

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total	1,091	81,440

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

Based on FY 2022 receipts, we estimate that for Center for Drug Evaluation and Research (CDER) products, 81 respondents will submit 124 requests for priority review designation annually, and we assume 30 hours are needed to prepare such a request. We estimate 71 respondents will submit 77 requests for breakthrough designation annually, and we assume 70 hours are needed to prepare such a request. We estimate that 235 respondents will submit 277 requests for fast-track designation requests annually, and we assume 60 hours are required to prepare such a request. We estimate 26 respondents will submit 33 accelerated approval designation requests annually and we assume 100 hours are required to prepare such a request. Finally, CDER received 165 pre-meeting package submissions from 163 respondents. We assume 100 hours are needed to prepare a pre-meeting package.

Similarly, also based on FY 2022 receipts, we estimate that for CBER products, 8 applicants will submit 8 requests for priority review designation annually, and we assume 30 hours are required to prepare such a request. We estimate 15 respondents will submit 17 requests for breakthrough designation annually, and we assume 70 hours are needed to prepare such a request. We estimate that 64 respondents will submit 78 requests for fast-track designation annually, and we assume 60 hours is required to prepare such a request. We also estimate 33 respondents will submit 35 requests for RMAT designation annually and assume that 60 hours are needed to prepare each RMAT designation request. Finally, CBER received 283 pre-meeting package submissions from 146 respondents. We assume 100 hours are needed to prepare a pre-meeting package.

Based on a review of the information collection since our last request for OMB approval, we have increased our burden estimate by 143 responses and 10,350 hours to reflect actual submissions we have received. We attribute these changes to increased interest in the expedited programs, new expedited programs, and an increase in the number of submissions we received over the last few years.

Dated: April 15, 2024.
Lauren K. Roth,
Associate Commissioner for Policy.
 [FR Doc. 2024-08293 Filed 4-17-24; 8:45 am]
BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notification of Lender and Servicer Eligibility Criteria for Participation in the Health Center Loan Guarantee Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Request for public comment.

SUMMARY: This notice seeks public comment to update the Health Center Loan Guarantee Program lender and servicer eligibility criteria in accordance with OMB Circular A-129. The original notice of lender eligibility criteria for the Health Center Loan Guarantee Program was published in the Commerce Business Daily on January 7, 2000.

DATES: Submit comments no later than May 20, 2024.

ADDRESSES: Electronic or written comments should be submitted through the Bureau of Primary Health Care (BPHC) Contact Form (new users must request access) or to 5600 Fishers Lane, Rm. 16N-20, Rockville, MD 20857, no later than 30 days after the publication date.

FOR FURTHER INFORMATION CONTACT: Mary Lou Ojeda, Lead Public Health Analyst, or Valerie Green, Loan Specialist, BPHC, Office of Policy and Program Development, Strategic Initiatives, HRSA, 5600 Fishers Lane, Rm. 16N-20, Rockville, MD 20857, 301-594-4300, or the BPHC Contact Form.

SUPPLEMENTARY INFORMATION: Title XVI, part A of the Public Health Service Act established the authority for the Department of Health and Human Services to guarantee the principal and interest on certain loans made by non-Federal lenders. Under this authority, the Health Center Loan Guarantee Program guarantees up to 80 percent of

the outstanding principal and interest on eligible loans for the construction, renovation, and modernization of medical facilities that are operated by health centers funded under the Public Health Service Act. These health centers, which are community-based private nonprofit or public entities, provide primary health care services for medically underserved populations. The approximately 1,400 organizations that receive funding are located in urban and rural communities throughout the nation.

HRSA's BPHC administers the Health Center Loan Guarantee Program, which has a total current lending authority of \$825 million. Under the Program, lender and servicer eligibility requirements have been established, with participation open to eligible non-Federal lenders. Consistent with the policies set forth in OMB Circular A-129, this notice provides interested parties information regarding eligibility criteria for participating as a lender or servicer in the Loan Guarantee Program. Specifically, to participate in the Program, a lender or servicer must: (a) Be regulated or certified and in good standing with a Federal financial institution regulatory agency, or furnish satisfactory evidence of adequate financial and capital condition showing that the lender has (i) a minimum adjusted net worth of \$250,000, or (ii) at least \$50,000 in working capital plus 1 percent of the total volume in excess of \$25 million in guaranteed loans originated, serviced, or purchased during the lender's prior fiscal year, up to a maximum required adjusted net worth of \$2.5 million, and one or more lines of credit with a minimum aggregated of \$1 million; (b) Not be currently debarred or suspended from participation in any United States government contract or delinquent on a debt owed to the United States government or any agency or instrumentality thereof; (c) Be able to obtain and submit proof of fidelity/surety bonding and/or errors and omissions insurance with the Federal Government as a loss payee if the lender has previously had questionable performance under Federal guarantee programs or is not regulated by the Federal Government or certified by the U.S. Department of the Treasury; (d)

Provide, if so requested, the qualifications of principal officers and staff of the lender or servicer who will be or are responsible for the administration of the loan(s) guaranteed under the Program showing that principal officers have a minimum of 2 years of experience in originating or servicing guaranteed loans; (e) Provide, if the lender or servicer has one or more loans guaranteed under the Program, proof of acceptable performance as a lender or servicer, which shall include for each and every loan adherence to all the terms and conditions as set forth in the agreement between HRSA and the lender or servicer; and (f) Be able to demonstrate the capacity to hold and account for loan documents, receive all payments of principal and interest, and otherwise service and administer the loan in a manner consistent with accepted standards of loan servicing employed by prudent lenders or servicers generally. A lender or servicer's eligibility for participation in additional loans guaranteed under the Program will be newly assessed and reviewed at each application submission during the application financial sustainability and viability technical review and at least every 2 years in accordance with monitoring and evaluation procedures.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024-08219 Filed 4-17-24; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 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 on Aging Special Emphasis Panel; Ketogenic Diets for Cognitive Decline.

Date: June 6, 2024.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rajasri Roy, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Bldg., Suite 2W200, Bethesda, MD 20892, 301-496-6477, rajasri.roy@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 12, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-08246 Filed 4-17-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 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 on Aging Special Emphasis Panel; Aging and Bone regulation.

Date: May 15, 2024.

Time: 10:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nijaguna Prasad, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Bldg. Suite 2W200, Bethesda, MD 20892, (301) 496-9667, prasadnb@nia.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 12, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-08277 Filed 4-17-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 1009 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: Center for Scientific Review Special Emphasis Panel; Mucosal Immunology.

Date: May 1, 2024.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Frederique Yiannikouris, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-3313, frederique.yiannikouris@nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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: April 12, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-08244 Filed 4-17-24; 8:45 am]

BILLING CODE 4140-01-P