

importer in FY 2024 based on these figures would be $\$4,359 + (\$10,608 \times \frac{1}{4}) + (\$7,616 \times \frac{3}{4}) + (\$4,504 \times \frac{1}{2}) = \$14,975$.

IV. How must the fee be paid?

An invoice will be sent to VQIP importers approved to participate in the program. Payment must be made prior to October 1, 2023, to be eligible for VQIP participation for the benefit year beginning October 1, 2023. FDA will not refund the VQIP user fee for any reason.

The payment must be made in U.S. currency from a U.S. bank by one of the following methods: wire transfer, electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. The preferred payment method is online using an electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay>. (Note: only full payments are accepted. No partial payments can be made online.) Once you have found your invoice, select "Pay Now" to be redirected to [Pay.gov](https://pay.gov). Electronic payment options are based on the balance due. Payment by credit card is available only for balances less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

When paying by check, bank draft, or U.S. postal money order, please include the invoice number in the check stub. Also write the FDA post office box number (P.O. Box 979108) on the enclosed check, bank draft, or money order. Mail the payment including the invoice number on the check stub to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197-9000.

When paying by wire transfer, it is required that the invoice number is included; without the invoice number the payment may not be applied. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. For international wire transfers, please inquire with the financial institutions prior to submitting the payment. Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, Swift No.: FRNYUS33.

To send a check by a courier such as Federal Express, the courier must deliver the check to: U.S. Bank, Attn: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314-418-4013. This phone number is only for questions about courier delivery.)

The tax identification number of FDA is 53-0196965. (Note: Invoice copies do not need to be submitted to FDA with the payments.)

V. What are the consequences of not paying this fee?

The consequences of not paying these fees are outlined in Section J of "FDA's Voluntary Qualified Importer Program; Guidance for Industry" document (available at <https://www.fda.gov/media/92196/download>). If the user fee is not paid before October 1, a VQIP importer will not be eligible to participate in VQIP. For the first year a VQIP application is approved, if the user fee is not paid before October 1, 2023, you are not eligible to participate in VQIP. If you subsequently pay the user fee, FDA will begin your benefits after we receive the full payment. The user fee may not be paid after December 31, 2023. For a subsequent year, if you do not pay the user fee before October 1, FDA will send a Notice of Intent to Revoke your participation in VQIP. If you do not pay the user fee within 30 days of the date of the Notice of Intent to Revoke, we will revoke your participation in VQIP.

Dated: July 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-15920 Filed 7-27-23; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 30-Day Information Collection: Indian Health Service Medical Staff Credentials Application

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments; request for revision to a collection.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to comment on the information collection titled, "Indian

Health Service Medical Staff Credentials Application," OMB Control Number 0917-0009, which expires August 31, 2023.

DATES:

Comment Due Date: August 28, 2023.

Your comments regarding this information collection are best assured of having full effect if received within 30 days of the date of this publication.

Direct Your Comments to OMB: Send your comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS.

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Evonne Bennett, Information Collection Clearance Officer by email at: Evonne.Bennett@ihs.gov or telephone at 240-472-1996.

SUPPLEMENTARY INFORMATION: This previously approved information collection project was last published in the **Federal Register** on May 11, 2023 (88 FR 30317), and allowed 60 days for public comment. There was one public comment received in response to the notice. This notice announces our intent to submit this collection, which expires August 31, 2023, to OMB for approval of an extension with revisions, and to solicit comments on specific aspects for the proposed information collection.

A copy of the supporting statement is available at www.regulations.gov (see Docket ID IHS-2023-0001).

Comment: Commenter requested the IHS review the medical staff credentials application and revise or remove any invasive or stigmatizing language around mental health.

Response to Comment: The IHS does not believe there are any stigmatizing language around mental health in the application. Should specific stigmatizing language be presented to IHS, IHS will review the language and then determine whether remedial action needs to be taken.

Information Collection Title: "Indian Health Service Medical Staff Credentials Application, 0917-0009."

Type of Information Collection Request: Revision of an approved information collection, and retitled to, "Indian Health Service Medical Staff Credentials and Privileges Records, 0917-0009."

Form Numbers: 0917-0009.

Need and Use of Information Collection: This collection of

information is used to evaluate IHS medical and health care professionals to include: licensed practitioners (LP) applying for medical staff membership, credentialing and privileges at IHS health care facilities. Practitioner credentialing and privileging in the IHS has been identified as a priority area for quality improvement to support patient safety, demonstrate quality of care, and improve practitioner satisfaction.

Indian Health Service policy specifically requires all LP (*i.e.*, Federal employees, contractors, and/or volunteers) who intend to provide health care services at IHS facilities to be credentialed and privileged prior to providing such care. When a practitioner applies to provide health care services at an IHS clinic or hospital, that application contains two parts. The first is for membership in the medical staff. Criteria for such membership may include type of licensure, education, training, and experience. The second part is for privileges, which define the scope of clinical care that a practitioner can administer and matches the practitioner's current clinical competency. There are certain criteria that practitioners must meet in order to exercise particular privileges in the facilities. These criteria may overlap with criteria for membership on the medical staff, but those for privileges are more specific and must be facility specific to meet the facility's requirements.

The IHS operates health care facilities that provide health care services to American Indian and Alaska Native patients. To provide these services, the IHS employs (direct-hire and direct-contract) several categories of fully licensed, registered, or certified individuals permitted by law to independently provide patient care services within the scope of the individual's license, registration, or certification, and in accordance with individually granted clinical privileges when the individual is a credentialed member of the IHS medical staff. Licensed Practitioners who are eligible may become medical staff members, depending on the local health care facility's capabilities and medical staff bylaws.

All LP who provide care at IHS facilities must maintain full, active,

unrestricted, and current licensure and credentials, and be proficient in their granted privileges in accordance with the facility's medical staff bylaws, accreditation standards, privilege criteria, agency and local policies, and applicable law and guidelines.

National health care standards developed by the Centers for Medicare and Medicaid Services, the Joint Commission, and other accrediting organizations require health care facilities to review, evaluate, and prime-source verify credentials of medical staff applicants prior to granting medical staff privileges. Medical credentials specifically include the primary source verified and documented evidence of competence, character, judgment, education, and training. In order to meet these standards, IHS health care facilities require all medical staff applicants to provide verifiable information concerning their education, training, licensure, work experience, health status, and current professional conduct and competence and any adverse disciplinary actions taken against them. This information is collected through the agency's current commercial off the shelf credentialing software to make the following application packets electronically available via the internet. The Application packets are: (1) Pre-Application; (2) Initial Application for Membership & Privileges; (3) Reappointment Application for Membership and Privileges; and (4) Credentialing by Proxy (CBP) Intake Form. The first three application packets include an IHS Conditions of Application and Release and Health Attestation Statement for the LP to sign; Item 4, the CBP Intake Form, only includes an IHS Conditions of Application and Release.

Privileges vary across all IHS Areas and clinics, as services and procedures provided and equipment utilized varies across facilities and can change often. Privilege forms are required to be current and modified to reflect only services and procedures provided by that specific facility in order to be in compliance with accreditation standards. The electronic credentialing system allows tailoring the privileging needs to site specifications.

Information collected in the application packets are prime-source

verified by IHS staff using standard IHS forms (Affiliation, Peer Reference, Insurance, and Education) with the original source of the credential. The credentials review includes, but is not limited to, verifying information from: the state medical boards, the Drug Enforcement Administration, Excluded Parties List System/System for Awards Management, National Practitioner Data Bank, Office of Inspector General, colleges or universities, residency programs, peer references, insurance companies, etc.

Once the LP application packet is approved, agency policy requires licensure, registration, and certification requirements and clinical competency be continuously verified on an ongoing basis until the time of the next reappointment. At the time of reappointment the health care practitioner will go through a similar reappointment process to renew their membership and privilege status. This review evaluates the current competence of the health care providers and verifies whether they are maintaining the licensure or certification requirements of their specialty.

The medical staff credentials and privileges records are stored in two ways: records stored in file folders are stored at the IHS facilities or the Federal Record Center, and computer-based or electronic records are located at the IHS Albuquerque Data Center in Albuquerque, New Mexico.

The IHS is continuing to standardize, transform, and optimize the medical staff credentialing and privileging process into a centrally automated, standardized, electronic/digital, measurable, portable, accessible, and efficient business process to improve the effectiveness of application and re-application to medical staff, movement of practitioners within the IHS system, and recruitment/retention of high-quality LP.

Affected Public: Individuals and households.

Type of Respondents: Individuals.

The table below provides: Types of data collection instruments, Estimated Number of Respondents, Number of Annual Responses per Respondent, Average Burden per Response, and Total Annual Burden Hours.

Data collection instrument(s)	Estimated number of respondents	Responses per respondent	Average burden hour per response *	Total annual burden (current) **
Pre-Application Package to Medical Staff	500	1	.50 (30 min)	250
Initial Application Package to Medical Staff and/or Privileges	878	1	1 (60 min)	878
Reappointment Application Package to Medical Staff and/or Privileges	2,212	1	0.50 (30 min)	1,106

Data collection instrument(s)	Estimated number of respondents	Responses per respondent	Average burden hour per response *	Total annual burden (current) **
Credentialing by Proxy Intake Form	250	1	.25 (15 min)	63
Affiliation Verification	4,225	1	.25 (15 min)	1,056
Education Verification	3,289	1	.25 (15 min)	822
Malpractice Verification	2,535	1	.25 (15 min)	634
Peer Reference Verification	6,180	1	.25 (15 min)	1,545
Total	20,069	6,354

For ease of understanding:

* Average Burden Hour per Response are provided in actual minutes.

** Total Annual Burden (Current) are provided in hours.

Annual number of respondents and average burden hour were factored based on total IHS providers credentialed and privileged Calendar Year 2022, accreditation requirements with estimates of verification per applicant, and respondent estimate time of completion in the paragraphs above.

There are no capital costs, operating costs, and/or maintenance costs to respondents.

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.

P. Benjamin Smith,

Deputy Director, Indian Health Service.

[FR Doc. 2023-16011 Filed 7-27-23; 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 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; RFA-OD-23-005: NIH Research Evaluation and Commercialization Hubs (REACH) Awards (U01) 2.

Date: August 8, 2023.

Time: 9:00 a.m. to 11:30 a.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: Megan L. Goodall, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-8334 megan.goodall@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: July 24, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-15992 Filed 7-27-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 1009 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: National Cancer Institute Special Emphasis Panel; NCI Review of Applications to Research Projects in Physical Sciences Oncology.

Date: September 29, 2023.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W640, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Saejeong J. Kim, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W640, Rockville, Maryland 20850, 240-276-7684, saejeong.kim@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP-3: NCI Clinical and Translational Cancer Research.

Date: October 12, 2023.

Time: 9:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W248, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Shree Ram Singh, Ph.D., Scientific Review Officer, Special Review