

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; 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 Biomedical Imaging and Bioengineering Special Emphasis Panel; BRAIN Initiative: Theories, Models and Methods for Analysis of Complex Data from the Brain (2020/05).

Date: February 13, 2020.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dennis Hlasta, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Bethesda, MD 20892, (301) 451-4794, dennis.hlasta@nih.gov.

Dated: November 26, 2019.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-26063 Filed 12-2-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the National Deafness and Other Communication Disorders Advisory Council.

The meetings 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 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: National Deafness and Other Communication Disorders Advisory Council.

Date: January 31, 2020.

Closed: 8:30 a.m. to 10:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center Building (NSC), Room C and D, 6001 Executive Boulevard, Rockville, MD 20852.

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

Agenda: Staff reports on divisional, programmatic, and special activities.

Place: National Institutes of Health, Neuroscience Center Building (NSC), Room C and D, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Craig A. Jordan, Ph.D., Director, Division of Extramural Activities, NIDCD, NIH, Room 8345, MSC 9670, 6001 Executive Blvd., Bethesda, MD 20892-9670, 301-496-8693, jordanc@nidcd.nih.gov.

Name of Committee: National Deafness and Other Communication Disorders Advisory Council.

Date: May 29, 2020.

Closed: 8:30 a.m. to 10:00 a.m.

Agenda: To review and evaluate grant applications.

Place: Porter Neuroscience Research Center, Building 35A, Room 620, 35 Convent Drive, Bethesda, MD 20892.

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

Agenda: staff reports on divisional, programmatic, and special activities.

Place: Porter Neuroscience Research Center, Building 35A, Room 620, 35 Convent Drive, Bethesda, MD 20892.

Contact Person: Craig A. Jordan, Ph.D., Director, Division of Extramural Activities, NIDCD, NIH, Room 8345, MSC 9670, 6001 Executive Blvd., Bethesda, MD 20892-9670, 301-496-8693, jordanc@nidcd.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles

will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <https://www.nidcd.nih.gov/about/advisory-council>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: November 26, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-26065 Filed 12-2-19; 8:45 am]

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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) 276-1243.

Project: Notification of Intent To Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction 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 narcotic treatment drugs for the treatment of opiate addiction. The legislation set eligibility requirements 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 meets 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 treatment that affords practitioners greater flexibility in the provision of medication-assisted treatment (MAT).

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 MAT in a qualified practice setting, to start treating up to 100 patients in the first year of MAT 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 medication-assisted treatment 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 opiate-dependent patients, 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 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. Practitioners may use the form for four types of notifications: (a) New Notification to treat up to 30 patients; (b) New Notification, with the intent to immediately facilitate treatment of an individual (one) patient; (c) Second notification of need and intent to treat up to 100 patients; and (d) New notification to treat up to 100 patients. Under “new” notifications, practitioners may make their initial

waiver requests to SAMHSA.

“Immediate” notifications inform SAMHSA and the Attorney General of a practitioner’s intent to prescribe immediately to facilitate the treatment of an individual (one) patient under 21 U.S.C. 823(g)(2)(E)(ii). The form collects data on the following items: Practitioner name; state medical license number; medical specialty; and DEA registration number; address of primary practice location, telephone and fax numbers; email address; name and address of group practice; group practice employer identification number; names and DEA registration numbers of group practitioners; purpose of notification: New, immediate, or renewal; certification of qualifying criteria for treatment and management of opiate dependent patients; certification of capacity to provide directly or refer patients for appropriate counseling and other appropriate ancillary services; certification of maximum patient load, certification to use only those drug products that meet the criteria in the law. The form also notifies practitioners of Privacy Act considerations, and permits practitioners to expressly consent to disclose limited information to the SAMHSA Buprenorphine Physician and Behavioral Health Treatment Services locators. The following table summarizes the estimated annual burden for the use of this form.

42 CFR citation	Purpose of submission	Estimated number of respondents	Responses/ respondent	Burden/ response (hrs.)	Total burden (hrs.)
	Notification of Intent	1,500	1	0.083	125
	Notification to Prescribe Immediately	50	1	0.083	4
	Notice to Treat up to 100 patients	500	1	0.04	20
	Notice to Treat up to 275 patients	800	1	1	65
	Subtotal	2,850	214

Burden Associated with the Final Rule That Increased the Patient Limit

8.620 (a)–(c)	Request for Patient Limit Increase *	517	1	0.5	259
	Request for Patient Limit Increase *	517	1	0.5	259
	Request for Patient Limit Increase *	517	1	0.5	259
8.64	Renewal Request for a Patient Limit Increase *	260	1	0.5	130
	Renewal Request for a Patient Limit Increase *	260	1	0.5	130
	Renewal Request for a Patient Limit Increase *	260	1	0.5	130
8.655	Request for a Temporary Patient Increase for an Emergency *	10	1	3	30
	Request for a Temporary Patient Increase for an Emergency *	10	1	3	30
	Request for a Temporary Patient Increase for an Emergency *	10	1	3	30
	Subtotal	2,361	1,256

New Burden Associated with the Final Rule That Outlined the Reporting Requirements

8.635	Practitioner Reporting Form *	1,350	1	3	4,050
	“Qualifying Other Practitioner” under 21 U.S.C. 823(g)(2)—Nurse Practitioners.	816	1	0.066	54

42 CFR citation	Purpose of submission	Estimated number of respondents	Responses/ respondent	Burden/ response (hrs.)	Total burden (hrs.)
	"Qualifying Other Practitioner" under 21 U.S.C. 823(g)(2)—Physician Assistants.	590	1	0.066	39
	"Qualifying Other Practitioner" under 21 U.S.C. 823(g)(2)—Certified Nurse Specialists.	590	1	0.066	39
	"Qualifying Other Practitioner" under 21 U.S.C. 823(g)(2)—Certified Nurse Mid-Wives.	590	1	0.066	39
	"Qualifying Other Practitioner" under 21 U.S.C. 823(g)(2)—Certified Registered Nurse Anesthetists.	590	1	0.066	39
	Subtotal	4,526	4,260
	Total Burden	6,561	5,519

Written comments and recommendations concerning the proposed information collection should be sent by January 2, 2020 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@omb.eop.gov. Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202-395-7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory

Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2019-26001 Filed 12-2-19; 8:45 am]

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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

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chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Project: Confidentiality of Alcohol and Drug Abuse Patient Records—(OMB No. 0930-0092)—Revision

Statute (42 U.S.C. 290dd-2) and regulations (42 CFR part 2) require federally conducted, regulated, or directly or indirectly assisted alcohol and drug abuse programs to keep alcohol and drug abuse patient records confidential. Information requirements are (1) written disclosure to patients about Federal laws and regulations that protect the confidentiality of each patient, and (2) documenting "medical personnel" status of recipients of a disclosure to meet a medical emergency. Annual burden estimates for these requirements are summarized in the table below:

ANNUALIZED BURDEN ESTIMATES

	Annual number of respondents ¹	Responses per respondent	Total responses	Hours per Response	Total hour burden
Disclosure					
42 CFR 2.22	11,779	163	² 1,920,844	.20	384,169
Recordkeeping					
42 CFR 2.51	11,779	2	23,558	.167	3,934
Total	11,779	1,944,402	388,103

¹ The number of publicly funded alcohol and drug facilities from SAMHSA's 2017 National Survey of Substance Abuse Treatment Services (N-SSATS).

² The average number of annual treatment admissions from SAMHSA's 2015-2017 Treatment Episode Data Set (TEDS).

Written comments and recommendations concerning the proposed information collection should be sent by January 2, 2020 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of

comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@omb.eop.gov. Although commenters are encouraged to send their comments via email,

commenters may also fax their comments to: 202-395-7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory