilities. The PCPID Executive Order stipulates that the Committee shall: (1) Provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President concerning the following for people with intellectual disabilities: (A) Expansion of educational opportunities; (B) promotion of homeownership; (C) assurance of workplace integration; (D) improvement of transportation options; (E) expansion of full access to community living; and (F) increasing access to assistive and universally designed technologies.

Dated: May 13, 2011.

**Sharon Lewis,**

*Commissioner, Administration on Developmental Disabilities.*

[FR Doc. 2011-12508 Filed 5-19-11; 8:45 am]

**BILLING CODE 4184-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2006-D-0094]

#### Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls; Guidance Document: Topical Oxygen Chamber for Extremities; Availability; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of April 25, 2011 (76 FR 22906). The document announced the availability of the guidance entitled "Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Documents: Topical Oxygen Chamber for Extremities." The document published inadvertently with outdated information in the **ADDRESSES, FOR FURTHER INFORMATION CONTACT**, and Electronic Access sections. This document corrects those errors.

**FOR FURTHER INFORMATION CONTACT:** Charles N. Durfor, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. G424, Silver Spring, MD 20993-0002, 301-796-6438.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2011-9898, appearing on page 22906, in the **Federal Register** of Monday, April 25, 2011, the following corrections are made:

1. On page 22906, in the first column, correct the **ADDRESSES** caption to read: **ADDRESSES:** Submit written request for single copies of the guidance document entitled "Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on 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.

2. On page 22906, in the second column, correct the **FOR FURTHER INFORMATION CONTACT** caption to read:

**FOR FURTHER INFORMATION CONTACT:** Charles N. Durfor, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G424, Silver Spring, MD 20993-0002, 301-796-6438.

3. On page 22906, in the third column, correct the Electronic Access caption to read:

### III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are available at <http://www.regulations.gov>. To receive "Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities" you may send an e-mail request to [dismica@fda.hhs.gov](mailto:dismica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1582 to identify the guidance you are requesting.

Dated: May 17, 2011.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

[FR Doc. 2011-12409 Filed 5-19-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA