

Dated: October 28, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Centers for AIDS Research (P30 Clinical Trial Not Allowed); Developmental Centers for AIDS Research (P30 Clinical Trial Not Allowed).

Date: December 5-6, 2022.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Cynthia L. De La Fuente, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31, Rockville, MD 20852, 240-669-2740, delafuentecl@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 28, 2022.

Tyeshia M. Roberson-Curtis,

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: Notification of Intent To Use Schedule III, IV, or V Controlled Medications for the Treatment of Opioid Use Disorder Under 21 U.S.C. 823(g)(2) (OMB No. 0930-0234 and OMB No. 0930-0369)—Revision

The Drug Addiction Treatment Act of 2000 (“DATA,” Pub. L. 106-310) amended the Controlled Substances Act (21 U.S.C. 823(g)(2)) to permit qualifying practitioners to seek and obtain waivers to prescribe certain approved controlled medications for the treatment of opioid use disorder. The legislation set eligibility and certification requirements as well as an interagency notification review process for practitioners who seek waivers. To implement these provisions, SAMHSA developed Notification of Intent Forms that facilitate the submission and review of notifications. The forms provide the information necessary to determine whether practitioners meet the qualifications for waivers set forth under the law at the 30-, 100-, and 275-patient limits. This includes the annual reporting requirements for practitioners with waivers for a 275-patient limit. On October 24, 2018, the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (Pub. L. 115-71) was signed into law. Sections 3201-3202 of the SUPPORT Act made several amendments to the Controlled Substances Act regarding office-based opioid use disorder treatment that affords practitioners greater flexibility in the provision of Medications for Opioid Use Disorder (MOUD).

The SUPPORT Act expands the definition of “qualifying other practitioner” enabling Clinical Nurse Specialists, Certified Registered Nurse Anesthetists, and Certified Nurse Midwives (CNSs, CRNAs, and CNMs) to apply for a Drug Addiction Treatment

Act of 2000 (DATA) waiver until October 1, 2023. It also allows qualified practitioners (*i.e.*, MDs, DOs, NPs, PAs, CNSs, CRNAs, and CNMs) who are board certified in addiction medicine or addiction psychiatry, -or- practitioners who provide MOUD in a qualified practice setting, to start treating up to 100 patients in the first year of practice (as defined in 42 CFR 8.2) with a waiver. Further, the SUPPORT Act extends the ability to treat up to 275 patients to “qualifying other practitioners” (*i.e.*, NPs, PAs, CNSs, CRNAs, and CNMs) if they have a waiver to treat up to 100 patients for at least one year and provide treatment of Opioid Use Disorder with covered medications (as such terms are defined under 42 CFR 8.2) in a qualified practice setting as described under 42 CFR 8.615. Finally, the SUPPORT Act also expands how physicians could qualify for a waiver. Under the statute now, physicians can qualify for a waiver if they have received at least 8 hours of training on treating and managing patients with opioid use disorder, as listed in the statute if the physician graduated in good standing from an accredited school of allopathic medicine or osteopathic medicine in the United States during the 5-year period immediately preceding the date on which the physician submits a Notice of Intent to SAMHSA. In order to expedite the new provisions of the SUPPORT Act, SAMHSA sought and received a Public Health Emergency Paperwork Reduction Act Waiver.

On April 28, 2021 the Department of Health and Human Services (HHS) issued the new Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder (86 FR 22439) in an expedited manner. The Practice Guidelines allow practitioners who wish to obtain a 30-patient waiver to forego the 8-hour training requirement for physicians and 24-hour training for other qualifying practitioners. Practitioners utilizing this training exemption are limited to treating no more than 30-patients at a time and time spent practicing under this exemption will not qualify the practitioner to qualify for a higher patient level. In addition, the new Practice Guidelines removed the requirement to provide counseling and other ancillary services (*i.e.*, psychosocial services).

The collection of information within the application is essential to the implementation of SAMHSA’s mission to reduce the impact of substance use disorders on America’s communities. Practitioners may use these forms for various types of notifications: (a) New