

open, responsive, and understandable to the public. We share the goal of increasing public participation in the development of Medicare coverage issues. This will assist us in obtaining the information we require to make a national coverage determination in a timely manner and ensuring that the Medicare program continues to meet the needs of its beneficiaries. *Form Number:* CMS–R–290 (OMB control number: 0938–0776); *Frequency:* Annual; *Affected Public:* Private Sector: Business or other for-profits; *Number of Respondents:* 200; *Total Annual Responses:* 200; *Total Annual Hours:* 8,000. (For policy questions regarding this collection contact Katherine Tillman at 410–786–9252.)

Dated: August 18, 2016.

**William N. Parham, III,**

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

[FR Doc. 2016–20216 Filed 8–23–16; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS–7042–N]

#### Health Insurance Marketplace<sup>SM</sup>; and the Medicare, Medicaid, and Children's Health Insurance Programs; Meeting of the Advisory Panel on Outreach and Education (APOE), September 21, 2016

**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> and the Medicare, Medicaid, and Children's Health Insurance Programs consumer education strategies. This meeting is open to the public.

**DATES:** *Meeting Date:* Wednesday, September 21, 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, September 7, 2016, 5:00 p.m., e.d.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/apoesept2016meeting> 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>1</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, Public Law 111–148, and Health Care and Education Reconciliation Act of 2010, Public Law 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 now able to purchase private health insurance coverage through competitive marketplaces, called Affordable Insurance Exchanges (we also call an Exchange a Health

<sup>1</sup> We note that the Citizen's 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.

Insurance Marketplace<sup>SM 2</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 CHIP or coverage available through the 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 Orthopaedic Surgery, Department of Orthopaedics, 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; 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; Alvia Siddiqi, 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 Invincibles Advisors; and Paula Villescaz, Senior Consultant, Assembly Health Committee, California State Legislature.

## II. Provisions of This Notice

In accordance with section 10(a) of the FACA, this notice announces a meeting of the APOE. The agenda for the September 21, 2016 meeting will include the following:

- Welcome and listening session with CMS leadership
- Recap of the previous (June 22, 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 an oral 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

<sup>2</sup> Health Insurance Marketplace<sup>SM</sup> and Marketplace<sup>SM</sup> are service marks of the U.S. Department of Health & Human Services.

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: August 16, 2016.

**Andrew M. Slavitt,**

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

[FR Doc. 2016-20187 Filed 8-23-16; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-D-1580]

#### **Patient Preference Information—Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling; Guidance for Industry, Food and Drug Administration Staff and Other Stakeholders; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled “Patient Preference Information—Voluntary Submission, Review in PMAs, HDE Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling.” This document explains the principal concepts that sponsors and other stakeholders should consider when choosing to collect patient preference information (PPI), which may inform FDA’s benefit-risk determinations in the premarket review of premarket approval applications (PMAs), humanitarian device exemption

(HDE) applications, and *de novo* classification requests. This guidance also discusses FDA’s inclusion of PPI in its decision summaries and provides recommendations for the inclusion of such information in device labeling for certain devices. FDA is also issuing a Level 2 updated version of the guidance document entitled “Factors To Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications,” originally issued on March 28, 2012, that has been edited to be consistent with this guidance document.

**DATES:** Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments,

except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA-2015-D-1580 for “Patient Preference Information—Voluntary Submission, Review in PMAs, HDE Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling.” If you are making submissions that also address the edits to the Level 2 guidance, the submissions received must include the Docket No. FDA-2011-D-0577 for “Factors To Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications.” Received comments will be placed in the docket(s) noted and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the