

information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202-501-4755.

Please cite OMB Control No. 9000-0024, Buy American, Trade Agreements, and Duty-Free Entry in all correspondence.

Dated: July 25, 2017.

**Lorin S. Curit,**

*Director, Federal Acquisition Policy Division, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10110]

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

**AGENCY:** Centers for Medicare & Medicaid Services.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by September 29, 2017.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and

recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development Attention: Document Identifier/OMB Control Number \_\_\_\_\_ Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786-4669.

#### SUPPLEMENTARY INFORMATION:

##### Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

#### CMS-10110 Manufacturer Submission of Average Sales Prices (ASP) Data for Medicare Part B Drugs

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for

approval. To comply with this requirement, CMS is publishing this notice.

#### Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection;

*Title of Information Collection:* Manufacturer Submission of Average Sales Prices (ASP) Data for Medicare Part B Drugs; *Use:* In accordance with Section 1847A of the Social Security Act (the Act), Medicare Part B covered drugs and biologicals not paid on a cost or prospective payment basis are paid based on the average sales price (ASP) of the drug or biological, beginning in Calendar Year (CY) 2005. The ASP data reporting requirements are specified in Section 1927 of the Act. The reported ASP data are used to establish the Medicare payment amounts. *Form Number:* CMS-10110 (OMB control number: 0938-0921); *Frequency:* Quarterly; *Affected Public:* Business or other For-profits; *Number of Respondents:* 180; *Total Annual Responses:* 720; *Total Annual Hours:* 9360. (For policy questions regarding this collection contact Felicia Eggleston at 410-786-9287.)

Dated: July 25, 2017.

**William N. Parham, III,**

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

[FR Doc. 2017-16016 Filed 7-28-17; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-7045-N]

#### Health Insurance Marketplace<sup>SM</sup>, Medicare, Medicaid, and Children's Health Insurance Programs; Announcement of the Renewal of the Charter for the Advisory Panel on Outreach and Education (APOE)

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the renewal of the charter 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 consumer education strategies concerning the Health Insurance Marketplace<sup>SM</sup>, Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). Additional information about the Panel 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.

**FOR FURTHER INFORMATION CONTACT:**  
Thomas Dudley, (410) 786-1442.

**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).

On January 21, 1999, 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) 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). (For more detailed information, see the February 17, 1999 **Federal Register** (64 FR 7899)).

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. CMS has 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 CMS to consider 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, CMS has 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 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 an Affordable Insurance Exchange (also called Health 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 the Marketplace<sup>SM</sup>. 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.

**II. Provisions of This Notice**

Pursuant to the charter approved on January 19, 2017, the APOE was renewed. The APOE will advise the Department of Health and Human Services and CMS on developing and implementing education programs that support individuals enrolled in or eligible for Medicare, Medicaid, the CHIP, coverage through the Health Insurance Marketplace and other CMS programs about options for selecting health care coverage under these and other programs envisioned under health care reform to ensure improved access to quality care, including prevention services. The scope of this FACA group also includes advising on education of providers and stakeholders with respect to health care reform and certain provisions of the HITECH Act enacted as part of ARRA. The charter will terminate on January 19, 2019, unless renewed by appropriate action. The APOE was chartered under 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended. The APOE is governed by provisions of Public Law 92-463, as amended (5 U.S.C. appendix 2), which sets forth standards for the formation and use of advisory committees.

Pursuant to the renewed charter, the APOE will advise the Secretary of Health and Human Services and the CMS Administrator concerning optimal strategies for the following:

- Developing and implementing education and outreach programs for individuals enrolled in or eligible for Medicare, Medicaid, and CHIP or health coverage available through the Health Insurance Marketplace and other CMS programs.
- Enhancing the Federal government's effectiveness in informing the Medicare, Medicaid, CHIP or the Health Insurance Marketplace consumers, issuers, providers and stakeholders pursuant to 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 Medicare, Medicaid, CHIP, and Health Insurance Marketplace education programs and other CMS programs as designated.
- Assembling and sharing an information base of "best practices" for helping consumers evaluate health coverage options.

<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.

<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.

- 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 preventive 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; 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, 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 Invincibles Advisors; and Paula Villescay, Senior Consultant, Assembly Health Committee, California State Legislature.

### III. Copies of the Charter

The Secretary's Charter for the APOE is available on the CMS Web site at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/APOECharter2017.pdf> or you may obtain a copy of the charter by submitting a request to: Thomas Dudley, Designated Federal Official (DFO), Office of Communications, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop S1 05-06, Baltimore, MD 21244 1850 or via email at [Thomas.Dudley@cms.hhs.gov](mailto:Thomas.Dudley@cms.hhs.gov).

Dated: July 21, 2017.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2017-15960 Filed 7-28-17; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-4179]

#### Cardiac Troponin Assays; Public Workshop; Request for Comments

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

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled "Cardiac Troponin Assays." The purpose of the workshop is to discuss the development of innovative troponin assays designed to aid in the diagnosis of myocardial infarction (MI) and additional clinical uses of these assays. The workshop is intended to enhance engagement with stakeholders to facilitate device development and to discuss scientific and regulatory challenges associated with the analytical and clinical validation methods for troponin assay devices. Public input and feedback gained through this workshop may aid in the development of science-based approaches to aid in the efficient development of innovative, safe and effective, troponin diagnostic assays, which may lead to better patient care.

**DATES:** The public workshop will be held on November 28, 2017, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by November 27, 2017. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (The Great Room), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered.

Electronic comments must be submitted on or before November 27, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of November 27, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** Go to <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2017-N-4179 for "Cardiac Troponin Assays." Received comments, those filed in a timely manner (see

**ADDRESSES**) will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov>