the relevant sections of the labeling identified in this notice, which include the ''Dosage and Administration'' and ''Use in Specific Populations'' sections of BTOD labeling.

III. Electronic Submissions

Submit any draft labeling as a prior approval supplement to your NDA. Any labeling supplement must be submitted in the electronic common technical document (eCTD) standard format. The eCTD is the standard format for electronic regulatory submissions to FDA's Center for Drug Evaluation and Research. The FDA Electronic Submissions Gateway (available at: *https://www.fda.gov/industry/electronic-submissions-gateway)* is the central transmission point for sending information electronically to FDA and enables the secure submission of regulatory information for review.

IV. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. * Labeling for SUBUTEX (buprenorphine HCl) (NDA 020732) and SUBOXONE (buprenorphine HCl and naloxone HCl) (NDA 020733) sublingual tablets, Oct. 8, 2002, available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/20732,20733lbl.pdf.*
2. * Supplement Approval for SUBUTEX (buprenorphine HCl) sublingual tablets (NDA 020732), Dec. 22, 2011, available at: *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/020732s006,s007ltr.pdf.*
3. * Labeling for SUBUTEX (buprenorphine HCl) sublingual tablets (NDA 020732), Dec. 22, 2011, available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020732s006s007lbl.pdf.*
4. * Supplement Approval for SUBOXONE (buprenorphine HCl and naloxone HCl) sublingual tablets (NDA 020733), Dec. 22, 2011, available at: *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/020733s007,s008ltr.pdf.*

* 5. Labeling for SUBOXONE (buprenorphine HCl and naloxone HCl) sublingual tablets (NDA 020733), Dec. 22, 2011, available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020733s007s008lbl.pdf.*

* 6. Labeling for SUBUTEX (buprenorphine HCl) sublingual tablets (NDA 020732), June 17, 2022, available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/020732s027s028lbl.pdf.*

* 7. Labeling for SUBOXONE (buprenorphine HCl and naloxone HCl) sublingual tablets (NDA 020733), June 17, 2022, available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/020733s031s032lbl.pdf.*

* 8. ZUBSOLV (buprenorphine HCl and naloxone HCl) sublingual tablets (NDA 204242), Dec. 15, 2023, available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204242s027lbl.pdf.*

* 9. BUNAVAIL (buprenorphine HCl and naloxone HCl) buccal film (NDA 205637), June 17, 2022, available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/205637s023s024lbl.pdf.*

* 10. Citizen petition submitted by the Colorado Society of Addiction Medicine (FDA–2022–P–1863), posted Aug. 10, 2022, available at: *https://www.regulations.gov/docket/FDA-2022-P-1863.*

11. Reagan-Udall Foundation, virtual public meeting entitled ''Considerations for Buprenorphine Initiation and Maintenance Care,'' May 10–11, 2023, meeting materials and transcripts available at: *https://reaganudall.org/news-and-events/events/considerations-buprenorphine-initiation-and-maintenance-care.*

12. Reagan-Udall Foundation, Meeting Transcript, ''Considerations for Buprenorphine Initiation and Maintenance Care—Day One,'' May 10, 2023, available at: *https://reaganudall.org/sites/default/files/2023-07/Transcript%20-%20Buprenorphine%20Initiation%20-%20Day%201%20-%20REVISED%20FINAL.pdf.*

13. Reagan-Udall Foundation, Meeting Transcript, ''Considerations for Buprenorphine Initiation and Maintenance Care—Day Two,'' May 11, 2023, available at: *https://reaganudall.org/sites/default/files/2023-05/Transcript%20-%20Buprenorphine%20Initiation%20-%20Day%202%20-%20final.pdf.*

* 14. SAMHSA, Meeting Summary, ''Listening Session: Use of High Dose Buprenorphine for the Treatment of Opioid Use Disorder,'' December 11, 2023, available at: *https://store.samhsa.gov/sites/default/files/high-dose-buprenorphine-report-pep24-02-013.pdf.*

15. Grande, LA, D Cundiff, MK Greenwald, et al., 2023, ''Evidence on Buprenorphine Dose Limits: A Review,'' *J Addict Med,* 17(5): 509–516.

16. Tiako, MJN, A Dolan, M Abrams, et al., 2023, ''Thematic Analysis of State Medicaid Buprenorphine Prior Authorization Requirements,'' *JAMA Netw Open,* 6(6):e2318487.

17. Bakaysa, S, S Heil, and M Meyer, 2009, ''833: Buprenorphine Dose Changes During Gestation,'' *Am J Obstet Gynecol,* 201(6):S297–S298.

18. Martin, CE, C Shadowen, B Thakkar, et al., 2020, ''Buprenorphine Dosing for the Treatment of Opioid Use Disorder Through Pregnancy and Postpartum,'' *Curr Treat Options Psychiatry,* 7(3): 375–399.

19. The American College of Obstetricians and Gynecologists, ''Opioid Use and Opioid Use Disorder in Pregnancy,'' Committee Opinion Number 711, August 2017, available at: *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/08/opioid-use-and-opioid-use-disorder-in-pregnancy.*

* 20. Substance Abuse and Mental Health Services Administration (SAMHSA) Advisory, ''Evidence-Based, Whole-Person Care for Pregnant People Who Have Opioid Use Disorder,'' March 2024, available at: *https://store.samhsa.gov/sites/default/files/whole-person-care-pregnant-people-oud-pep23-02-01-002.pdf.*

* 21. Supplement Approval for SUBOXONE (buprenorphine HCl and naloxone HCl) sublingual film (NDA 022410), Feb. 13, 2017, available at: *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/022410Orig1s023ltr.pdf.*

22. Concheiro, M, HE Jones, RE Johnson, et al., 2011, ''Preliminary Buprenorphine Sublingual Tablet Pharmacokinetic Data in Plasma, Oral Fluid and Sweat During Treatment of Opioid-Dependent Pregnant Women,'' *The Drug Monit,* 33(5):619–626.

Dated: December 18, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–30776 Filed 12–26–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60-Day Notice for Extension of the Indian Health Service Loan Repayment Program

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments; request for extension of approval.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to take this opportunity to comment on the information collection Office of Management and Budget (OMB) Control Number 0917–

0014, titled, ''IHS Loan Repayment Program (LRP).'' This notice announces our intent to submit this collection, which expires February 28, 2025, to the OMB for approval of an extension and solicit comments on specific aspects for the proposed information collection.

DATES: Consideration will be given to all comments received by February 25, 2025.

ADDRESSES:

For Comments: Submit comments to Correy Ahhaitty by one of the following methods:

- *Email: Correy.Ahhaitty@ihs.gov.*
- *Phone:* (301) 443–2544.

Comments submitted in response to this notice will be made available to the public by publishing them in the 30-day **Federal Register** Notice for this information collection. For this reason, please do not include information of a confidential nature, such as sensitive personal information or proprietary information. If comments are submitted via email, the email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

A copy of the draft supporting statement is available at *www.regulations.gov* (see Docket ID (IHS_FRDOC_0001)).

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Patricia Lawton, Information Collection Clearance Officer at: *Patricia.Lawton@ihs.gov* or 240–381–9031.

SUPPLEMENTARY INFORMATION: This previously approved information collection project was last published in the **Federal Register** (86 FR 60055) on October 29, 2021, and allowed 30 days for public comment. No public comment was received in response to the notice.

The IHS is submitting the proposed information collection to the OMB for review, as required by the Paperwork Reduction Act of 1995, as amended, and its implementing regulations. This notice is soliciting comments from members of the public and affected agencies as required by 44 U.S.C. 3506(c)(2)(A) and 5 CFR 1320.8(d) concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques of other forms of information technology, *e.g.,* permitting electronic submission of responses.

Title: 0917–0014, ''Indian Health Service Loan Repayment Program.''

Type of Information Collection Request: 3-year extension approval of this information collection.

OMB Control Number: 0917–0014.

Forms: Educational and Professional Background, Financial Information, and General Applicant Information (*i.e.,* all forms are part of the LRP application). The LRP application is available in an electronically fillable and fileable format.

Need and Use of Information Collection: The IHS LRP identifies health professionals with pre-existing financial obligations for education expenses that meet program criteria and who are qualified and willing to serve at, often remote, IHS health care facilities. Under the program, eligible health professionals sign a contract through which the IHS agrees to repay part or all of their indebtedness in exchange for an initial 2-year service commitment to practice full-time at an eligible Indian health program. This program is necessary to augment the critically low health professional staff at IHS health care facilities.

Eligible health professionals wishing to have their health education loans repaid may apply to the IHS LRP. A 2-year contract obligation is signed by both parties, and the individual agrees to work at an eligible Indian health program location and provide health services to American Indian and Alaska Native individuals.

The information collected via the online application from individuals is analyzed and a score is given to each applicant. This score will determine which applicants will be awarded each fiscal year (FY). The administrative scoring system assigns a score to the geographic location according to vacancy rates for that FY and also considers whether the location is in an isolated area. When an applicant accepts employment at a location, the applicant in turn ''picks-up'' the score of that location.

Status of the Proposed Information Collection: Renewal of a current collection.

Affected Public: Individuals and households.

Type of Respondents: Individuals.

The table below provides: Types of data collection instruments, estimated number of respondents, number of responses per respondent, average burden hour per response, and total annual burden hours.

ESTIMATED BURDEN HOURS

Data collection instrument(s)	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden responses (in hours)
LRP Application (3 forms in total)	1999	1	1.5	2998.5

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Roselyn Tso,

Director, Indian Health Service.

[FR Doc. 2024–31030 Filed 12–26–24; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Mental Health.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Mental Health, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Mental Health.

Date: February 5–7, 2025.

Time: February 05, 2025, 9:30 a.m. to 6:15 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Address: Porter Neuroscience Research Center, Building 35A, 35 Convent Drive, Bethesda, MD 20892 (In Person and Virtual Meeting).

Time: February 06, 2025, 10:00 a.m. to 5:15 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Address: Porter Neuroscience Research Center, Building 35A, 35 Convent Drive, Bethesda, MD 20892 (In Person and Virtual Meeting).

Time: February 07, 2025, 10:00 a.m. to 3:15 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Address: Porter Neuroscience Research Center, Building 35A, 35 Convent Drive, Bethesda, MD 20892 (In Person and Virtual Meeting).

Contact Person: Jennifer E Mehren, Ph.D., Scientific Advisor, Division of Intramural Research Programs, National Institute of Mental Health, National Institutes of Health, 35A Convent Drive, Bethesda, MD 20892–3747, 301–496–3501, email: *mehrenj@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: December 20, 2024.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–30957 Filed 12–26–24; 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 Spinal Cord Injury.

Date: February 12, 2025.

Time: 1:30 p.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institute on Aging, 5601 Fishers Lane, Suite 8B, Rockville, MD 20892.

Meeting Format: Virtual Meeting.*Contact Person:* Michael James Butler, Ph.D., Scientific Review Officer National Institute on Aging, National Institutes of Health, 5601 Fishers Lane, Suite 8B, Rockville, MD 20852, (301) 496–9666, *michael.butler@nih.gov.*

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

Dated: December 19, 2024

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–30879 Filed 12–26–24; 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; Maternal Nutrition and Aging.

Date: February 4, 2025.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institute on Aging, 5601 Fishers Lane, Suite 8B, Rockville, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Kaitlyn Noel Lewis Hardell, Ph.D., MPH, Scientific Review Officer, National Institute on Aging, National Institutes of Health, 5601 Fishers Lane, Suite 8B, Rockville, MD 20892, (301) 594–7945, *kaitlyn.hardell@nih.gov.*

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

Dated: December 19, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–30881 Filed 12–26–24; 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