

product under the FD&C Act and (2) that the conduct which served as the basis for the conviction undermines the process for the regulation of drugs. FDA has considered the applicable factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 5 years is appropriate.

As a result of the foregoing findings, Patel is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective September 27, 2018 (see 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application, who knowingly uses the services of Patel, in any capacity during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Patel, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Patel during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: September 21, 2018.

**George M. Warren,**

*Director, Office of Scientific Integrity.*

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BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

[OMB NO. 0917-0028]

#### **Request for Public Comment: 60-Day Proposed Information Collection: Addendum to Declaration for Federal Employment, Child Care and Indian Child Care Worker Positions**

**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, which requires 60 days for public comment on proposed information collection projects, the Indian Health Service (IHS) invites the general public to take this opportunity to comment on

the information collection titled, "Addendum to Declaration for Federal Employment, Child Care and Indian Child Care Worker Positions," Office of Management and Budget (OMB) Control Number 0917-0028.

**DATES:** November 26, 2018. Your comments regarding this information collection are best assured of having full effect if received within 60 days of the date of this publication.

**ADDRESSES:** Send your written comments, requests for more information on the proposed collection, or requests to obtain a copy of the data collection instrument and instructions to Evonne Bennett-Barnes by one of the following methods:

- **Mail:** Evonne Bennett-Barnes, Information Collection Clearance Officer, 5600 Fishers Lane, Mail stop: 09E21B, Rockville, MD 20857.

- **Email:** [Evonne.Bennett-Barnes@ihs.gov](mailto:Evonne.Bennett-Barnes@ihs.gov).

- **Phone:** 301-443-4750.

**SUPPLEMENTARY INFORMATION:** This previously approved information collection project was last published in the **Federal Register** (80 FR 53812) on September 8, 2015, and allowed 30 days for public comment. No public comment was received in response to the notice. This notice announces our intent to submit this collection, which expires November 30, 2018, to OMB for approval of an extension, and to solicit comments on specific aspects for the proposed information collection.

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

**Proposed Collection: Title:** Addendum to Declaration for Federal Employment, Child Care and Indian Child Care Worker Positions (OMB No. 0917-0028). **Type of Information Collection Request:** Extension, without revision, of currently approved information collection, 0917-0028, Addendum to Declaration for Federal Employment, Child Care and Indian Child Care Worker Positions. There are no program changes or adjustments in burden hours. **Form(s):** Addendum to Declaration for Federal Employment, Child Care and Indian Child Care Worker Positions. **Need and Use of Information Collection:** This is a request for approval of the collection of information as required by section 408 of the Indian Child Protection and Family Violence Prevention Act, Public Law (Pub. L.) 101-630, 104 Stat. 4544, and 25 United States Code (U.S.C.) §§ 3201-3210.

The IHS is required to compile a list of all authorized positions within the

IHS where the duties and responsibilities involve regular contact with, or control over, Indian children; and to conduct an investigation of the character of each individual who is employed, or is being considered for employment, in a position having regular contact with, or control over, Indian children. 25 U.S.C. 3207(a)(1) and (2). Title 25 U.S.C. 3207(a)(3) requires regulations prescribing the minimum standards of character for individuals appointed to positions involving regular contact with, or control over, Indian children, and section 3207(b) provides that such standards shall ensure that no such individuals have been found guilty of, or entered a plea of nolo contendere or guilty to any felonious offense, or any two or more misdemeanor offenses, under Federal, State, or Tribal law involving crimes of violence; sexual assault, molestation, exploitation, contact or prostitution; crimes against persons; or offenses committed against children.

In addition, 34 U.S.C. 20351 (formerly codified at 42 U.S.C. 13041, which was transferred to 34 U.S.C. 20351) requires each agency of the Federal Government, and every facility operated by the Federal Government (or operated under contract with the Federal Government), that hires (or contracts for hire) individuals involved with the provision of child care services to children under the age of 18 to assure that all existing and newly hired employees undergo a criminal history background check. The background investigation is to be initiated through the personnel program of the applicable Federal agency. This section requires employment applications for individuals who are seeking work for an agency of the Federal Government, or for a facility or program operated by (or through contract with) the Federal Government, in positions involved with the provision of child care services to children under the age of 18, to contain a question asking whether the individual has ever been arrested for or charged with a crime involving a child, and if so, requiring a description of the disposition of the arrest or charge.

**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 hour(s).

## ESTIMATED ANNUAL 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)
Addendum to Declaration for Federal Employment (OMB 0917-0028) .....	3000	1	12/60	600
Total .....	3000	.....	.....	600

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

*Requests for Comments:* Your written comments and/or suggestions are invited on one or more of the following points:

(a) Whether the information collection activity is necessary to carry out an agency function;

(b) whether the agency processes the information collected in a useful and timely fashion;

(c) the accuracy of the public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information);

(d) whether the methodology and assumptions used to determine the estimates are logical;

(e) ways to enhance the quality, utility, and clarity of the information being collected; and

(f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Dated: September 20, 2018.

**RADM Michael D. Weahkee,**

*Assistant Surgeon General, USPHS, Acting Director, Indian Health Service.*

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**BILLING CODE 4165-16-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Minority Health and Health Disparities; 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 materials, 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 Minority Health and Health Disparities Special Emphasis Panel; NIMHD Mentored K Awards.

*Date:* October 30, 2018.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Gateway Building, 7201 Wisconsin Ave., Suite 533, Bethesda, MD 20814 (Virtual Meeting).

*Contact Person:* Maryline Laude-Sharp, Ph.D., Scientific Review Officer, National Institute on Minority Health and Health Disparities, National Institutes of Health, 7201 Wisconsin Ave., Bethesda, MD 20814, (301) 451-9536, [mllaudesharp@nih.gov](mailto:mllaudesharp@nih.gov).

Dated: September 20, 2018.

**David D. Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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; Molecular and Cellular Endocrinology Study Section.

*Date:* October 11, 2018.

*Time:* 11:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Lorien Hotel & Spa, 1600 King Street, Alexandria, VA 22314.

*Contact Person:* Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, EMNR IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6182, MSC 7892, Bethesda, MD 20892, 301 435-2514, [riverase@csr.nih.gov](mailto:riverase@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Cellular Aspects of Diabetes and Obesity.

*Date:* October 16, 2018.

*Time:* 11:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* St. Gregory Hotel, 2033 M Street NW, Washington, DC 20036.

*Contact Person:* Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, EMNR IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6182, MSC 7892, Bethesda, MD 20892, 301 435-2514, [riverase@csr.nih.gov](mailto:riverase@csr.nih.gov).

*Name of Committee:* Healthcare Delivery and Methodologies Integrated Review Group; Health Disparities and Equity Promotion Study Section.

*Date:* October 17-18, 2018.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Lorien Hotel & Spa, 1600 King Street, Alexandria, VA 22314.

*Contact Person:* Jessica Bellinger, Ph.D., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, Bethesda, MD 20892, 301-827-4446, [bellingerjd@csr.nih.gov](mailto:bellingerjd@csr.nih.gov).

*Name of Committee:* Oncology 2—Translational Clinical Integrated Review Group; Cancer Immunopathology and Immunotherapy Study Section.

*Date:* October 18-19, 2018.

*Time:* 8:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* InterContinental Chicago Hotel, 505 North Michigan Avenue, Chicago, IL 60611.

*Contact Person:* Denise R. Shaw, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6158, MSC 7804, Bethesda, MD 20892, 301-435-0198, [shawdeni@csr.nih.gov](mailto:shawdeni@csr.nih.gov).

*Name of Committee:* Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Musculoskeletal Rehabilitation Sciences Study Section.

*Date:* October 18-19, 2018.

*Time:* 8:00 a.m. to 6:00 p.m.