DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces a meeting for the initial review of applications in response to Special Interest Projects (SIP) 15–007, HPV Vaccine Impact among Men who have Sex with Men (MSM), and, SIP 15–009, Serosorting and Other Seroadaptive Behaviors among Men who have Sex with Men (MSM) in the US-designing a Brief Survey Tool for Use in Clinical Practice.

Time and Date: 10:00 a.m.–6:00 p.m., May 18, 2015 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''HPV Vaccine Impact among Men who have Sex with Men (MSM), SIP 15–007, and, Serosorting and Other Seroadaptive Behaviors among Men who have Sex with Men (MSM) in the US-designing a Brief Survey Tool for Use in Clinical Practice, SIP 15–009.''

Contact Person for More Information: Brenda Colley Gilbert, Ph.D., M.S.P.H., Director, Extramural Research Program Operations and Services, CDC, 4770 Buford Highway NE., Mailstop F–80, Atlanta, Georgia 30341, Telephone: (770) 488–6295, *BJC4@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015–09647 Filed 4–24–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces a meeting for the initial review of applications in response to Special Interest Projects (SIP) 15–002, Economic Impact of Clinical Trials among Children Diagnosed with Cancer, and, SIP 15–005, Economic Costs of Quality Assurance in Lung Cancer Screening Programs.

Time and Date: 11:00 a.m.–6:00 p.m., May 19, 2015.

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''Economic Impact of Clinical Trials among Children Diagnosed with Cancer, SIP 15–002, and, Economic Costs of Quality Assurance in Lung Cancer Screening Programs, SIP 15–005.''

Contact Person for More Information: Brenda Colley Gilbert, Ph.D., M.S.P.H., Director, Extramural Research Program Operations and Services, CDC, 4770 Buford Highway NE., Mailstop F–80, Atlanta, Georgia 30341, Telephone: (770) 488–6295, *BJC4@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015–09645 Filed 4–24–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–7036–N2]

Health Insurance Marketplace, Medicare, Medicaid, and Children's Health Insurance Programs; Additional Request for Nominations for the Advisory Panel on Outreach and Education (APOE)

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

ACTION: Notice.

SUMMARY: This notice requests nominations for individuals to serve on the Advisory Panel on Outreach and Education (APOE).

DATES: Nominations will be considered if we receive them at the appropriate address, provided in the ''**ADDRESSES**'' section of this notice, no later than 5 p.m., Eastern Daylight Time (e.d.t.) on May 18, 2015.

ADDRESSES: Mail or deliver nominations to the following address: Abigail Huffman, Designated Federal Official, Office of Communications, CMS, 7500 Security Boulevard, Mail Stop S1–05–06, Baltimore, MD 21244–1850 or email nominations to *Abigail.Huffman1@cms.hhs.gov.*

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* or visit the Web site 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 on Medicare Education (the predecessor to the APOE) was created in 1999 to advise and make 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 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. Successful MA program implementation required us 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, the Secretary, and by delegation, the Administrator of CMS were authorized under Title I of MMA 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 now able to purchase private health insurance coverage through a competitive marketplace, called the Affordable Insurance Exchange (or Health Insurance Marketplace, or ''Marketplace''). 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 the Marketplace. 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 APOE charter was originally created in 1999, as the charter for the Advisory Panel on Medicare Education. The panel's charter was renewed, and the panel was renamed the Advisory Panel for Outreach and Education, on January 21, 2011. The charter was most recently renewed on January 21, 2015. The APOE will advise HHS and CMS on developing and implementing education programs for individuals with, or who are eligible for, the Health Insurance Marketplace, Medicare, Medicaid, and CHIP about options for selecting health care coverage under these and other programs intended to ensure improved access to quality care, including preventive services. The scope of this panel, convened under the Federal Advisory Committee Act (FACA), also includes advising on 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).

The charter will terminate on January 21, 2017, unless renewed by appropriate action. The APOE was chartered under 42 U.S.C. 222 of the Public Health Service Act, as amended. The APOE is governed by the provisions of 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.

In accordance with the renewed 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 the Health Insurance Marketplace.
- Enhancing the federal government's effectiveness in informing Health Insurance Marketplace, Medicare, Medicaid, and CHIP consumers, issuers, providers, and stakeholders through education and outreach programs of 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, 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.
- Establishing links 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 preventive services, envisioned under the Affordable Care Act.

In the February 27, 2015 **Federal Register** (80 FR 10688), we published a notice titled ''Health Insurance Marketplace, Medicare, Medicaid, and Children's Health Insurance Programs; Renewal of the Advisory Panel on Outreach and Education (APOE) and Request for Nominations''. The notice announced the renewal of the APOE charter and requested nominations for individuals to serve on the APOE.

II. Provisions of this Notice

This notice is an additional solicitation of nominees for the Panel. The APOE shall consist of no more than 20 members. The Chair shall either be appointed from among the 20 members, or a federal official will be designated to serve as the Chair. The charter requires that meetings shall be held approximately four times per year. Members will be expected to attend all meetings. The members and the Chair shall be selected from authorities knowledgeable in one or more of the following fields:

- Senior citizen advocacy
- Outreach to minority and underserved communities
- Health communications
- Disease-related advocacy
- Disability policy and access
- Health economics research
- Behavioral health
- Health insurers and plans
- Health information technology (IT)
- Social media
- Direct patient care
- Matters of labor and retirement

Representatives of the general public may also serve on the APOE.

This notice announces that, in July 2015, the terms of 11 existing members will expire, and in October 2015, the terms of 2 additional members will expire. This notice invites interested organizations or individuals to submit nominations for membership for all 13 upcoming vacancies on the APOE (no self-nominations will be accepted). The Secretary, or designee, will appoint new members to the APOE from among those candidates determined to have the expertise required to meet specific agency needs, in a manner to ensure an appropriate balance of membership. We are committed to ensuring that the interests of both women and men, members of all racial and ethnic groups, and disabled individuals are adequately

represented on the APOE. Therefore, we encourage nominations of qualified candidates who can represent these interests. Any interested organization or person may nominate one or more qualified persons.

Each nomination must include a letter stating that the nominee has expressed a willingness to serve as a Panel member and must be accompanied by a curricula vitae and a brief biographical summary of the nominee's experience.

While we are looking for experts in a number of fields, our most critical needs are for experts in Health IT, Tribal Affairs, Community Health Centers/Medically Underserved Populations, African-American Health/Disparities, Health/Disability, Quality/Disparities, and State Programs/Medicaid/Rural.

We are requesting that all curricula vitae include the following:

- Date of birth
- Place of birth
- Title and current position
- Professional affiliation
- Home and business address
- Telephone and fax numbers
- Email address
- List of areas of expertise

Phone interviews of nominees may also be requested after review of the nominations.

In order to permit an evaluation of possible sources of conflict of interest, potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts.

Members are invited to serve for 2-year terms, contingent upon the renewal of the APOE by appropriate action prior to its termination. A member may serve after the expiration of his or her term until a successor takes office. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term.

III. Copies of the Charter

The Secretary's Charter for the APOE is available on the CMS Web site at: *http://www.cms.gov/Regulations-andGuidance/Guidance/FACA/APOE.html,* or you may obtain a copy of the charter by submitting a request to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

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: *April 21, 2015.*

Andrew M. Slavitt

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–09730 Filed 4–24–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1309]

M8 Electronic Common Technical Document v4.0 Draft Implementation Guide v2.0; Electronic Common Technical Document v4.0 Implementation Package Draft Specification for Submission Formats v2.0; International Conference on Harmonisation; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance entitled ''M8 Electronic Common Technical Document (eCTD) v4.0 Draft Implementation Guide v2.0'' (the M8 eCTD draft implementation guidance) and a related document entitled ''eCTD v4.0 Implementation Package Draft Specification for Submission Formats v2.0'' (the draft specifications document). The M8 eCTD draft implementation guidance and the draft specifications document were prepared under the auspices of the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use. The M8 eCTD draft implementation guidance provides instructions for creating the eCTD v4.0 Health Level 7 Regulated Product Submission (RPS) message for Modules 2 through 5 of the eCTD. The draft specifications document provides specifications for creating files for inclusion in the eCTD. These draft documents represent major updates to the eCTD specifications.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the Agency considers your comment on these draft documents before it begins work on the final versions of the documents, submit either electronic or written comments on the draft documents by May 27, 2015.

ADDRESSES: Submit written requests for single copies of the draft documents to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft documents may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance documents.

Submit electronic comments on the draft documents 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: *Regarding the guidance:* Jared Lantzy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1116, Silver Spring, MD 20993–0002, 301–796–0597; or Mark Gray, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7217, Silver Spring, MD 20993–0002, 301–796–2081.

Regarding the ICH: Michelle Limoli, Center for Drug Evaluation and Research, International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1174, Silver Spring, MD 20993–0002, 301–796–8377.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input