

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| Information collection activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|--|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Submission of Generic Drug User Fee Cover Sheet | 500 | 7.616 | 3,808 | 0.5 (30 minutes) | 1,904 |
| Submission of Controlled Correspondence as Discussed in Agency Topic-Specific Guidance Documents | 400 | 12.5 | 5000 | 5 | 25,000 |
| Total | | | 8,808 | | 26,904 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated is based on available Agency data. Our burden estimate reflects an overall increase attributable to the inclusion of controlled correspondence and new generic drug product CPA requests.

Dated: January 7, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–00564 Filed 1–13–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Physician-Focused Payment Model Technical Advisory Committee; Meetings

ACTION: Notice of meetings.

SUMMARY: This notice announces the 2025 meetings of the Physician-Focused Payment Model Technical Advisory Committee (PTAC). These meetings include deliberation and voting on proposals for physician-focused payment models (PFPMs) submitted by individuals and stakeholder entities and may include discussions on topics related to current or previously submitted PFPMs. All meetings are open to the public.

DATES: The 2025 PTAC meetings will occur on the following dates:

- Monday–Tuesday, March 3–4, 2025, from 9 a.m. to 5 p.m. ET
- Tuesday–Wednesday, June 3–4, 2025, from 9 a.m. to 5 p.m. ET
- Monday–Tuesday, September 8–9, 2025, from 9 a.m. to 5 p.m. ET
- Tuesday–Wednesday, December 9–10, 2025, from 9 a.m. to 5 p.m. ET

Please note that times are subject to change. If the times change, the ASPE PTAC website will be updated (<https://aspe.hhs.gov/ptac-physician-focused-payment-model-technical-advisory-committee>) and registrants will be notified directly via email.

ADDRESSES: All PTAC meetings will be held virtually and/or in the Great Hall

of the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC, 20201.

FOR FURTHER INFORMATION CONTACT: Lisa Shats, Designated Federal Officer at Lisa.Shats@hhs.gov (202) 875–0938.

SUPPLEMENTARY INFORMATION:

Agenda and Comments. PTAC will hear presentations on proposed PFPMs that have been submitted by individuals and stakeholder entities and/or discussion on topics related to current or previously submitted PFPMs. Regarding proposed PFPMs, following each presentation, PTAC will deliberate on the proposed PFPM. If PTAC completes its deliberation, PTAC will vote on the extent to which the proposed PFPM meets criteria established by the Secretary of Health and Human Services and on an overall recommendation to the Secretary (if applicable). Time will be allocated for public comments. The agenda and other documents will be posted on the PTAC section of the ASPE website, <https://aspe.hhs.gov/ptac-physician-focused-payment-model-technical-advisory-committee>, prior to the meeting. The agenda is subject to change. If the agenda does change, registrants will be notified directly via email, the website will be updated, and notification will be sent out through the PTAC email listserv (<https://list.nih.gov/cgi-bin/wa.exe?A0=PTAC> to subscribe).

Meeting Attendance. These meetings are open to the public and may be hosted in-person or virtually. We intend that in-person meetings will be held in the Great Hall of the Hubert H. Humphrey Building. The public may attend in person, when feasible, virtually, or view the meeting via livestream at www.hhs.gov/live. Information about how to access the meeting virtually or via livestream will be sent to registrants prior to the meeting; and a telephone number will be sent to registrants participating via the dial-in only option prior to the meeting. Space may be limited, and registration is preferred. When

registration opens, a link to the registration page will be available at <https://aspe.hhs.gov/collaborations-committees-advisory-groups/ptac/ptac-meetings-prior-to-the-meeting>. Registrants will receive a confirmation email shortly after completing the registration process.

Special Accommodations. If sign language interpretation or other reasonable accommodation for a disability is needed, please contact PTAC@hhs.gov, no later than two weeks prior to the scheduled meeting.

Authority. 42 U.S.C. 1395(ee); section 101(e)(1) of the Medicare Access and CHIP Reauthorization Act of 2015; section 51003(b) of the Bipartisan Budget Act of 2018.

PTAC is governed by provisions of the Federal Advisory Committee Act, as amended (5 U.S.C app.), which sets forth standards for the formation and use of federal advisory committees.

Dated: January 3, 2025.

Tisamarie B. Sherry,

Deputy Assistant Secretary for Behavioral Health, Disability and Aging Policy, Performing the Delegable Duties of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2025–00612 Filed 1–13–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

Pursuant to section 1009 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 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: Eunice Kennedy Shriver National Institute of Child Health and Human Development Special Emphasis Panel; Multicenter Clinical Trials; Leveraging Network (U01).

Date: March 7, 2025.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710 B Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Vera A. Cherkasova, Ph.D., Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Room 2137B, Bethesda, MD 20892, (240) 478-4580, vera.cherkasova@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: January 8, 2025.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-00597 Filed 1-13-25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

Pursuant to section 1009 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 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: Eunice Kennedy Shriver National Institute of Child Health and Human Development Special Emphasis Panel; the Road to Prevention of Stillbirth—Data Coordinating Center (UM2) Companion.

Date: March 28, 2025.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710 B Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Luis E. Dettin, Ph.D., Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH 6710B, Rockledge Drive, Rm. 2131B, Bethesda, MD 20892, (301) 827-8231, luis_dettin@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: January 8, 2025.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-00605 Filed 1-13-25; 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 Closed Meeting

Pursuant to section 1009 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 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: Eunice Kennedy Shriver National Institute of Child Health and Human Development Special Emphasis Panel; the Road to Prevention of Stillbirth—Clinical Research Center (UG1).

Date: March 24, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: Eunice Kennedy Shriver National Institute of Child Health and Human

Development, 6710 B Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Luis E. Dettin, Ph.D., Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH 6710B, Rockledge Drive, Rm. 2131B Bethesda, MD 20892, (301) 827-8231, luis_dettin@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: January 8, 2025.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-00607 Filed 1-13-25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

Pursuant to section 1009 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 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: Eunice Kennedy Shriver National Institute of Child Health and Human Development Initial Review Group, Population Sciences Study Section.

Date: March 6, 2025.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710 B Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Christiane M. Robbins, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Rm 2121B, Bethesda, MD 20817, 301-451-4989, crobbs@mail.nih.gov.