V. Comments

As with all of FDA’s guidances, the public is encouraged to submit written or electronic comments pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the Federal Register.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access


Dated: June 6, 2006.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. E6–9327 Filed 6–14–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Privacy Act System of Records—Medical Staff Credentials and Privileges Records

AGENCY: Indian Health Service (IHS), HHS.

ACTION: Amendment of one altered Privacy Act system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, 5 U.S.C. 552a(e)(4), the IHS has amended and is publishing the proposed alteration of a system of records, System No. 09–17–0003, “Medical Staff Credentials and Privileges Records.” The amended and altered system of records makes only one administrative revision as necessary.

DATES: The amended and altered system, which incorporates no public comments received following the initial publication, shall become effective June 15, 2006.

FOR FURTHER INFORMATION: Contact Stephen Heath, MD, IHS Risk Management Consultant, Albuquerque Indian Health Center, 801 Vassar Drive, NE., Albuquerque, New Mexico 87106 or via the Internet at stephen.heath@ihs.gov.

SUPPLEMENTARY INFORMATION: As required by the Privacy Act of 1974, as amended, 5 U.S.C. 552a(e)(4), this document sets forth the amendment of the proposed alteration of a system of records maintained by the IHS, following the initial publication in the Federal Register at 71 FR 16320 on March 31, 2006. The purpose of altering System No. 09–17–0003, “Medical Staff Credentials and Privileges Records,” is to enable IHS to reflect current program changes, technology changes, statutory and implementation changes. During the comment period, IHS received no comments from the public. The revision or modification of the IHS addresses in Appendix 1 is necessary to this system of records as administrative changes. In Appendix 1, the address for the Elko Service Unit, Newe Medical Clinic under the Phoenix Area IHS was removed as this facility is no longer under the control of the IHS.

This Notice meets the requirement to notify the public that the IHS is amending the proposed changes in the IHS system of records by incorporating the administrative change following the initial publication at 71 FR 16320, March 31, 2006. With this notification, this system of records is effective June 15, 2006.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

09–17–0003

SYSTEM NAME: Indian Health Service Medical Staff Credentials and Privileges Records, HHS/IHS/OCPS.

SECURITY CLASSIFICATION: None.

SYSTEM LOCATION: Each Indian Health Service (IHS) Area Office and each IHS Service Unit (Appendix 1). Records may also be located at hospitals and offices of health care providers who are under contract with IHS. A current list of contractor sites is available by writing to the appropriate System Manager (Area or Service Unit Director) at the address shown in Appendix I.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Prospective, current and former IHS medical staff members. The term IHS medical staff includes fully licensed individuals permitted by law to provide patient care services independently and without concurrent professional direction or supervision, within the scope of his/her license and in accordance with individually granted clinical privileges. The IHS medical staff includes physicians (M.D. and D.O.) and dentists and may include other health care practitioners such as psychologists, optometrists, podiatrists, audiologists, and, in some states, certified nurse midwives. Types of assignment categories of current and former IHS medical staff members include the following:

Provisional—Those new members of the medical staff who are serving a required initial probationary period, as specified in the local medical staff bylaws. During this time, their qualifications for membership on the active or courtesy IHS medical staff are assessed.

Active—Those members who are Federal employees and/or spend at least fifty percent of their professional time providing patient care related services in the facility.

Temporary—Those members who provide services on a short-term basis or have applied for active medical staff membership and are awaiting a full credential review.

Courtesy or Associate—Those members who generally provide services on a periodic or episodic basis (e.g., consultants for specialty clinics).

CATEGORIES OF RECORDS IN THE SYSTEM:

Contains name, Social Security number, IHS medical staff membership and privileges applications and associated forms, employment data, liability insurance coverage, credentialing history of licensed health professionals, personal, educational, and demographic background information, professional performance information consisting of continuing education, performance awards, and adverse or disciplinary actions, and evaluations and approvals completed by IHS medical staff reviewers.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:


PURPOSE(S):

The purposes of this system are:
1. To ensure that IHS medical staff members are qualified, competent and capable of delivering quality health services consistent with those of the medical community at large and that they are granted privileges commensurate with their training and competence and with the ability of the facility to provide adequate support equipment, services, and staff.
2. To inform health care practitioner(s) and staff of health care facilities, state or county health professional societies or licensing boards to whom the subject individual may apply for clinical privileges, membership or licensure, of the subject individual’s professional competence, character and ethical qualifications. This may include information regarding drug or alcohol abuse or dependency. Within the Department such releases may be made to personnel staffs of DHHS Regional Offices.
3. To provide adverse health care practice information to the National Practitioner Data Bank-Healthcare Integrity and Protection Data Bank (NPDB–HIPDB) established under Title IV of Pub. L. 99–660, the Health Care Quality Improvement Act of 1986, as amended, and Section 221(a) of Pub. L. 104–191, the Health Insurance Portability and Accountability Act of 1996. The purpose of such a release is to provide information concerning a current or former IHS medical staff member whose professional health care activity failed to conform to generally accepted standards of professional medical practice. This will be done within the guidelines for notice, hearing, and review as delineated in the medical staff bylaws for the IHS facility and/or within other HHS or IHS regulations or policies.
4. IHS may disclose biographic data and information supplied by potential applicants to (a) references listed on the IHS medical staff and/or privileges application and associated forms for the purpose of evaluating the applicant’s professional qualifications, experience, and suitability, and (b) a state or local government health profession licensing board, to a health-related professional organization, to the Federation of State Medical Boards, and to the NPDB–HIPDB or a similar entity for the purpose of verifying that all claimed background and employment data are current and in good standing.
5. The Department may disclose records consisting of name, Social Security number, employment history and any professional qualification information concerning medical staff membership and privileges, professional competence, clinical judgment and personal character to a state or local government health professional licensing board, to the Federation of State Medical Boards, to the NPDB–HIPDB, and/or to a similar entity which has the authority to maintain records concerning the issuance, retention or revocation of licenses or registrations necessary to practice a health professional occupation or specialty. The purpose of this disclosure is to inform medical profession licensing boards and appropriate entities about the health care practices of a current, terminated, resigned, or retired IHS medical staff member whose professional health care activity significantly failed to conform to generally accepted standards of professional medical practice. This will be done within the guidelines for notice, hearing, and review as delineated in the medical staff bylaws for the IHS facility and/or within other HHS or IHS regulations or policies.
6. Records may be disclosed to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.
7. In the event that a system of records maintained by the IHS to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred to the appropriate agency, whether Federal, state, or local, charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders and computer-based or electronic files.

RETRIEVABILITY:

Indexed and retrieved by name, Social Security number, and any other identifying numbers necessary to establish the identity of an individual whose record is maintained in the system of records.

SAFEGUARDS:

1. Authorized Users: Access is limited to authorized personnel for use in the performance of their official duties. Authorized personnel include: Physician Recruitment and other Health Professions Branch Staff and Area Governing Board Members at IHS Area Offices, and Service Unit Directors, Clinical Directors and members of the Credentialing and Privilege Committee of each IHS Service Unit. At each location where records in this system will be
maintained, a list of personnel or categories of personnel having an official need-to-know has been developed and is maintained.

2. Physical Safeguards: Records are kept in locked metal filing cabinets or in locked desk drawers in secured rooms at all times when not actually in use during working hours and at all times during non-working hours. Record storage areas, including file cabinets and desks, are not left unattended or unlocked during office hours, including lunch hours. Computer-based or electronic records are password protected security and any additional internal security for database (linked or unlinked).

3. Procedural Safeguards: Persons who have an official need-to-know are entrusted with records from this system of records and are instructed to safeguard the confidentiality of these records and to destroy all copies or to return such records when the need to know has expired. Instructions include the statutory penalties for noncompliance. Proper charge-out procedures are followed for the removal of records from the area in which they are maintained. Before an employee who will control disclosure of records can work with the records (i.e., employees who report to the system manager) the system manager or designee ensures that the employee has received training in the safeguards applicable to the records and is aware of the actions to take to restrict disclosure. When copying records for authorized purposes, care is taken to ensure that any imperfect pages are not left in the reproduction room where they can be read but are destroyed or obliterated.


RETENTION AND DISPOSAL:
Records are maintained by IHS for at least ten years after the individual's termination of employment or association with IHS. Records of unsuccessful applicants for medical staff membership will be retained for three years after his/her rejection. After these periods of retention expire, records are destroyed by shredding or burning.

SYSTEM MANAGER(S) AND ADDRESS:

See Appendix 1.

Policy Coordinating Official: Director, Office of Clinical and Preventive Services, IHS, 801 Thompson Avenue, Suite 300, Rockville, Maryland 20852. The IHS Clinical Directors at all IHS Service Units listed in Appendix 1 are System Managers. IHS medical staff credentials and privileges files are stored at these locations. Other addresses listed in Appendix 1 are locations at which all or parts of these records may also be stored (Physician Recruiter at IHS Area Offices). Post Office Box designations appearing in Appendix 1 should be specified when making requests by mail.

NOTIFICATION PROCEDURE:

Requests must be made to the appropriate System Manager (Clinical Director for the appropriate Service Unit) listed in Appendix 1.

Requests by mail: Requests for information and/or access to records received by mail must contain information providing the identity of the writer and a reasonable description of the record desired. Written requests must contain, at a minimum, the name, signature, Social Security number, and address of the requester, and for unsuccessful applicants the date when the application was submitted, and for current or former IHS health care providers the dates and locations of service. We may request additional identification when we hold records for different persons with the same name or where an apparent discrepancy exists between information contained in the record and that provided by the individual requesting access to the record.

Other names used: Where an individual is seeking to obtain information about himself/herself which may be retrieved by a different name than his/her current name, he/she shall be required to produce evidence to verify that he/she is the person whose record he/she seeks.

Requests in person: A subject individual who appears in person at a specific location (where he or she currently works or formerly worked) seeking access or disclosure of records contained in this system of records relating to him/her shall provide the information described in "Requests by mail" (above) and at least one piece of tangible identification such as a driver's license or passport.

Requests by telephone: Since positive identification of the caller cannot be established, telephone requests are not honored.

RECORD ACCESS PROCEDURES:

Same as Notification Procedure: Requesters should also provide a reasonable description of the record being sought. Requesters may also request an accounting of disclosures that have been made of their records, if any.

Contesting record procedures: Write to the appropriate Service Unit Clinical Director at the address specified in Appendix 1 and reasonably identify the record, specify the information being contested, and state the corrective action sought, and the reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Subject individual, IRS health care personnel, references supplied by the subject individual, professional societies or associations, specialty boards, colleges and universities attended by the subject individual, former employers, health facilities or health providers with which the subject individual was associated, liability insurance carriers, organizations providing cardiopulmonary resuscitation (CPR) training to the subject individual, state and local health and health care licensing or certifying organizations, and organizations which serve as repositories of information on health care professionals.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

Appendix 1: System Managers and IRS Locations Under Their Jurisdiction Where Records Are Maintained

Director, Aberdeen Area Indian Health Service, Room 309, Federal Building, 115 Fourth Avenue, SE., Aberdeen, South Dakota 57401.

Director, Cheyenne River Service Unit, Eagle Butte Indian Hospital, P.O. Box 1012, Eagle Butte, South Dakota 57625.

Director, Crow Creek Service Unit, Pt. Thompson Indian Health Center, P.O. Box 200, Pt. Thompson, South Dakota 57339.

Director, Fort Berthold Service Unit, Fort Berthold Indian Health Center, P.O. Box 400, New Town, North Dakota 58763.

Director, Carl T. Curtis Health Center, P.O. Box 250, Macy, Nebraska 68039.

Director, Fort Totten Service Unit, Fort Totten Indian Health Center, P.O. Box 200, Fort Totten, North Dakota 58335.

Director, Kyle Indian Health Center, P.O. Box 540, Kyle, South Dakota 57752.

Director, Lower Brule Indian Health Center, P.O. Box 191, Lower Brule, South Dakota 57548.
Director, McLaughlin Indian Health Center, P.O. Box 879, McLaughlin, South Dakota 57642.
Director, Omaha-Winnebago Service Unit, Winnebago Indian Hospital, Winnebago, Nebraska 68071.
Director, Pine Ridge Service Unit, Pine Ridge Indian Hospital, Pine Ridge, South Dakota 57770.
Director, Rapid City Service Unit, Rapid City Indian Hospital, 3200 Canyon Lake Drive, Rapid City, South Dakota 57701.
Director, Rosebud Service Unit, Rosebud Indian Hospital, Rosebud, South Dakota 57700.
Director, Rapid City Service Unit, Fort Yates Indian Hospital, P.O. Box J, Fort Yates, North Dakota 58538.
Director, Warren Indian Hospital, P.O. Box 104, Fort Yates, North Dakota 58538.
Director, Alpena-Northwinds Indian Health Center, P.O. Box 210, Trenton, North Dakota 58253.
Director, Turtle Mountain Service Unit, Belcourt Indian Hospital, P.O. Box 160, Belcourt, North Dakota 58316.
Director, Wanblee Indian Health Center, 100 Clinic Drive, Wanblee, South Dakota 57777.
Director, Yankton-Wahpeton Service Unit, Acoma-Canoncito-Laguna Indian Health Center, P.O. Box 103, N5114 BIA School Road, Toadlena, New Mexico 87420.
Director, Los Alamos Health Center, P.O. Box 368, Kayenta, Arizona 86533.
Director, Albuquerque Area Health Service, 5300 Homestead Road, NE., Albuquerque, New Mexico 87110.
Director, Acoma-Canoncito-Laguna Service Unit, Acoma-Canoncito-Laguna Indian Hospital, P.O. Box 130, San Fidel, New Mexico 87049.
Director, To-Hajille Health Center, P.O. Box 3528, Canoncito, New Mexico 87026.
Director, New Sunrise Treatment Center, P.O. Box 219, San Fidel, New Mexico 87049.
Director, Albuquerque Service Unit, Albuquerque Indian Hospital, 801 Vassar Drive, NE., Albuquerque, New Mexico 87049.
Director, Albuquerque Indian Dental Clinic, P.O. Box 67830, Albuquerque, New Mexico 87193.
Director, Alamo Navajo Health Center, P.O. Box 907, Magdalena, New Mexico 87825.
Director, Jemez PHS Health Center, P.O. Box 279, Jemez, New Mexico 87024.
Director, Santa Ana PHS Health Center, P.O. Box 37, Bernalillo, New Mexico 87004.
Director, Sandia PHS Health Center, P.O. Box 500, Bernalillo, New Mexico 87004.
Director, Zia PHS Health Center, 155 Capital Square, Zia, New Mexico 87053.
Director, Santa Fe Service Unit, Santa Fe Indian Hospital, 1700 Cerrillos Road, Santa Fe, New Mexico 87501.
Director, Santa Clara Health Center, RRS, Box 446, Espanola, New Mexico 87532.
Director, San Felipe Health Center, P.O. Box 4344, San Felipe, New Mexico 87001.
Director, Cochiti Health Center, P.O. Box 105, 255 Cochiti Street, Cochiti, New Mexico 87072.
Director, Santo Domingo Health Center, P.O. Box 340, Santo Domingo, New Mexico 87052.
Director, Southern Colorado-Ute Service Unit, P.O. Box 778, Ignacio, Colorado 81137.
Director, Ignacio Indian Health Center, P.O. Box 849, Ignacio, Colorado 81137.
Director, Tohono O’odham Health Center, 11420 N. Hwy. 80, Sahuarita, Arizona 85629.
Director, Tonto Service Unit, Fort Thomas Indian Hospital, P.O. Box 67830, Albuquerque, New Mexico 87049.
Director, To-Apache Health Center, P.O. Box 60, Tohache, Arizona 86515.
Director, Yavapai-Apache Health Center, P.O. Box 380, Camp Verde, Arizona 86322.
Director, Clinton Service Unit, Clinton Indian Hospital, Route 1, Box 3060, Clinton, Oklahoma 73601–9303.

Director, El Reno PHS Indian Health Clinic, 1631 A E Highway 66, El Reno, Oklahoma 73036.

Director, Watonga Indian Health Center, Route 1, Box 34–A, Watonga, Oklahoma 73772.

Director, Haskell Service Unit, PHS Indian Health Center, 2415 Massachusetts Avenue, Lawrence, Kansas 66044.

Director, Lawton Service Unit, Lawton Indian Hospital, 1515 Lawrie Tatum Road, Lawton, Oklahoma 73501.

Director, Anadarko Indian Health Center, P.O. Box 828, Anadarko, Oklahoma 73005.

Director, Carnegie Indian Health Center, P.O. Box 1120, Carnegie, Oklahoma 73150.

Director, Holton Service Unit, PHS Indian Health Center, 100 West 6th Street, Holton, Kansas 66436.

Director, Pawnee Service Unit, Pawnee Indian Service Center, RR2, Box 1, Pawnee, Oklahoma 74056.

Director, Pawhuska Indian Health Center, 715 Grandview, Pawhuska, Oklahoma 74056.

Director, Tahlequah Service Unit, W. W. Hastings Indian Hospital, 100 S. Bliss, Tahlequah, Oklahoma 74464.

Director, Wewoka Indian Health Center, P.O. Box 1475, Wewoka, Oklahoma 74884.

Director, Phoenix Area Indian Health Service, Two Renaissance Square, 40 North Central Avenue, Phoenix, Arizona 85004.

Director, Colorado River Service Unit, Chemehuevi Indian Health Clinic, P.O. Box 1858, Havasu Landing, California 92363.

Director, Colorado River Service Unit, Havasupai Indian Health Station, P.O. Box 129, Supai, Arizona 86435.

Director, Colorado River Service Unit, Parker Indian Health Center, 12033 Agency Road, Parker, Arizona 85344.

Director, Colorado River Service Unit, Peach Springs Indian Health Center, P.O. Box 190, Peach Springs, Arizona 86434.

Director, Colorado River Service Unit, Shonto Indian High School, 9010 Magnolia Avenue, Riverside, California 92503.

Director, Elko Service Unit, Southern Bands Health Center, 515 Shoshone Circle, Elko, Nevada 89801.

Director, Fort Yuma Service Unit, Fort Yuma Indian Hospital, P.O. Box 1368, Fort Yuma, Arizona 85366.

Director, Kearns Canyon Service Unit, Hopi Health Care Center, P.O. Box 4000, Polacca, Arizona 86042.

Director, Phoenix Service Unit, Phoenix Indian Medical Center, 4212 North 16th Street, Phoenix, Arizona 85016.

Director, Phoenix Service Unit, Salt River Health Center, 10005 East Osborn Road, Scottsdale, Arizona 85256.

Director, San Carlos Service Unit, Bylas Indian Health Center, P.O Box 208, Bylas, Arizona 85550.

Director, San Carlos Service Unit, San Carlos Indian Hospital, P.O. Box 208, San Carlos, Arizona 85550.

Director, Schurz Service Unit, Schurz Service Unit Administration, Drawer A, Schurz, Nevada 89427.

Director, Fort McDermitt Clinic, P.O. Box 315, McDermitt, Nevada 89421.

Director, Unitah and Ouray Service Unit, Fort Duchesne Indian Health Center, P.O. Box 160, Fort Duchesne, Utah 84026.

Director, Whiteriver Service Unit, Cibecue Health Center, P.O. Box 37, Cibecue, Arizona 85941.

Director, Whiteriver Service Unit, Whiteriver Indian Hospital, P.O. Box 860, Whiteriver, Arizona 85941.

Director, Desert Vision Youth Wellness Center/RTC, P.O. Box 458, Sacaton, AZ 85247.

Director, Portland Area Indian Health Service, Room 476, Federal Building, 1220 Southwest Third Avenue, Portland, Oregon 97204–2829.

Director, Colville Service Unit, Colville Indian Health Center, P.O. Box 71-Agency Campus, Nespelem, Washington 99155.

Director, Fort Hall Service Unit, Not-Tsoo Gah-Nee Health Center, P.O. Box 717, Fort Hall, Idaho 83203.

Director, Neah Bay Service Unit, Sophie Trettevick Indian Health Clinic, P.O. Box 410, Neah Bay, Washington 98357.

Director, Warm Springs Service Unit, Warm Springs Indian Health Center, P.O. Box 1209, Warm Springs, Oregon 97761.

Director, Wellpinit Service Unit, David C. Wyneecop Memorial Clinic, P.O. Box 357, Wellpinit, Washington 99040.

Director, Western Oregon Service Unit, Chemawa Indian Health Center, 3750 Chemawa Road, NE, Salem, Oregon 97305–1198.

Director, Yakama Service Unit, Yakama Indian Health Center, 401 Buster Road, Toppenish, Washington 98948.

Director, Tucson Area Indian Health Service, 7900 South “J”’ Stock Road, Tucson, Arizona 85746.

Director, Tuscon Area Indian Health Service, 7900 South “J” Stock Road, Tucson, Arizona 85746–9352.

Director, Pascua Yaqui Service Unit, Division of Public Health, 7900 South “J” Stock Road, Tucson, Arizona 85746.

Director, San Xavier Indian Health Center, 7900 South “J” Stock Road, Tucson, Arizona 85746.

Director, Sells Service Unit, Santa Rosa Indian Health Center, HC01, Box 8700, Sells, Arizona 85634.

Director, Sells Service Unit, Sells Indian Hospital, P.O. Box 548, Sells, Arizona 85634.

Director, Sells Service Unit, West Side Health Station, P.O. Box 548, Sells, Arizona 85634.

Dated: June 8, 2006.

Robert G. McSwain,
Deputy Director, Indian Health Service.

[FR Doc. 06–5410 Filed 6–14–06; 8:45 am]

BILLING CODE 4165–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of Inspector General

Program Exclusions: May 2006

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of May 2006, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject name, address

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