organizations include Health Maintenance Organizations (HMOs) and Competitive Medical Plans (CMPs) under Section 1876, in addition to, Health Care Prepayment Plans (HCPPs) under Section 1833. These entities may be collectively referred to as Managed Care Organizations (MCOs). The cost and statistical data is submitted to CMS within the cost report, Form CMS 276 (OMB No.0938–0165). CMS is responsible for the receipt and processing of Form CMS 276. Form CMS 276, provided by CMS as excel worksheets, covers the prescribed format for the cost reports.

The cost report worksheets are designed to be of sufficient flexibility to take into account the diversity of operations, yet provide the necessary cost and statistical information to enable CMS to determine the proper amount of payment to the Plan. Cost-based MCOs must submit through HPMS an annual Budget Forecast, semi-annual interim, and final cost report to CMS, all of which are included in this collection. Additionally, HMOs/CMPs are required to submit fourth quarter interim reports annually to CMS; however, the required submission of 4th quarter interim reports is waived until further notice by CMS. Please note that HCPPs are not required to submit fourth quarter interim reports. *Form Number:* CMS–276 (OMB control number: 0938–0165); *Frequency:* Quarterly; *Affected Public:* Private Sector *Number of Respondents:* 17; *Number of Responses:* 51; *Total Annual Hours:* 1,612. (For questions regarding this collection contact Frank Cisar at 410–786–7553).

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* The PACE Organization Application Process in 42 CFR part 460; *Use:* The Programs of All-Inclusive Care for the Elderly (PACE) consist of pre-paid, capitated plans that provide comprehensive health care services to frail, older adults in the community who are eligible for nursing home care according to State standards. PACE organizations (PO) must provide all Medicare and Medicaid covered services; financing of this model is accomplished through prospective capitation of both Medicare and Medicaid payments. Upon approval of a PACE application, CMS executes a 3-way program agreement with the applicant entity and the applicable State Administering Agency (SAA). CMS regulations at 42 CFR 460.98(b)(2) require a PO to provide PACE services in at least the PACE center, the home, and inpatient facilities. The PACE center is the focal point for the delivery of PACE services; the center is where the interdisciplinary team (IDT) is located, services are provided, and socialization occurs with staff that is consistent and familiar to participants.

Collection of this information is mandated by statute under sections 1894(f) and 1934(f) of the Act and at 42 CFR part 460, subpart B, which addresses the PO application and waiver process. In general, PACE services are provided through a PO. An entity wishing to become a PO must submit an application to CMS that describes how the entity meets all the requirements in the PACE program. An entity's application must be accompanied by an assurance from the SAA of the State in which the PO wishes to operate its PACE program. CMS accepts applications on a designated date four times per year (*i.e.,* on a quarterly basis, generally the last Friday of March, June, September and December). *Form Number:* CMS–10631 (OMB control number: 0938–1326); *Frequency:* Occasionally; *Affected Public:* Private Sector, State, Local or Tribal governments, Business or other for-profits; *Number of Respondents:* 72; *Total Annual Responses:* 130; *Total Annual Hours:* 7,271. For policy questions regarding this collection contact Debbie Vanhoven at 410–786–6625.

Dated: January 11, 2022.

William N. Parham, III,

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

[FR Doc. 2022–00735 Filed 1–14–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–7065–N]

Announcement of the Advisory Panel on Outreach and Education (APOE) February 3, 2022 Virtual Meeting

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of 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, February 3, 2022 from 12:00 p.m. to 5:00 p.m. eastern standard time (e.s.t).

Deadline for Meeting Registration, Presentations, Special Accommodations, and Comments: Thursday, January 27, 2022 5:00 p.m. (e.s.t).

ADDRESSES:

Meeting Location: Virtual. All those who RSVP will receive the link to attend.

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 *https://www.eventbrite.com/e/apoe-february-3-2022-virtual-meeting-tickets-212590763697* 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 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 [1] (the predecessor to the APOE) on January 21, 1999 (64 FR 7899) 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 Prescription Drug, Improvement, and 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 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 Patient Protection and Affordable Care Act (Pub. L. 111–148) and Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively referred to as the Affordable Care Act) expanded the availability of other options for health care coverage and enacted a number of changes to Medicare as well as to Medicaid and CHIP. Qualified individuals and qualified employers are now able to purchase private health insurance coverage through a competitive marketplace, called an Affordable Insurance Exchange (also called Health Insurance Marketplace®, or Marketplace® [2]). 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 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) (Pub. L. 111–5).

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 19, 2021, and will terminate on January 19, 2023 unless renewed by appropriate action.

B. Charter Renewal

In accordance with the January 19, 2021, charter, the APOE will advise the HHS and CMS on developing and implementing education programs that support individuals who are enrolled in or eligible for Medicare, Medicaid, CHIP, or coverage available through the Health Insurance Marketplace® and other CMS programs. 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 the ARRA.

The charter will terminate on January 19, 2023, 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.

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 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, partners and stakeholders.
- Expanding outreach to minority and underserved communities, including racial and ethnic minorities, in the context of Medicare, Medicaid, the 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 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 as of September 15, 2021, are as follows:

- Julie Carter, Senior Federal Policy Associate, Medicare Rights Center.
- Scott Ferguson, Director of Care Transitions and Population Health, Mount Sinai St. Luke's Hospital.
- Jean-Venable Robertson Goode, Professor, Department of Pharmacotherapy and Outcomes Science, School of Pharmacy, Virginia Commonwealth University.
- Ted Henson, Director of Health Center Performance and Innovation, National Association of Community Health Centers.

[1] 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.

[2] Health Insurance Marketplace® and Marketplace® are service marks of the U.S. Department of Health and Human Services.

- Joan Ilardo, Director of Research Initiatives, Michigan State University, College of Human Medicine.
- Cheri Lattimer, Executive Director, National Transitions of Care Coalition.
- Cori McMahon, Vice President, Tridiuum.
- Alan Meade, Director of Rehabilitation Services, Holston Medical Group.
- Michael Minor, National Director, H.O.P.E. HHS Partnership, National Baptist Convention USA, Incorporated.
- Jina Ragland, Associate State Director of Advocacy and Outreach, AARP Nebraska.
- Morgan Reed, Executive Director, Association for Competitive Technology.
- Margot Savoy, Senior Vice President, American Academy of Family Physicians.
- Congresswoman Allyson Schwartz, Senior Advisor, FTI Consulting.
- Tia Whitaker, Statewide Director, Outreach and Enrollment, Pennsylvania Association of Community Health Centers.

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 February 3, 2022 meeting will include the following:

- Welcome and listening session with CMS leadership
- Recap of the previous (September 15, 2021) meeting
- CMS programs, initiatives, and priorities
- 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. Meeting Participation

The meeting is open to the public, but attendance is limited to registered participants. Persons wishing to attend this meeting must register at the website *https://www.eventbrite.com/e/apoe-february-3-2022-virtual-meeting-tickets-212590763697* or contact the DFO at the address or 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 virtually. Individuals who are not registered in advance 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 Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: January 11, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–00745 Filed 1–14–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1037]

Fresenius USA, Inc., et al.; Withdrawal of Approval of 216 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of October 22, 2021. The document announced the withdrawal of approval of 216 abbreviated new drug applications (ANDAs) from multiple applicants, as of November 22, 2021. The document was published with an incorrect date. In addition, the document indicated that FDA was withdrawing approval of ANDA 075941, Strontium Chloride SR–89 Injection, 1 millicurie/milliliter, held by Bio-Nucleonics, Inc., 1600 Market St., Suite 13200, Philadelphia, PA 19103, for repeated failure to submit annual reports. Before FDA withdrew the approval of this ANDA, the application holder informed FDA that it submitted annual reports for ANDA 075941. Therefore, FDA rescinds its withdrawal of approval of ANDA 075941. The approval of ANDA 075941 is still in effect.

FOR FURTHER INFORMATION CONTACT: James Hanratty, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–4718, *James.Hanratty@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Corrections

In the **Federal Register** of Friday, October 22, 2021 (86 FR 58675), in FR Doc. 2021–23075, the following corrections are made:

1. On page 58675, in the second column, correct the **DATES** section to read: **DATES:** Approval is withdrawn as of October 22, 2021.''

2. On page 58679, in the table, remove the entry for ANDA 075941.

Dated: January 12, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–00831 Filed 1–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–0885]

Determination That PEPCID (Famotidine) Tablet, 20 Milligrams and 40 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that PEPCID (famotidine) tablet, 20 milligrams (mg) and 40 mg, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring,