Sherrette A. Funn,

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

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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]

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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