

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 Health, Behavior, and Context Study Section.

Date: October 28, 2024.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Child Health and Human Development, 6710B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kimberly L. Houston, M.D., Scientific Review Officer, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Room 2137C, Bethesda, MD 20892, (301) 827-4902, kimberly.houston@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: August 2, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-0361.

Project: Medications for the Treatment of Opioid Use Disorder—42 CFR Part 8 (OMB No. 0930-0206) and Opioid Treatment Programs (OTPs)—Revision

42 CFR part 8 establishes a certification program managed by SAMHSA's Center for Substance Abuse Treatment (CSAT). The regulation requires that opioid treatment programs (OTPs) be certified. "Certification" is the process by which SAMHSA determines that an OTP is qualified to provide opioid use disorder treatment under the federal opioid use disorder treatment standards established by the Secretary of Health and Human Services. To become certified, an OTP must be accredited by a SAMHSA-approved accreditation body. The regulation also provides standards for such services as individualized treatment planning, increased medical supervision, and assessment of patient outcomes. This submission seeks continued approval of the information collection requirements in the

regulation and of the forms used in implementing the regulation.

SAMHSA currently has approval for the Application for Certification to Use Medications for the Treatment of Opioid Use Disorder in a Treatment Program Under 42 CFR 8.11 (Form SMA-162); the Application for Approval as Accreditation Body Under 42 CFR 8.3(b) (Form SMA-163); and the Exception Request and Record of Justification Under 42 CFR 8.11(h) (Form SMA-168), which may be used on a voluntary basis by OTP practitioners when there is a patient care situation in which the OTP practitioner must make a treatment decision that falls outside of the standards delineated in the regulation. Form SMA-168 is a simplified, standardized form to facilitate the documentation, request, and approval process for exceptions.

SAMHSA believes that the recordkeeping requirements in the regulation are customary and usual practices within the medical and rehabilitative communities and has not calculated a response burden for them. The recordkeeping requirements set forth in 42 CFR 8.4, 8.11 and 8.12 include maintenance of the following: 5-year retention by accreditation bodies of certain records pertaining to accreditation; documentation by an OTP of the following: a patient's medical examination when admitted to treatment, a patient's medical history, a care plan, any prenatal support provided the patient if applicable, the medical rationale for initial starting doses above 50mg, the medical rationale for a patient's dosage schedule, and care decisions made as a result of follow-up medical examinations.

The table that follows summarizes the annual reporting burden associated with the regulation, including burden associated with the forms. There are minor changes to these forms to improve data collection, remove unnecessary questions, and align terms with the final 42 CFR part 8 rule released February 2, 2024.

Table with 6 columns: Form, Number of respondents, Responses/respondent, Total responses, Hours/response, Total hours. It contains two sections: 'Estimated Annual Reporting Requirement Burden for Accreditation Bodies' and 'Estimated Annual Reporting Requirement Burden for Opioid Treatment Programs'.