

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1.914; Waiver petitions	2	1	2	24	48

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

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.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
1.908; Disclosure of sanitary specifications; operating temperature conditions.	226	1	226	0.5833 (~35 mins.)	132

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

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.

Dated: May 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-11532 Filed 6-3-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation for Written Comments on an Updated Health Literacy Definition for Healthy People 2030

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) provides notice of a request for comments about the proposed update to the definition of health literacy. The Secretary’s Advisory Committee on National Health

Promotion and Disease Prevention Objectives for Healthy People 2030 used the following working definition: “Health literacy occurs when a society provides accurate health information and services that people can easily find, understand, and use to inform their decisions and actions.”

DATES: Written comments must be submitted by August 5, 2019.

ADDRESSES: Written comments will be accepted via email at Definehealthliteracy@HHS.gov.

FOR FURTHER INFORMATION CONTACT: Stephanie Santana, Public Health Analyst, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Disease Prevention and Health Promotion, 1101 Wootton Parkway, Rockville, MD 20852. 240-453-8265 Email: Definehealthliteracy@HHS.gov.

SUPPLEMENTARY INFORMATION: Healthy People and health literacy. Healthy People provides science-based, 10-year national objectives for improving the health of all Americans. Health literacy objectives have been tracked in Healthy People 2010 and 2020 and will also be included in Healthy People 2030.

Health literacy is one of the Healthy People 2030 framework’s foundational principles (“Achieving health and well-being requires eliminating health disparities, achieving health equity, and attaining health literacy”) and one of its overarching goals (“Eliminate health disparities, achieve health equity, and attain health literacy to improve the health and well-being of all”).

Current Healthy People health literacy definition. The following definition of health literacy has been used in Healthy People 2010 and Healthy People 2020:

“Health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information needed to make appropriate health decisions.”

This definition of health literacy has had a tremendous impact on the field, influencing health literacy measurement and improvement efforts around the world.

The Secretary’s Advisory Committee on National Health Promotion and Disease Prevention Objectives used this working definition of health literacy for 2030: “Health literacy occurs when a society provides accurate health information and services that people can easily find, understand, and use to inform their decisions and actions.”

This working definition reflects the evolution of the concept of health literacy toward a consensus that health literacy is affected not only by an individual’s capacities, but also by the accessibility, clarity, and actionability of health information and health services.

Submission Instructions. Comments should:

1. Address the strengths and/or weaknesses of the recommended definition,
2. Be brief and concise; Limit 250 words
3. Make specific editing suggestions, and
4. Cite articles that support suggested changes (if any).

Reference Material

Healthy People 2030 Framework. Available at <https://www.healthypeople.gov/2020/About-Healthy-People/Development-Healthy-People-2030/Framework>. Pleasant, A., R.E. Rudd, C. O’Leary, M.K. Paasche-Orlow, M.P. Allen, W. Alvarado-Little, L. Myers, K. Parson, and

S. Rosen. 2016. Considerations for a New Definition of Health Literacy. NAM Perspectives. Discussion Paper, National Academy of Medicine, Washington, DC. doi: 10.31478/201604a. <https://doi.org/10.31478/201604a>.

Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030. Issue Briefs to Inform Development and Implementation of Healthy People 2030. Retrieved from: https://www.healthypeople.gov/sites/default/files/HP2030_Committee-Combined-Issue%20Briefs_2019-508c.pdf.

Dated: May 22, 2019.

Donald Wright,

Deputy Assistant Secretary for Health.

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

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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. Laffan, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18J, 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, HHS)

Dated: May 29, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-11535 Filed 6-3-19; 8:45 am]

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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 SMIs, 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 SMIs, 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) increased rates of 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