To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. 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–10849 Drug Price Negotiation for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request

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 Collections

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Drug Price Negotiation for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (ICR) (CMS–10849, OMB 0938–1452); *Use:* Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (Pub. L. 117–169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (''the Act''). The Act establishes the Negotiation Program to negotiate maximum fair prices (''MFPs''), defined at 1191(c)(3) of the Act, for certain high expenditure, single source selected drugs covered under Medicare Part B and Part D. For the third cycle of the Negotiation Program, the Secretary of Health and Human Services (the ''Secretary'') will select up to 15 high expenditure, single source drugs payable under Part B and/or covered under Part D for negotiation. In accordance with section 1194(f)(4) of the Act, CMS will also renegotiate MFPs for drugs selected for renegotiation, if any, for initial price applicability year 2028.

Negotiation Data Elements: The statute requires that CMS consider certain data from Primary Manufacturers as part of the negotiation process. To the extent that more than one entity meets the statutory definition of manufacturer (specified in section 1193(a)(1) of the Act) for a selected drug for purposes of initial price applicability year 2028, CMS will designate the entity that holds the New Drug Application(s) (NDA(s))/Biologics License Application(s) (BLA(s)) for the selected drug to be ''the manufacturer'' of the selected drug (hereinafter the ''Primary Manufacturer''). The Primary Manufacturer's data submissions include the non-Federal average manufacturer price and related data for selected drugs for the purpose of establishing a ceiling price, as outlined in section 1193(a)(4)(A) of the Act, and information that the Secretary requires, pertaining to the negotiation factors outlined in section 1194(e)(1) of the Act, for the purpose of formulating offers and counteroffers pursuant to section 1193(a)(4)(B) of the Act. Some of these data are held by the Primary Manufacturer and are not currently available to CMS. Data described in sections 1194(e)(1) and 1193(a)(4) of the Act must be submitted by the Primary Manufacturer.

Section 1194(e)(2) of the Act requires CMS to consider certain data on selected drugs and their alternative treatments. Because the statute does not specify where these data come from, CMS will allow for optional submission from Primary Manufacturers and the public for drugs selected for negotiation or renegotiation. CMS will additionally review existing literature, conduct internal analyses, and consult subject matter and clinical experts on the factors listed in section 1194(e)(2) of the Act. Manufacturers may optionally submit this information as part of their Negotiation Data Elements Information Collection Request Form. The public may also optionally submit evidence about the selected drugs and their alternative treatments.

Drug Price Negotiation and Renegotiation Process: Any MFPs that are negotiated or renegotiated for these selected drugs will apply beginning in initial price applicability year 2028. For initial price applicability year 2028, the negotiation and renegotiation period begins on the earlier of the date that the Primary Manufacturer enters into a Medicare Drug Price Negotiation Program Agreement or February 28, 2026.

Section 1194(b)(2)(C) of the Act provides that if the Primary Manufacturer does not accept CMS' written initial offer, the Primary Manufacturer may submit an optional written counteroffer no later than 30 days after the date of receipt of CMS' written initial offer. If the Primary Manufacturer chooses to develop and submit a written counteroffer to CMS' written initial offer during the drug price negotiation or renegotiation process for initial price applicability year 2028, the Primary Manufacturer must submit the Counteroffer Form. *Form Number:* CMS–10849 (OMB control number: 0938–1452); *Frequency:* Once; *Affected Public:* Private sector, Business or other for-profit; *Number of Respondents:* 405; *Number of Responses:* 405; *Total Annual Hours:* 51,940. (For questions regarding this collection, contact Elisabeth Daniel at 667–290–8793.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025–11979 Filed 6–27–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant

applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; DP1 Catalyst—HIV Comorbidities, Coinfections, and Complications.
Date: July 28, 2025.
Time: 1:00 p.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Anuja Mathew, Ph.D., Scientific Review Officer, NIAID/SRP BG 5601FL RM 3G58, 5601 Fishers Lane, Rockville, MD 20852, (301) 761–6911, *anuja.mathew@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Topics in HIV-Related Investigator Initiated Clinical Trials.
Date: July 30, 2025.
Time: 11:00 a.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.
Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Lee G Klinkenberg, Ph.D., Primary is AI, Scientific Review Program, Division of Extramural Activities, National Institutes of Health, NIAID, Rockville, MD 20892, 301–761–7749, *lee.klinkenberg@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–DK–25–021: Cellular Models of HIV Pathogenesis.
Date: July 30, 2025.
Time: 11:00 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Santanu Banerjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2106, Bethesda, MD 20892, (301) 435–5947, *banerjees5@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: NIDCD Clinical Research Center Grant Review.
Date: July 30–31, 2025.
Time: 1:00 p.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Andrea B Kelly, Ph.D., Scientific Review Officer, NIDCD, National Institutes of Health, 6001 Executive Blvd., Room 8343, Rockville, MD 20852, (301) 451–6339, *kellya2@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Sensory-Motor Systems.
Date: July 30, 2025.
Time: 2:00 p.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Kirk Thompson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5184, MSC 7844, Bethesda, MD 20892, 301–435–1242, *kgt@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Health Services and Systems—Risks, Interventions, and Outcomes.
Date: July 31, 2025.
Time: 9:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Shiv A. Prasad, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health, NIAID, Rockville, MD 20892, *shiv.prasad@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: BRAIN development of novel brain function tools.
Date: July 31, 2025.
Time: 9:30 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Victor Henriquez, Ph.D., Scientific Review Officer. National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1066, Bethesda, MD 20892–4878, (301) 435–0813, *victor.henriquez@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Complementary and Integrative Health Approaches and Mind and Body Interventions.
Date: July 31, 2025.
Time: 9:30 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Cheryl K Nordstrom, Ph.D., MPH, Scientific Review Officer, NIDDK/Scientific Review Branch, National Institutes of Health, 6707 Democracy Blvd., Room 7013, Bethesda, MD 20892, 301–402–6711, *cheryl.nordstrom@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 26, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–12027 Filed 6–27–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors *Eunice Kennedy Shriver* National Institute of Child Health and Human Development.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: *https://videocast.nih.gov/.*

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual grant applications conducted by the *Eunice Kennedy Shriver* National Institute of Child Health & Human Development, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors *Eunice Kennedy Shriver* National Institute of Child Health and Human Development.
Date: December 5, 2025.
Open: 10:00 a.m. to 12:40 p.m.
Agenda: Scientific Director's Report on the status of the NICHD Division of Intramural Research and current organizational structure.
Address: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 31 Center Drive, Room 2A03, Bethesda, MD 20892 (Virtual Meeting).
Closed: 12:40 p.m. to 2:45 p.m.
Agenda: Confidential Discussions; To review and evaluate personnel qualifications and performance, and competence of individual investigators.