

Section 510(m)(2) of the FD&C Act provides that, 1 day after the date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section, as amended by the 21st Century Cures Act (Pub. L. 114–255), requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 60-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

## II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the Agency issued on February 19, 1998, entitled "Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff." That guidance is available through the internet at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf> or by sending an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive a copy of the document. Please use the document number 159 to identify the guidance you are requesting.

## III. Proposed Class II Device Exemptions

FDA has received the following petition requesting an exemption from premarket notification for a class II device: Paul Hyman, Hyman, Phelps & McNamara, PC, 700 13th St. NW., Suite 1200, Washington, DC 20005–5929, for OTC denture repair kits, classified under 21 CFR 872.3570.

## IV. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 807, subpart E, regarding premarket notification submissions,

have been approved under OMB control number 0910–0120.

Dated: November 9, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017–25065 Filed 11–17–17; 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 previously approved information collection project was last published in the **Federal Register** (80 FR 23558) on April 28, 2015, and allowed 60 and 30 days for public comment. No public comment was received in response to the notices. This notice announces our intent to submit this collection, which expires July 31, 2018, to OMB for approval of an extension and solicit comments on specific aspects for the proposed information collection.

A copy of the draft supporting statement is available at [www.regulations.gov](http://www.regulations.gov) (see Docket ID IHS\_FRDOC\_0001).

**DATES:** Consideration will be given to all comments received by January 19, 2018.

**ADDRESSES:** Submit comments to Jackie Santiago by one of the following methods:

- *Mail:* Jackie Santiago, Chief, Loan Repayment Program, 5600 Fishers Lane, Mail Stop: 11E53A, Rockville, MD 20857.
- *Phone:* 301–443–2486.
- *Email:* [Jackie.Santiago@ihs.gov](mailto:Jackie.Santiago@ihs.gov).
- *Fax:* 301–443–4815.

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.

**FOR FURTHER INFORMATION CONTACT:** To request additional information, please contact Evonne Bennett-Barnes, Information Collection Clearance Officer at: [Evonne.Bennett-Barnes@ihs.gov](mailto:Evonne.Bennett-Barnes@ihs.gov) or 301–443–4750.

**SUPPLEMENTARY INFORMATION:** The IHS is submitting the proposed information collection to OMB for review, as required by section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995. This notice is soliciting comments from members of the public and affected agencies as required by 44 U.S.C. 3506(c)(2)(A) 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:* Three 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 two-year service commitment to practice fulltime 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 two-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 on-line 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. The administrative scoring system assigns a score to the geographic location according to vacancy rates for that fiscal year 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, Annual number of responses, Average burden hour per response, and Total annual burden hour(s).

ESTIMATED BURDEN HOURS

Data collection instrument(s)	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual responses (in hours)
LRP Application (3 forms in total) .....	1,726	1	1.5	2,589

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

**RADM Michael D. Weahkee,**  
Assistant Surgeon General, U.S. Public Health Service, Acting Director, Indian Health Service.

[FR Doc. 2017-25049 Filed 11-17-17; 8:45 am]

**BILLING CODE 4165-16-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Center for Scientific Review; 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:* Center for Scientific Review Special Emphasis Panel: Member Conflict: Clinical Neurological Disorders and Aging.

*Date:* December 4, 2017.

*Time:* 10:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Samuel C. Edwards, Ph.D., Chief, Brain Disorders and Clinical Neuroscience, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435-1246, [edwardss@csr.nih.gov](mailto:edwardss@csr.nih.gov).

(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: November 13, 2017.

**Sylvia L. Neal,**

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017-25043 Filed 11-17-17; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of General Medical Sciences Notice of Organizational Change**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Institute of General Medical Sciences (NIGMS) of the National Institutes of Health (NIH) is seeking public comment regarding its proposal to reorganize and to rename its Center for Research Capacity Building to the Division for Research Capacity Building, and transfer the Office of

Emergency Care Research to the National Institute of Neurological Disorders and Stroke.

**DATES:** Any interested person may file written comments by sending an email to [reorgcomments@nigms.nih.gov](mailto:reorgcomments@nigms.nih.gov) by December 4, 2017. The statement should include the individual’s name, and when applicable, professional affiliation.

**ADDRESSES:** The following email address has been established for comments on the reorganization: [reorgcomments@nigms.nih.gov](mailto:reorgcomments@nigms.nih.gov).

**FOR FURTHER INFORMATION CONTACT:** Stephanie Older, Chief, Office of Communications and Public Liaison, NIGMS, [reorgcomments@nigms.nih.gov](mailto:reorgcomments@nigms.nih.gov), 301-496-7301.

**SUPPLEMENTARY INFORMATION:** The National Institute of General Medical Sciences (NIGMS) of the National Institutes of Health (NIH) is seeking public comment regarding its proposal to reorganize four of its scientific divisions into three: (1) Biophysics, Biomedical Technology and Computational Biosciences; (2) Genetics and Molecular, Cellular and Developmental Biology; and (3) Pharmacology, Physiology, and Biological Chemistry. Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), NIGMS will launch public Web site information at <https://nigms.nih.gov> to encourage further public discussion of the proposal to reorganize. NIGMS will also provide information via its blog, <https://loop.nigms.nih.gov/>.