Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2022–22319 Filed 10–13–22; 8:45 am]

BILLING CODE 4153–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Establishment of the Medicare Drug Rebate and Negotiations Group Within the Center for Medicare (CM)

AGENCY: Centers for Medicare & Medicaid Services, HHS.

SUMMARY: Establish the Medicare Drug Rebate and Negotiations Group within the Center for Medicare (CM) to implement the Drug Price Negotiation Program and the Inflation Rebate Program in Medicare Part B and Part D as authorized under the Inflation Reduction Act of 2022. CMS is responsible for implementing these new programs.

DATES: This reorganization was approved by the Secretary of Health and Human Services and takes effect October 8, 2022.

SUPPLEMENTARY INFORMATION: Statement of Organization, Functions, and Delegations of Authority Part F of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) (last amended at **Federal Register**, Vol. 75, No. 56, pp. 14176–14178, dated March 24, 2010; Vol. 76, No. 203, pp. 65197–65199, dated October 20, 2011; Vol. 78, No. 86, p. 26051, dated May 3, 2013; Vol. 79, No. 2, pp. 397–398, dated January 3, 2014; and Vol. 84, No. 32, p. 4470, dated February 15, 2019) is amended to reflect the establishment of the Medicare Drug Rebate and Negotiations Group within the Center for Medicare (CM) to implement the Drug Price Negotiation Program and the Inflation Rebate Program in Medicare Part B and Part D as authorized under the Inflation Reduction Act of 2022. CMS is responsible for implementing these new programs.

Title I, Subtitle B, Part 1, sections 11001–11004, of the Inflation Reduction Act of 2022 (IRA) Public Law 117–169 enacted on August 16, 2022, establishes a new Drug Price Negotiation Program under Medicare Part B and Medicare Part D to lower prices for certain high-spend single source drugs. Title I, Subtitle B, sections 11101 and 11102 of the IRA also enacts a new program to establish Inflation Rebates in Medicare Part B and Medicare Part D. CMS is responsible for implementing these new programs.

The work required to implement and administer these new programs will be novel and differ significantly from the Medicare functions that CMS performs today. Given the unique nature of this new work, there is not an existing operating component, group, office or division in CMS or CM that performs these actions. Moreover, the scope and complexity of these new programs, and the deadlines for implementation, require that a new, dedicated organization be established to ensure that CMS is able to implement these programs successfully and on time. In order to implement and operate these new programs, CMS is creating a new group—the Medicare Drug Rebate and Negotiations Group—within CM.

Part F, Section FC. 10 (Organization) is revised as follows:

Center for Medicare, Medicare Drug Rebate and Negotiations Group

Part F, Section FC. 20 (Functions) for the new organization is as follows:

Medicare Drug Rebate and Negotiations Group

With regard to the Drug Price Negotiation Program, each year, the new group will negotiate drug prices with pharmaceutical manufacturers for certain Part B and Part D drugs. This will require identifying negotiation-eligible drugs, entering into agreements with manufacturers, collecting extensive data from manufacturers and other sources, calculating ceiling and maximum fair prices, negotiating prices with manufacturers, re-negotiating prices as necessary and publishing the results of the negotiation. Under the Inflation Rebate Program, manufacturers of certain drugs will be required to pay a penalty or ''rebate'' if the price of their drug increases faster than the rate of inflation. For this program, the new group will need to identify the universe of rebatable drugs under Part B and Part D; determine which drugs had price increases in excess of inflation; and compute, invoice, and collect rebates owed by manufacturers.

To carry out these functions, the major tasks of the new group will include:

- Developing policy, including identifying and vetting policy options and preparing policy memoranda, rulemaking and technical guidance;
- Briefing policy officials in CMS, U.S. Department of Health and Human Services (HHS), and Executive Office of the President (EOP);
- Establishing operational processes to collect data from manufacturers and other sources;
- Conducting pharmacoeconomic analyses and assessments of selected drugs;
- Establishing operational processes to negotiate and re-negotiate drug prices and conducting those negotiations with manufacturers;
- Establishing operational processes to calculate and invoice rebates;
- Developing contractual agreements with manufacturers necessary to effectuate both programs;
- Monitoring manufacturer compliance with programmatic rules;
- Procuring and managing contractors to support these functions;
- Conducting stakeholder outreach and educational materials; and
- Responding to inquiries from Congress, the press, and other external stakeholders.

Authority: 44 U.S.C. 3101.

Dated: October 7, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–22296 Filed 10–12–22; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Blueprint MedTech (BPMT) Biocompatibility, Sterilization, and Animal Studies.

Date: November 15, 2022.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ipolia R. Ramadan, Ph.D., Scientific Review Officer, Scientific Review

Branch, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827–4471, *ramadanir@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: October 11, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–22361 Filed 10–13–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2021–0345]

Notice of Availability of Draft Study; Extension of Comment Period

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability and extension of comment period.

SUMMARY: The Coast Guard is extending the comment period of the draft Pacific Coast Port Access Route Study (PAC–PARS) in order to provide stakeholders with additional time to provide the Coast Guard with valuable input. This study evaluates safe access routes for the movement of vessel traffic proceeding to or from ports or places along the western seaboard of the United States and determines whether a shipping safety fairway (''fairway'') and/or routing measures should be established, adjusted or modified.

DATES: Comments must be submitted to the online docket via *https://www.regulations.gov* on or before November 8, 2022.

ADDRESSES: You may submit comments identified by docket number USCG–2021–0345 using the Federal Decision Making Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email LCDR Sara Conrad, Coast Guard Pacific Area (PAC–54), U.S. Coast Guard; telephone (510) 437–3813, email *Sara.E.Conrad@uscg.mil* or Mr. Tyrone Conner, Eleventh Coast Guard District (dpw), U.S. Coast Guard; telephone (510) 437–2968, email *Tyrone.L.Conner@uscg.mil* or Mr. John Moriarty, Thirteenth Coast Guard District (dpw), U.S. Coast Guard; telephone (206) 220–7274, email *John.F.Moriarty@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Public Participation and Comments

Two webinars are being offered to present the contents of the draft study to the public and answer questions. The first webinar was held on October 4th, 2022. The presentation slides and a recording of the webinar are available on the PAC–PARS Homeport website here: *https://cglink.uscg.mil/efedac43.* The second webinar will be held on Tuesday, October 11th, 2022 at 11:00am PST. The link to register can also be found on the PAC–PARS Homeport website: *https://cglink.uscg.mil/efedac43.*

We encourage you to submit comments (or related material) on the draft PAC–PARS. We will consider all submissions and may adjust our final recommendations based on your comments. If you submit a comment, please include the docket number for this notice, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision Making Portal at *http://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2021–0345 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Viewing material in docket. To view documents mentioned in this notice as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. We review all comments received, but we may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Discussion

The draft PAC–PARS was published on August 26, 2022 (87 FR 52587). The original comment period closes on October 25, 2022. However, the Coast Guard has been notified that several stakeholders would like more time to prepare their comments on the draft study. The Coast Guard has decided that an extension of the public comment period would be appropriate to allow interested parties additional time to submit comments for Coast Guard's consideration. Thus, the comment period is extended by 14 days until November 8, 2022. This notice is issued under authority of 46 U.S.C. 70003(c)(1).

Dated: October 6, 2022.

L. Hannah,

Captain, U.S. Coast Guard, Chief, Pacific Area Preparedness Division.

[FR Doc. 2022–22339 Filed 10–13–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2022–0002; Internal Agency Docket No. FEMA–B–2279]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the