

public comments on four separate information collection requests. Through the publication of this correction document, we are notifying the public that we are no longer requesting or accepting public comments on the information collection request that published on Wednesday, February 10, 2016 (81 FR 7124), and is titled "Medicare Prior Authorization of Home Health Services Demonstration." *Form number:* CMS-10599 (OMB control number: 0938—New). All public comments regarding CMS-10599 should be submitted via the instructions listed in the original notice. The original notice for CMS-10599 published on Friday, February 5, 2016 (81 FR 6275). The original 60-day comment period for the notice that published on February 5, 2016 (81 FR 6275) remains in effect and ends on April 5, 2016.

Dated: February 19, 2016.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2016-03922 Filed 2-24-16; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-7040-N]

#### Health Insurance Marketplace<sup>SM</sup>, Medicare, Medicaid, and the Children's Health Insurance Program; Meeting of the Advisory Panel on Outreach and Education (APOE)

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

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces the new 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 the U.S. Department of Health and Human Services (HHS) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of Health Insurance Marketplace<sup>SM</sup>,<sup>1</sup> Medicare, Medicaid, and Children's Health Insurance Program (CHIP) consumer education

<sup>1</sup> Health Insurance Marketplace<sup>SM</sup> and Marketplace<sup>SM</sup> are service marks of the U.S. Department of Health & Human Services.

strategies. This meeting is open to the public.

**DATES:**

*Meeting Date:* Wednesday, March 23, 2016, 8:30 a.m. to 4:00 p.m. eastern daylight time (e.d.t.).

*Deadline for Meeting Registration, Presentations, Special Accommodations and Comments:* Wednesday, March 9, 2016, 5:00 p.m., eastern standard time (e.s.t.).

**ADDRESSES:**

*Meeting Location:* U.S. Department of Health & Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW., Room 425A, Conference Room, Washington, DC 20201.

*Presentations and Written Comments:* Presentations and written comments should be submitted to: Abigail Huffman, Designated Federal Official (DFO), Division of Forum and Conference Development, Office of Communications, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop S1 05-06, Baltimore, MD 21244 1850 or via email at [Abigail.Huffman1@cms.hhs.gov](mailto:Abigail.Huffman1@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 <https://www.regonline.com/apoemar2016meeting> or by contacting the DFO as 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:**

Abigail Huffman, Designated Federal Official, Office of Communications, CMS, 7500 Security Boulevard, Mail Stop S1-05-06, Baltimore, MD 21244, 410-786-0897, email [Abigail.Huffman1@cms.hhs.gov](mailto:Abigail.Huffman1@cms.hhs.gov).

Additional information about the APOE is available on the Internet at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/APOE.html>. Press inquiries are handled through the CMS Press Office at (202) 690-6145.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

The Advisory Panel for Outreach and Education (APOE) (the Panel) is governed by the provisions of Federal Advisory Committee Act (FACA) (Pub. L. 92-463), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of federal advisory committees. The Panel is

authorized by section 1114(f) of the Social Security Act (42 U.S.C. 1314(f)) and section 222 of the Public Health Service Act (42 U.S.C. 217a).

The Secretary of the U.S. Department of Health and Human Services (HHS) (the Secretary) signed the charter establishing the Citizen's Advisory Panel on Medicare Education<sup>2</sup> (the predecessor to the APOE) on January 21, 1999 (64 FR 7899, February 17, 1999) to advise and make recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on the effective implementation of national Medicare education programs, including with respect to the Medicare+Choice (M+C) program added by the Balanced Budget Act of 1997 (Pub. L. 105-33).

The Medicare Modernization Act of 2003 (MMA) (Pub. L. 108-173) expanded the existing health plan options and benefits available under the M+C program and renamed it the Medicare Advantage (MA) program. We have had substantial responsibilities to provide information to Medicare beneficiaries about the range of health plan options available and better tools to evaluate these options. The successful MA program implementation required CMS to consider the views and policy input from a variety of private sector constituents and to develop a broad range of public-private partnerships.

In addition, Title I of the MMA authorized the Secretary and the Administrator of CMS (by delegation) to establish the Medicare prescription drug benefit. The drug benefit allows beneficiaries to obtain qualified prescription drug coverage. In order to effectively administer the MA program and the Medicare prescription drug benefit, we have substantial responsibilities to provide information to Medicare beneficiaries about the range of health plan options and benefits available, and to develop better tools to evaluate these plans and benefits.

The Affordable Care Act (Patient Protection and Affordable Care Act, Pub. L. 111-148, and Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152) expanded the availability of other options for health care coverage and enacted a number of changes to Medicare as well as to Medicaid and the Children's Health Insurance Program (CHIP). Qualified individuals and qualified employers are

<sup>2</sup> We note that the Citizens' Advisory Panel on Medicare Education is also referred to as the Advisory Panel on Medicare Education (65 FR 4617). The name was updated in the Second Amended Charter approved on July 24, 2000.

now able to purchase private health insurance coverage through competitive marketplaces, called Affordable Insurance Exchanges (we also call an Exchange a Health Insurance Marketplace<sup>SM</sup> or Marketplace<sup>SM</sup>). In order to effectively implement and administer these changes, we must provide information to consumers, providers, and other stakeholders through education and outreach programs regarding how existing programs will change and the expanded range of health coverage options available, including private health insurance coverage through a Marketplace<sup>SM</sup>. The APOE (the Panel) allows us to consider a broad range of views and information from interested audiences in connection with this effort and to identify opportunities to enhance the effectiveness of education strategies concerning the Affordable Care Act.

The scope of this panel also includes advising on issues pertaining to the education of providers and stakeholders with respect to the Affordable Care Act and certain provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act enacted as part of the American Recovery and Reinvestment Act of 2009 (ARRA).

On January 21, 2011, the Panel's charter was renewed and the Panel was renamed the Advisory Panel for Outreach and Education. The Panel's charter was most recently renewed on January 21, 2015, and will terminate on January 21, 2017 unless renewed by appropriate action.

Under the current charter, the APOE will advise the Secretary and the Administrator on optimal strategies for the following:

- Developing and implementing education and outreach programs for individuals enrolled in, or eligible for, Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), or coverage available through a Health Insurance Marketplace<sup>SM</sup>.
- Enhancing the federal government's effectiveness in informing Health Insurance Marketplace<sup>SM</sup>, Medicare, Medicaid, and CHIP consumers, issuers, providers, and stakeholders, through education and outreach programs, on issues regarding these programs, including the appropriate use of public-private partnerships to leverage the resources of the private sector in educating beneficiaries, providers, and stakeholders.
- Expanding outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of Health Insurance

Marketplace<sup>SM</sup>, Medicare, Medicaid, and CHIP education programs.

- Assembling and sharing an information base of "best practices" for helping consumers evaluate health coverage options.
- Building and leveraging existing community infrastructures for information, counseling, and assistance.
- Drawing the program link between outreach and education, promoting consumer understanding of health care coverage choices, and facilitating consumer selection/enrollment, which in turn support the overarching goal of improved access to quality care, including prevention services, envisioned under the Affordable Care Act.

The current members of the Panel are: Kellan Baker, Associate Director, Center for American Progress; Robert Blancato, President, Matz, Blancato & Associates; Dale Blasier, Professor of Orthopedic Surgery, Department of Orthopedics, Arkansas Children's Hospital; Deborah Britt, Executive Director of Community & Public Relations, Piedmont Fayette Hospital; Deena Chisolm, Associate Professor of Pediatrics & Public Health, The Ohio State University, Nationwide Children's Hospital; Josephine DeLeon, Director, Anti-Poverty Initiatives, Catholic Charities of California; Robert Espinoza, Vice President of Policy, Paraprofessional Healthcare Institute; Jennifer Gross, Manager of Political Field Operations, Planned Parenthood of Montana; Louise Scherer Knight, Director, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins; Miriam Mobley-Smith, Director of Strategic Alliances, Pharmacy Technician Certification Board; Roanne Osborne-Gaskin, M.D., Senior Medical Director, MDWise, Inc.; Cathy Phan, Outreach and Education Coordinator, Asian American Health Coalition DBA HOPE Clinic; Kamilah Pickett, Litigation Support, Independent Contractor; Brendan Riley, Outreach and Enrollment Coordinator, NC Community Health Center Association; Jeanne Ryer, Director, New Hampshire Citizens Health Initiative, University of New Hampshire; Alvia Siddiqi, Medicaid Managed Care Community Network (MCCN) Medical Director, Advocate Physician Partners, Carla Smith, Executive Vice President, Healthcare Information and Management Systems Society (HIMSS); Tobin Van Ostern, Vice President and Co-Founder, Young Invincible Advisors; and Paula Villescaz, Senior Consultant, Assembly Health Committee, California State Legislature.

## II. Meeting Agenda

In accordance with section 10(a) of the FACA, this notice announces a meeting of the APOE. The agenda for the March 23, 2016 meeting will include the following:

- Welcome and listening session with CMS leadership
- Recap of the previous (January 13, 2016) meeting
- Affordable Care Act initiatives
- An opportunity for public comment
- Meeting summary, review of recommendations, and next steps

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make a presentation may submit written comments to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

## III. Security, Building, and Parking Guidelines

This meeting will be held in a federal government building; therefore, federal security measures are applicable. The Real ID Act, enacted in 2005, establishes minimum standards for the issuance of state-issued driver's licenses and identification (ID) cards. It prohibits Federal agencies from accepting an official driver's license or ID card from a state unless the Department of Homeland Security determines that the state meets these standards. Beginning October 2015, photo IDs (such as a valid driver's license) issued by a state or territory not in compliance with the Real ID Act will not be accepted as identification to enter Federal buildings. Visitors from these states/territories will need to provide alternative proof of identification (such as a valid passport) to gain entrance into CMS buildings. The current list of states from which a Federal agency may accept driver's licenses for an official purpose is found at <http://www.dhs.gov/real-id-enforcement-brief>. 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:** Sec. 222 of the Public Health Service Act (42 U.S.C. 217a) and sec. 10(a) of Pub. L. 92-463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR 102-3).

Dated: February 18, 2016.

**Andrew M. Slavitt,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2016-04091 Filed 2-24-16; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-0001]

#### Developing an Evidentiary Standards Framework for Safety Biomarkers Qualification; Public Workshop

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

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA), in co-sponsorship with the Foundation for the National Institutes of Health Biomarkers Consortium (FNIH BC), is announcing a public workshop entitled "Developing an Evidentiary Standards Framework for Safety Biomarkers Qualification Workshop." The purpose of the workshop is to discuss the evidentiary standards needed to support biomarker qualification with a particular emphasis on drug safety markers. The 2-day

workshop will focus on the standards relevant to the qualification of a range of safety biomarkers and examine case studies in several different organ systems.

**DATES:** The public workshop will be held on April 14, 2016, from 9 a.m. to 5 p.m. and April 15, 2016, from 8 a.m. to 5 p.m.

**ADDRESSES:** The public workshop will be held at the Bethesda North Marriott Hotel and Conference Center, 5701 Marinelli Rd., Bethesda, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Janelle Lewis, Foundation for the National Institutes of Health, 9650 Rockville Pike, Bethesda, MD 20814, 301-594-2919, FAX: 301-480-2752, email: [jlewis@fnih.org](mailto:jlewis@fnih.org).

**SUPPLEMENTARY INFORMATION:** The need for evidentiary standards to qualify biomarkers was identified in FDA's Critical Path Initiative as essential to improving the efficiency and effectiveness of drug development. Evidentiary standards vary among different types of biomarkers and according to the context(s) of use (COU) for which qualification is being considered, and there are specific challenges involved in qualifying drug safety biomarkers. This workshop is aimed at creating alignment among scientific stakeholders including FDA, the National Institutes of Health (NIH), the biopharmaceutical industry, academic researchers, and patient groups regarding a proposed framework for determining the levels of evidence required to qualify biomarkers for use in drug development, with an emphasis on biomarkers used in determinations of drug safety assessments. Development of a general framework for biomarker qualification will be discussed, along with specific application to different COUs related to drug safety, including consideration of several specific case studies involving qualification of clinical markers of toxicity in different organ systems.

**Registration:** There is no fee to attend the workshop, but attendees must register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at [www.fnih.org/evidentiarystandardsworkshop](http://www.fnih.org/evidentiarystandardsworkshop) by April 1, 2016. For those persons without Internet access, please contact Janelle Lewis at the Foundation for the NIH (see **FOR FURTHER INFORMATION CONTACT**) to register.

Attendees are responsible for their own hotel accommodations. Attendees making reservations at the Bethesda North Marriott Hotel and Conference

Center (see **ADDRESSES**) are eligible for a reduced rate of \$226 per night (equivalent to the government per diem rate), not including applicable taxes. To receive the reduced rate, follow the Web link that will be provided to you upon completion of online registration.

If you need special accommodations due to a disability, please contact Janelle Lewis (see **FOR FURTHER INFORMATION CONTACT**) at the Foundation for the NIH at least 7 days in advance of the workshop.

Dated: February 19, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-04027 Filed 2-24-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

[Document Identifier: OS-4040-0010 60D]

#### Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

**AGENCY:** Electronic Government Office, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Electronic Government Office (EGOV), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a 3-year extension for OMB Control Number 4040-0010. The ICR will expire on September 30, 2016. The 4040-0010 is composed of the following forms: Project Abstract; Project Performance Site Location(s); and Key Contacts. The ICR also requests categorizing these forms as common forms, meaning HHS will only request approval for its own use of the form rather than aggregating the burden estimate across all Federal Agencies as was done for previous actions on this OMB control number. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

**DATES:** Comments on the ICR must be received on or before April 25, 2016.

**ADDRESSES:** Submit your comments to [ed.calimag@hhs.gov](mailto:ed.calimag@hhs.gov) or (202) 690-7569.