Requirements, Cost Principles, and Audit Requirements for Federal Awards,'' (Uniform Guidance) to have audits conducted of their federal award expenditures, and to file the resulting reporting packages (Single Audit reports) and data collection Form SF–SAC (Form) with the Federal Audit Clearinghouse. The Form SF–SAC is appendix X to 2 CFR part 200.

The Single Audit process is the primary method Federal agencies and pass-through entities use to provide oversight of Federal awards and reduce risk of non-compliance and improper payments. This oversight includes following up on audit findings and questioned costs.

The Office of Management and Budget has historically designated the U.S. Census Bureau (Census) as the FAC, to serve as the government-wide repository of record for Single Audit reports collected under OMB control number 0607–0518. At the direction of OMB, GSA will become the new FAC repository of record, by September 30, 2023, with collection of Single Audits with fiscal periods ending in 2023 and later. GSA will also begin data collection of 2016–2022 Single Audit reports currently collected by Census. All of these collections will be conducted under this PRA clearance application.

Single Audit reports under this clearance will be collected electronically through GSA's new FAC internet collection portal at *https://www.fac.gov/.*

There are few proposed changes to the existing data elements and data collection method in this clearance. Planned changes are intended to make the reporting process easier, improve data integrity, and ensure compliance with the GREAT Act. All changes listed below are intended to take effect for all audit years collected by GSA, unless specified otherwise.

The proposed changes include:

- end collection of the DUNS number
- upload the majority of data via templates rather than graphical user interface (GUI) in the initial GSA system, subject to creation of a GUI for additional data submission options before expiration of this proposed clearance (collection items are not changing, just the means of collection)
- collect auditee's Unique Entity Identifier (UEI) for audits with fiscal periods ending in 2016–2021 (already approved to be collected for audits with fiscal periods 2022 and future)
- when possible, import the auditee name and address directly from SAM.gov (when the auditee's UEI is entered, their auditee name and address will be pulled from *SAM.gov* into Part I of the Form)
- update terminology, similar to the following, in order to be in compliance with the GREAT Act: *change* ''*award*'' *to* ''*federal award*''*;* ''*CFDA*'' *to* ''*Assistance Listing*''
- clarify on-screen and/or Form instructions to improve data collection and accuracy, as part of the creation of an updated data collection and dissemination system

B. Annual Reporting Burden

Respondents: 90,000 (45,000 auditees and 45,000 auditors.

Responses per Respondent: 1.

Total Annual Responses: 90,000 (45,000 auditees and 45,000 auditors).

Hours per Response: 100 hours for each of the 450 large respondents and 21 hours for each of the 89,550 small respondents.

Total Burden Hours: 1,925,550.

C. Public Comments

A 60-day notice published in the **Federal Register** at 87 FR 78684 on December 22, 2022. Four comments were received. To view a summary of the comments and responses, go to *https://www.regulations.gov,* search for ''OMB control number 3090–XXXX Federal Audit Clearinghouse'', click ''Open Docket'', and view ''Supporting Documents''.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 3090–XXXX, Federal Audit Clearinghouse, in all correspondence.

Lesley Briante,

Deputy Chief Information Officer.

[FR Doc. 2023–17518 Filed 8–15–23; 8:45 am]

BILLING CODE 6820–AB–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–7072–N]

Announcement of the Advisory Panel on Outreach and Education (APOE) In-Person Meeting

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

ACTION: Notice.

SUMMARY: This notice announces the next meeting of the 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) (the Secretary) 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®, Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). This meeting is open to the public.

DATES:

Meeting Date: Thursday, September 21, 2023 from 8:30 a.m. to 4:00 p.m. eastern daylight time (e.d.t).

Deadline for Meeting Registration, Presentations, Special Accommodations, and Comments: Thursday, September 7, 2023, 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, Washington, DC 20201.

Presentations and Written Comments: Presentations and written comments should be submitted to: Lisa Carr Designated Federal Official (DFO), Office of Communications, Centers for Medicare & Medicaid Services, 200 Independence Avenue SW, Mailstop 325G HHH, Washington, DC 20201, 202–690–5742, or via email at *APOE@cms.hhs.gov.*

Registration: Persons wishing to attend this meeting must register at the website *http://CMS-APOE-September2023.rsvpify.com* or by contacting the DFO 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: Lisa Carr, Designated Federal Official, Office of Communications, 200 Independence Avenue SW, Mailstop 325G HHH, Washington, DC 20201, 202–690–5742, or via email at *APOE@cms.hhs.gov.*

Additional information about the APOE is available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/APOE.* Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION:

I. Background and Charter Renewal Information

A. Background

The Advisory Panel for Outreach and Education (APOE) (the Panel) is governed by the provisions of the 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 (the Act) (42 U.S.C. 1314(f)) and section 222 of the Public Health Service Act (42 U.S.C. 217a).

The Panel, which was first chartered in 1999, advises and makes recommendations to the Secretary of the U.S. Department of Health and Human Services (the Department) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on the effective implementation of national Medicare, Medicaid, Children's Health Insurance Program (CHIP) and Health Insurance Marketplace outreach and education programs.

The APOE has focused on a variety of laws, including the Medicare Modernization Act of 2003 (Pub. L. 108–173), and 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)).

The APOE helps the Department determine the best communication channels and tactics for various programs and priorities, as well as new rules and laws. In the coming years, we anticipate the American Rescue Plan, the Inflation Reduction Act, and the SUPPORT Act will be some of the topics the Panel will discuss. The Panel will provide feedback to CMS staff on outreach and education strategies, communication tools and messages and how to best reach minority, vulnerable and Limited English Proficiency populations.

B. Charter Renewal

The Panel's charter was renewed on January 19, 2023, and will terminate on January 19, 2025, unless renewed by appropriate action. The Charter can be found at *https://www.cms.gov/regulations-and-guidance/guidance/faca/apoe.*

In accordance with the renewed charter, the APOE will advise the Secretary 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, the CHIP, and coverage available through the Health Insurance Marketplace® and other CMS programs.
- Enhancing the federal government's effectiveness in informing Medicare, Medicaid, CHIP, or the Health Insurance Marketplace® consumers, issuers, providers, and stakeholders, pursuant to education and outreach programs regarding these programs, including public-private partnerships to leverage the resources of the private sector in educating beneficiaries, providers, partners and stakeholders.
- Expanding outreach to minority and underserved communities, including racial and ethnic minorities, in the context of Medicare, Medicaid, CHIP, and the 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.
- Building and leveraging existing community infrastructure 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 as of June 22, 2023, are as follows:

- Mitchell Balk, President, The Mt. Sinai Health Foundation.
- Ted Henson, Director of Health Center Performance and Innovation, National Association of Community Health Centers.
- Joan Ilardo, Director of Research Initiatives, Michigan State University, College of Human Medicine.
- Lydia Isaac, Vice President for Health Equity and Policy, National Urban League.
- Vacheria Keys, Director of Policy and Regulatory Affairs, National Association of Community Health Centers.
- Daisy Kim, Principal Legislative Analyst, University of California System.
- Erin Loubier, Senior Director for Health and Legal Integration and Payment Innovation, Whitman-Walker Health.
- Dr. Alister Martin, CEO, A Healthier Democracy; Physician, Massachusetts General Hospital; Assistant Professor, Harvard Medical School.
- Cori McMahon, Behavioral Medicine Psychologist and Digital Health Clinical Leader, Cooper University Health Care.
- Alan Meade, Director of Rehabilitation Services, Holston Medical Group.
- Neil Meltzer, President and CEO, LifeBridge Health.
- Dr. Carol Podgorski, Professor of Psychiatry, Associate Chair of Academic Affairs, University of Rochester Medical Center.
- Melanie Prince, President/CEO MAPYourWay, LLC; Immediate Past President, Case Management Society of America.
- Jina Ragland, Associate State Director of Advocacy and Outreach, AARP Nebraska.
- Morgan Reed, Executive Director, Association for Competitive Technology.
- Carrie Rogers, Associate Director, Community Catalyst.
- Mina Schultz, Health Policy and Advocacy Manager, Young Invincibles.
- Matthew Snider, JD, Senior Policy Analyst, Unidos US.
- Daniel Spirn, Vice President, Government Relations, Utilization Review Accreditation Commission.
- Emily Whicheloe, Director of Education, Medicare Rights Center.

II. Meeting Format and Agenda

In accordance with section 10(a) of the FACA, this notice announces a meeting of the APOE. The agenda for the September 21, 2023 meeting will include the following:

- Welcome and opening remarks from CMS leadership
- Recap of the previous (June 22, 2023) meeting
- Presentations on CMS programs, initiatives, and priorities; discussion of panel recommendations
- An opportunity for public comment
- Meeting adjourned

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. Meeting Participation

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 following weblink *http://CMS-APOE-September2023.rsvpify.com* by contacting the DFO at the address or telephone number listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice.

This meeting will be held in a federal government building, the Hubert H. Humphrey (HHH) Building; therefore, federal security measures are applicable.

The REAL ID Act of 2005 (Pub. L. 109–13) 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 for any official purpose unless the Secretary of 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 federal 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 a government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection, via metal detector or other applicable means, of all persons entering the building. We note that all items brought into the HHH Building, 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.

IV. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: August 11, 2023.

Evell J. Barco Holland,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–17569 Filed 8–15–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–1275]

Demonstrating Bioequivalence for Type A Medicated Articles Containing Active Pharmaceutical Ingredient(s) Considered To Be Poorly Soluble in Aqueous Media, That Exhibit Little to No Systemic Bioavailability, and Are Locally Acting; Draft Guidance for Industry; Availability; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the notice of availability that published in the **Federal Register** of June 8, 2023. In that notice, FDA requested comments on the draft guidance for industry (GFI) #279 entitled ''Demonstrating Bioequivalence for Type A Medicated Articles Containing Active Pharmaceutical Ingredient(s) Considered To Be Poorly Soluble in Aqueous Media, That Exhibit Little to No Systemic Bioavailability, and Are Locally Acting.'' The Agency is taking this action in response to a request for an extension to allow interested persons additional time to develop and submit comments.

DATES: FDA is reopening the comment period on the notice of availability published June 8, 2023 (88 FR 37551). Submit either electronic or written comments on the draft guidance by October 16, 2023 to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: 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–2023–D–1275 for ''Demonstrating Bioequivalence for Type A Medicated Articles Containing Active Pharmaceutical Ingredient(s) Considered To Be Poorly Soluble in Aqueous Media, That Exhibit Little to No Systemic Bioavailability, and Are Locally Acting.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the