

1 Supporting Statement for Indian Health Service Medical Staff Credentials and Privileges Files

A. Justification

1. Circumstances Making the Collection of Information Necessary

This is a request for a reinstatement, the Indian Health Service (IHS) information collection, 0917-0009, "Indian Health Service Medical Staff Credentials and Privileges Files", which will expire. The IHS collects and maintains this information under the following authorities: Snyder Act (25 U.S.C. 13), Indian Health Service Transfer Act (42 U.S.C. 2001-2004) and the Indian Self-Determination and Education Assistance Act (25 U.S.C 450), as amended, (Attachment 1).

2. Purpose and Use of Information Collection

This collection of information is used to evaluate individual health care providers applying for medical staff privileges at IHS health care facilities.

The IHS operates health care facilities that provide health care services to American Indians and Alaska Natives. To provide these services, the IHS employs (directly and under contract) several categories of health care providers including: physicians (M.D. and D.O.), dentists, psychologists, optometrists, podiatrists, audiologists, physician assistants, certified registered nurse anesthetists, nurse practitioners, and certified nurse midwives. IHS policy specifically requires physicians and dentists to be members of the health care facility medical staff where they practice. Health care providers become medical staff members, depending on the local health care facility's capabilities and medical staff bylaws. There are three types of IHS medical staff applicants: 1) health care providers applying for direct employment with IHS; 2) contractors who will not seek to become IHS employees; and, 3) employed IHS health care providers who seek to transfer between IHS health care facilities.

National health care standards developed by the Center for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA), the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and other accrediting organizations require health care facilities to review, evaluate and verify the credentials, training and experience of medical staff applicants prior to granting medical staff privileges. To meet these standards, IHS health care facilities require all medical staff applicants to provide information concerning their education, training, licensure, and work experience and any adverse disciplinary actions taken against them. This information is then verified with references supplied by the applicant and may include: former employers, educational institutions, licensure and certification boards, the American Medical Association, the Federation of State Medical Boards, the National Practitioner Data Bank, and the applicants themselves.

In addition to the initial granting of medical staff membership and clinical privileges, JCAHO standards require that a review of the medical staff be conducted not less than every two years. This review evaluates the current competence of the medical staff and verifies whether they are maintaining the licensure or certification requirements of their specialty.

The medical staff credentials and privileges records are maintained at the health care facility where the health care provider is a medical staff member. The establishment of these records at IHS health care facilities is not optional; such records must be established and maintained at all health care facilities in the United States that are accredited by JCAHO. Prior to the establishment of this JCAHO requirement, the degree to which medical staff applications were verified for completeness and accuracy varied greatly across America.

Experience helped determine the minimum data necessary to conduct this information collection activity and has led to the development of model formats for its collection. These formats are suggested formats because: 1) JCAHO standards require clinical privileges to be facility specific, and 2) each IHS health care facility has different needs and capabilities. The basic policy, procedures, and suggested formats for this collection of information are contained in IHS Circular 95-16 "Credentials and Privileges Review Process for the Medical Staff," superseded by IHS Manual Chapter, "Medical Credentials and Privileges Review Process," Indian Health Manual Part 3, Chapter 1, Revised November 19, 2008. TN No. 2008-19, (Attachment 2). A resource manual (not a statement of IHS policy) has also been developed to assist in this collection of information and is contained in the "Indian Health Service Medical Staff Credentialing and Privileging Guide", September 2005, (Attachment 2).

The suggested formats for credentials and privileges contained in IHM Part 3, Chapter 1 review process include:

- 1) Application for appointment to the medical staff format.
- 2) Suggested format for letter to be sent to references of applicants or for telephone solicitation of references.
- 3) Request for reappointment to the medical staff format.
- 4) Medical privileges request format.
- 5) Ob-gyn privileges format.
- 6) Surgery privileges request format.
- 7) Psychiatry privileges request format.
- 8) Anesthesia privileges request format.
- 9) Dental privileges request format.
- 10) Optometry privileges request format.
- 11) Psychology privileges request format.
- 12) Audiology privileges request format.
- 13) Podiatry privileges request format.

- 14) Radiology privileges request format.
- 15) Pathology privileges request format,

Although many of these forms continue to be used by the local IHS service units, many healthcare facilities are now using modified privileging forms to address more global “core privileges.” The “core privileges” approach is increasingly recommended in the professional literature and by professional specialty societies. At the same time, the applicant must specifically request privileges for less commonly performed procedures and services and provide verification of appropriate training and experience relevant to those procedures. IHS has developed a common application form for Medical Staff Appointment and Privileges contained in Manual Exhibit 3-1-A, “Indian Health Service Application for Medical Staff Appointment and/or Privileges”.

3. Use of Improved Information Technology and Burden Reduction

IHS has developed in 2009 and released a new IHS Risk Management Website which contains the “Indian Health Service Medical Staff and Credentialing and Privileging Guide” as well as an electronic version of the “Indian Health Service Application for Medical Staff Appointment and /or Privileges”. This now allows individual providers to submit information electronically.

4. Efforts to Identify Duplication and Use of Similar Information

The Division of Commissioned Personnel (DCP) and Office of Personnel Management (OPM) collect some similar information. However, the information collected in these personnel systems is too general for use in determining medical staff eligibility and privileges to practice medicine in an IHS health care facility. In addition, JCAHO and the CMS standards require that applications of medical staff applicants be thoroughly reviewed, evaluated and verified by qualified medical staff at the facility to which the applicant is applying. This medical peer review cannot be conducted by DCP and OPM personnel staff. There is no specifically similar information available which could be used or modified to evaluate and verify the applications of medical staff applicants and approve medical staff membership and privileges in IHS health care facilities.

Repeat application for clinical privileges and credential verification is necessary and required by accrediting entities; in order to perform surveillance of each provider's clinical practices, for services provided both in the past and present. It is necessary to conduct primary resource verification on a regular basis, and national practices are generally for provider re-privileging every one to two years.

5. Impact on Small Businesses or Other Small Entities

This collection of information, in general, does not involve small businesses or other small entities but rather individual health professionals, staffs of health care provider

organizations, colleges or universities, and state licensing boards. Rural hospitals may be considered small entities; however, the information requested of them (i.e., verification of employment and work history) should not impose an undue reporting burden since such information should be routinely contained in the rural hospital's personnel or medical staff records.

6. Consequences of Collecting the Information and Less Frequent Collection

The information must be collected at the time that the individual is initially applying for membership on the IHS medical staff (either as a direct or contract provider) and every one or two years thereafter, and at the time an IHS medical staff member's credentials and privileges are re-evaluated and re-certified. Less frequent information collection could jeopardize patient quality care and safety and the accreditation status of the facility.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information collection is consistent with the guidelines in 5 CFR 1320.5(d) (2).

8. Comments in Response to the Federal Register Notice/Outside Consultation

The Federal Register notice, required by 44 U.S.C. 3506(c) (2) (A) soliciting public comment on the information collection prior to submission to OMB was published in the Federal Register (74 FR 63754) on December 4, 2009 (Attachment 4). No public comments were received.

9. Explanation of any Payment/ Gift to Respondents

The respondents will not receive any payments or gifts for providing the information.

10. Assurance of Confidentiality Provided to Respondents

The records contained in this information collection activity are subject to Privacy Act system of records; 09-17-0003, "Indian Health Service Medical Staff Credentials and Privileges File, HHS/IHS/OPH" (Attachment 3). Information collected in the IHS credentials and privileges process, as well as the handling and storage of this information, will be in compliance with the Privacy Act and the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The file folders are secured in locked cabinets and access to them is restricted to staff directly involved with the credentialing/privileging process. The latter may include the medical staff coordinator, the Clinical Director, and the Credentials Committee. Elements of the information may be collected and updated by the assigned IHS or tribal facility staff, IHS Area Office staff, or a non-federal credential verification service under contract. Applicants sign a release authorizing IHS to verify the information provided in their applications, and they are provided a Privacy Act notification statement which describes the authority for collecting the information, the purposes for

which it is collected, and the routine use disclosures.

The Indian Health Manual Chapter on credentialing and privileging addresses the HIPAA compliance requirements, including amending its Privacy Act system of records notice, “09-17-0003 IHS Medical Staff Credentials and Privileges Records,” to add a new “purpose” and “routine use” to disclose data to the Health Integrity and Protection Data Bank (HIPDB) pursuant to the Health Insurance Portability and Accountability Act of 1996. The Report of an Altered System of Records Medical Staff Credentials and Privileges Records was published in the Federal Register, Volume 74, Number 173, Wednesday, September 9, 2009 (Attachment 3).

However, it should be noted that reporting of fraud by Federal providers is an extremely uncommon event because Federal employees do not collect fees for their professional services, but rather are salaried by the Federal employer. Violations requiring reporting would most likely involve default of health professions loans and scholarship obligations or would be reported by prior employers. Virtually all of the data needed for HIPDB reporting would be accessible in other administrative records such as the Official Personnel Folder or Federal scholarship record.

11. Justification for Sensitive Questions

Applicants for medical staff membership and privileges provide information of a sensitive nature concerning their professional experience with medical liability or adverse actions, as well as their health status and any alcohol or drug dependency. This information is collected, evaluated and verified to ensure that members of IHS medical staffs are fully qualified, competent and capable of delivering quality health services to patients without any impairment. By formally applying for IHS medical staff membership and privileges, signing the release statement and receiving the IHS Privacy Act notification statement described in item 10, applicants are informed and provide IHS informed consent to obtain this information and to use this information as described in the Privacy Act notification statement.

12. Estimates of Annualized Burden Hours (Total Hours and Wages)

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

12A. Estimated Annualized Burden Hours

Data Collection Instrument(s)	Estimated Number of Respondents	Responses per Respondent	Average Burden Hour per	Total Annual Burden
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)			Response*	Hours
Application to Medical Staff	570	1	1.00(60 mins)	570
Reference Letter	1710	1	0.33 (20 mins)	570
Reappointment Request	190	1	1.00 (60 mins)	190
Ob-Gyn Privileges	20	1	1.00 (60 mins)	20
Internal Medicine	325	1	1.00 (60 mins)	325
Surgery Privileges	20	1	1.00 (60 mins)	20
Psychiatry Privileges	13	1	1.00 (60 mins)	13
Anesthesia Privileges	15	1	1.00 (60 mins)	15
Dental Privileges	150	1	0.33 (20 mins)	50
Optometry Privileges	21	1	0.33 (20 mins)	7
Psychology Privileges	30	1	0.17 (10 mins)	5
Audiology Privileges	7	1	0.08 (5 mins)	1
Podiatry Privileges	7	1	0.08 (5 mins)	1
Radiology Privileges	8	1	0.33 (20 mins)	3
Pathology Privileges	3	1	0.33 (20 mins)	1
Total	3,089	-	-	1,791

*For ease of understanding, burden hours are provided in actual minutes. There are no capital costs, operating costs and/or maintenance costs to respondents.

12.B Estimated Annualized Cost to Respondents

Data Collection Instrument(s) *	Total Annual Burden Hours	Hourly Wage Rate	Total Respondent Costs
Application to Medical Staff	570	\$75.00	\$42,750
Reference Letter	570	\$75.00	\$42,750
Reappointment Request	190	\$75.00	\$14,250
Ob-Gyn Privileges	20	\$75.00	\$1,500
Internal Medicine	325	\$75.00	\$24,375
Surgery Privileges	20	\$75.00	\$1,500
Psychiatry Privileges	13	\$75.00	\$975
Anesthesia Privileges	15	\$75.00	\$1,125
Dental Privileges	50	\$75.00	\$3,750
Optometry Privileges	7	\$75.00	\$525
Psychology Privileges	5	\$75.00	\$375
Audiology Privileges	1	\$75.00	\$75
Podiatry Privileges	1	\$75.00	\$75
Radiology Privileges	3	\$75.00	\$225
Pathology Privileges	1	\$75.00	\$75
Total	1,791		\$134,325

*Instruments are completed by health care providers estimated at physician rate of \$75/hour.

13. Estimates of other Total Annual Cost Burden to Respondents or Record keepers/Capital Costs

Except for their time to complete the necessary application process, there is no annual cost burden to respondents for this information collection activity. This information collection places no additional computer or record keeping requirements upon the respondents. It will not require any capital equipment or create any start-up costs, and will not create additional costs associated with generating, maintaining, and disclosing or providing the information.

14. Annualized Cost to Federal Government

The estimated annual cost to the Federal Government for this information collection activity is \$182,500. This includes both clinician and support staff time, and includes an estimate of credential committee person-hours. This is based on the following:

A. Cost associated with new applicants to the medical staff (non-employees):

Collect and analyze data*	\$	120,000
Printing & Distribution	+ \$	<u>15,000</u>
Total	\$	135,000 for new applicants

*50.00/hr x 4 hours per applicant x 600 new applicants: \$120,000.

B. Cost associated with reappointments to the medical staff and requests for renewal of clinical privileges (most are employees)

Collect and analyze data*	\$	40,000
Printing & Distribution	+ \$	<u>7,500</u>
Total	\$	47,500 for re-applicants/renewals

*50.00/hr x 4 hours per applicant x 300 reappointments applicants: \$40,000.

15. Explanation for Program Changes or Adjustments

The forms were made more streamline, thus making the IC easier for respondents.

16. Plans for Tabulation and Publication and Project Time Schedule

The results of the proposed collection of information will not be published for statistical use.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB approval number and expiration date will be appropriately displayed on the

information collection form.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the Certification Statement in OMB 83-1 Question # 19 are being requested.

B. Collection of Information Employing Statistical Methods

This information collection will not employ statistical methods.

LIST OF ATTACHMENTS

INDIAN HEALTH SERVICE MEDICAL STAFF CREDENTIALS AND PRIVILEGES FILES

ATTACHMENT 1:

1. A Snyder Act, (25 U.S.C. 13).
1. B IHS Transfer Act, (42 U.S.C. 2001-2004).
1. C Indian Self-Determination and Education Assistance Act (25 U.S.C. 450).

ATTACHMENT 2:

2. A Indian Health Service Circular 95-16, "Credentials and Privileges Review Process for the Medical Staff."
2. B Indian Health Manual Part 3, Chapter 1, TN No. 2008-19, "Medical Credentials and Privileges Review Process."
2. C Indian Health Service Medical Staff Credentialing and Privileging Guide.
2. D Indian Health Service Application for Medical Staff Appointment and/or Privileges.

ATTACHMENT 3:

3. A Privacy Act Systems of Records Notice, 09-17-0003, Indian Health Service Medical Staff Credentials and Privileges Records, HHS/IHS/OHP.
3. B The Report of an Altered System of Records Medical Staff Credentials and Privileges Records. Federal Register Vol 74, No. 173, 9/9/2009.

ATTACHMENT 4:

4. A Federal Register 60-Day Notice (U.S.C. 3506 (c) (2) (A)).

ATTACHMENT 5:

5. A Federal Register 30-Day Notice (U.S.C. 3507 (a) (1) (D)).

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2. A Indian Health Service Circular 95-16, "Credentials and Privileges Review Process for the Medical Staff."

The instructions and the suggested formats used for this information collection are contained in this circular in the following sections:

<u>CREDENTIALS/PRIVILEGES FORMATS</u>	<u>SECTION</u>
Appointment to medical staff	99-00-B.1
References/Telephone letter	" " -B.3
Reappointment request	" " -B.4
Medical privileges	" " -C.1
Ob-gyn privileges	" " -C.2
Surgical privileges	" " -C.3
Psychiatric privileges	" " -C.4
Anesthesia privileges	" " -C.5
Dental privileges	" " -C.6
Optometry privileges	" " -C.7
Psychology privileges	" " -C.8
Audiology privileges	" " -C.9
Podiatry privileges	" " -C.10
Radiology privileges	" " -C.11
Pathology privileges	" " -C.12

2. B Indian Health Manual Part 3, Chapter 1, TN No. 2008-19, "Medical Credentials and Privileges Review Process."
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