

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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, Member Conflict: Psychiatric Disorders and Addiction.

Date: December 13, 2016.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Samuel C Edwards, Ph.D., IRG Chief, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435-1246, edwardss@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Neurovirology, Neuroimmunology, Neurodevelopmental Disorders, and Anticancer Drugs.

Date: December 15, 2016.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Samuel C. Edwards, Ph.D., IRG Chief, Center for Scientific Review, National Institutes of Health, 6701 Rockledge

Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435-1246, edwardss@csr.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: November 21, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-28415 Filed 11-25-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities Under Emergency Review by the Office of Management and Budget

The Substance Abuse and Mental Health Services Administration (SAMHSA) has submitted the following request (see below) for emergency OMB review under the Paperwork Reduction Act (44 U.S.C. Chapter 35). OMB approval has been requested by January 12, 2017. A copy of the information collection plans may be obtained by calling the SAMHSA Reports Clearance Officer at (240) 276-1243.

Title: Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a “Qualifying Other Practitioner”—NEW.
OMB Number: 0930—New.

Frequency: On Going.

Affected public: Nurse Practitioners and Physician Assistants.

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting an emergency Office of Management and Budget (OMB) review and approval of the Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the

Maintenance and Detoxification Treatment of Opiate Addiction by a “Qualifying Other Practitioner. The Notification of Intent would allow SAMHSA to determine whether other practitioners are eligible to prescribe certain approved narcotic treatment medications for the maintenance or detoxification treatment of opioid addiction.

This Notification of Intent is a result of the Comprehensive Addiction and Recovery Act (Pub. L. 114-198), which was signed into law on July 22, 2016. The law establishes criteria for nurse practitioners (NPs) and physician assistants (PAs) to qualify for a waiver to prescribe covered medications. To be eligible for a waiver, the NP or PA must: be licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain; fulfill qualification requirements in the law for training and experience; and fulfill qualification requirements in the law for appropriate supervision by a qualifying physician. SAMHSA has the responsibility to receive, review, approve, or deny waiver requests.

Practitioners who meet the statutory requirements will be eligible to prescribe only those opioid treatment medications that are controlled in Schedules III, IV, or V, under the Controlled Substance Act (CSA), that are specifically approved by the Food and Drug Administration (FDA) for the treatment of opioid addiction, and are not the subject of an “adverse determination.” The only medications that currently fulfill these requirements are ones that contain the active ingredient buprenorphine.

Given the severity of the opioid epidemic, SAMHSA is requesting an emergency OMB approval. Emergency OMB approval will enable NPs and PAs to dramatically increase access to buprenorphine among individuals with opioid use disorder.

The following table is the estimated hour burden:

Purpose of submission	Number of respondents	Responses/ respondent	Burden hours	Total burden hours
Notification of Intent for Qualifying Other Practitioner to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a “Qualifying Other Practitioner” under 21 USC § 823(g)(2)—Nurse Practitioners	816	1	.066	54
Notification of Intent for Qualifying Other Practitioner to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a “Qualifying Other Practitioner” under 21 USC § 823(g)(2)—Physician Assistants	590	1	.066	39
Total	1,406			93