We estimate one waiver petition from each of two firms will be submitted and respondents will spend 24 hours to prepare and submit the petition to FDA.

Finally, we estimate an annual third-party disclosure burden of 132 hours, consistent with the currently approved burden estimate for this collection of information. We assume each of 226 firms will spend an average of 35 minutes, annually, disclosing written records as required under 21 CFR 1.908.

Cumulatively, we have reduced our burden estimate for the information collection. We made this adjustment to reflect the removal of one-time burden associated with implementation of the new regulatory requirements. Because these provisions have since become effective, the one-time estimates previously included have been removed.


Lowell J. Schiller,
Principal Associate Commissioner for Policy.

[FR Doc. 2019–11532 Filed 6–3–19; 8:45 am]
BILLING CODE 4164–01–P
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 General Medical Sciences Special Emphasis Panel; Review of SCORE Applications.

Date: July 12, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Dupont Circle Hotel, 1500 New Hampshire Ave NW, Washington, DC 20036.

Contact Person: John J. Lafian, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18, Bethesda, MD 20892, 301-594-2773, laffanjo@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos: 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HH)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Subcommittee Meetings for the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC)

AGENCY: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services.

ACTION: Notice of subcommittee meetings (virtual).

SUMMARY: The Secretary of Health and Human Services (Secretary) announces subcommittee meetings of the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC).

The meetings are open to the public and can be accessed via telephone only. Agenda with call-in information will be posted on the SAMHSA website prior to the meetings at: https://www.samhsa.gov/about-us/advisory-councils/meetings.

The meetings will include information on the following focus areas: Data, Access, Treatment and Recovery, Justice, and Finance.

Committee Name: Interdepartmental Serious Mental Illness Coordinating Committee (subcommittee meetings).

DATES: June 20, 2019/1:00 p.m.–2:30 p.m. (EDT)/OPEN/Focus Area 1: Data June 26, 2019/9:00 a.m.–10:30 a.m. (EDT)/OPEN/Focus Area 2: Access June 26, 2019/9:00 a.m.–10:30 a.m. (EDT)/OPEN/Focus Area 3: Treatment and Recovery June 26, 2019/10:45 a.m.–12:15 p.m. (EDT)/OPEN/Focus Area 4: Justice June 26, 2019/10:45 a.m.–12:15 p.m. (EDT)/OPEN/Focus Area 5: Finance

ADDRESSES: The meetings will be held (virtually) at SAMHSA Headquarters, 5600 Fishers Lane, Rockville, Maryland 20857.

Substantive meeting information and a roster of Committee members is available at the Committee’s website: https://www.samhsa.gov/about-us/advisory-councils/smi-committee.

FOR FURTHER INFORMATION CONTACT: Pamela Foote, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, 14E53C, Rockville, MD 20857; telephone: 240–276–1279; email: pamela.foote@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Authority

The ISMICC was established on March 15, 2017, in accordance with section 6031 of the 21st Century Cures Act, and the Federal Advisory Committee Act, 5 U.S.C. App., as amended, to report to the Secretary, Congress, and any other relevant federal department or agency on advances in serious mental illness (SMI) and serious emotional disturbance (SED), research related to the prevention of, diagnosis of, intervention in, and treatment and recovery of SMI, SEDs, and advances in access to services and support for adults with SMI or children with SED. In addition, the ISMICC will evaluate the effect federal programs related to serious mental illness have on public health, including public health outcomes such as (A) rates of suicide, suicide attempts, incidence and prevalence of SMI, SEDs, and substance use disorders, overdose, overdose deaths, emergency hospitalizations, emergency room boarding, preventable emergency room visits, interaction with the criminal justice system, homelessness, and unemployment; (B) increases in employment and enrollment in educational and vocational programs; (C) quality of mental and substance use disorders treatment services; or (D) any other criteria as may be determined by the Secretary. Finally, the ISMICC will make specific recommendations for actions that agencies can take to better coordinate the administration of mental health services for adults with SMI or children with SED. Not later than 1 (one) year after the date of enactment of the 21st Century Cures Act, and 5 (five) years after such date of enactment, the ISMICC shall submit a report to Congress and any other relevant federal department or agency.

II. Membership

This ISMICC consists of federal members listed below or their designees, and non-federal public members.

Federal Membership: Members include, The Secretary of Health and Human Services; The Assistant Secretary for Mental Health and Substance Use; The Attorney General; The Secretary of the Department of Veterans Affairs; The Secretary of the Department of Defense; The Secretary of the Department of Housing and Urban


Donald Wright,

Deputy Assistant Secretary for Health.

[FR Doc. 2019–11571 Filed 6–3–19; 8:45 am]

BILLING CODE 4150–32–P

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