

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

Section of Draft Guidance/ Reporting Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
4.4.3.2 DMC reports of meeting minutes to the sponsor	370	2	740	1	740
5 Sponsor reporting to FDA on DMC safety-related recommendations	37	1	37	.5	18.5
Total					758.75

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

Reporting Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
4.1 and 6.4 SOPs for DMCs	37	1	37	8	296
4.4.3.2 DMC meeting records	370	1	370	2	740
Total					1,036

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: December 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Privacy Act System of 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. 09-17-0001, "Medical, Health and Billing Records." The amended and altered system of records makes only administrative edits and revisions as necessary.

DATES: The amended and altered system, which incorporates the comments received following the initial publication, shall become effective December 30, 2005.

FOR FURTHER INFORMATION: Contact Ms. Patricia Gowan, IHS Lead Health Information Management (HIM) Consultant (Acting), Office of Health Programs, Phoenix Area Office IHS, Two Renaissance Square, Suite 606, 40 North Central Avenue, Phoenix, AZ 85004 or via the Internet at Patricia.Gowan@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, in response to comments received following the initial publication in the **Federal Register** at 70 FR 49931 on August 25, 2005. The purpose of altering System No. 09-17-0001, "Health and Medical Records," is to enable the IHS to clarify that IHS also uses the records in the system to process, document, and monitor third-party payment billing and reimbursement claims, in addition to debt collection activities; to include contract health service records; to include several new and modified purposes and new and modified routine uses that are in line with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule provisions and Agency policy changes. IHS published the notification of the altered Privacy Act system of records in the **Federal Register** on August 25, 2005. During the comment period, IHS received several responses from the public. After a careful review of their concerns, IHS does not agree with the suggested changes and therefore has not revised the notice. One of the commentors suggested revising routine use #10 so that it would provide an exception that would enable IHS to disclose patient health information for public health purposes. IHS has decided not to accept the recommendation of this comment because the IHS already complies with state laws that specifically require disclosures of health

information for public health activities under the current routine use #7. In addition, the proposed routine use #10 modifies and replaces the current routine use #7 to allow disclosures "as authorized by law" which is a broader standard than the current "as required by law" standard. In fact, the particular example submitted by the commentor in support of the recommendation does not meet the public health authority and activities criteria of the HIPAA Privacy Rule. The Nevada State Pharmacy Board is not a public health authority and reporting such information to a state database appears to be primarily for law enforcement purposes. The Nevada statute also does not specifically require IHS or other Federal agencies to report to their database.

Another comment stated that "IHS consider changing the permissive word "may" to the mandatory word "shall" in regards to the proposed Routine Use Number 23." In response to the comment, IHS has decided to reject the comment based on the fact that routine use disclosures are not mandatory but are discretionary disclosures made by the appropriate IHS Privacy Act System Manager for which is defined in the Privacy Act of 1974, as amended, 5 U.S.C. 552a; and the OMB Privacy Act Implementation Guidelines and Responsibilities of July 9, 1975.

The revision or modification of various IHS and Federal Records addresses in Appendix 1 and Appendix 2 is necessary to this system of records as administrative edits or changes. In Appendix 1, the address for the Fort McDermitt Clinic under the Phoenix Area IHS was inadvertently omitted;

and under Appendix 2, the Federal Archives and Records Center located in Laguna Niguel, California has moved to Perris, California as noted by the IHS Records Officer.

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 changes following the initial publication at 70 FR 49931, August 25, 2005. With this notification, this system of records is effective December 30, 2005.

09-17-0001

SYSTEM NAME:

Medical, Health, and Billing Records Systems, HHS/IHS/OHP.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Indian Health Service (IHS) hospitals, health centers, school health centers, health stations, field clinics, Service Units, IHS Area Offices (Appendix 1), and Regional Federal Records Centers (Appendix 2). Automated, electronic and computerized records, including Patient Care Component (PCC) records, are stored at the Information Technology Support Center (ITSC), IHS, located in Albuquerque, New Mexico (Appendix 1). Records may also be located at contractor sites. A current list of contractor sites is available by writing to the appropriate System Manager (Area or Service Unit Director/Chief Executive Officer) at the address shown in Appendix 1.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals, including both IHS beneficiaries and non-beneficiaries, who are examined/treated on an inpatient and/or outpatient basis by IHS staff and/or contract health care providers (including tribal contractors).

CATEGORIES OF RECORDS IN THE SYSTEM:

Note: Records relating to claims by and against DHHS are maintained in the Administrative Claims System, 09-90-0062, HHS/OS/OGC. Such claims include those arising under the Federal Torts Claims Act, Military Personnel and Civilian Employees Claims Act, Federal Claims Collection Act, Federal Medical Care Recovery Act, and Act for Waiver of Overpayment of Pay.

1. Health and medical records containing examination, diagnostic and treatment data, proof of IHS eligibility, social data (such as name, address, date of birth, Social Security Number (SSN), tribe), laboratory test results, and dental, social service, domestic violence, sexual

abuse and/or assault, mental health, and nursing information.

2. Follow-up registers of individuals with a specific health condition or a particular health status such as cancer, diabetes, communicable diseases, suspected and confirmed abuse and neglect, immunizations, suicidal behavior, or disabilities.

3. Logs of individuals provided health care by staff of specific hospital or clinic departments such as surgery, emergency, obstetric delivery, medical imaging, and laboratory.

4. Surgery and/or disease indices for individual facilities that list each relevant individual by the surgery or disease.

5. Monitoring strips and tapes such as fetal monitoring strips and EEG and EKG tapes.

6. Third-party reimbursement and billing records containing name, address, date of birth, dates of service, third party insurer claim numbers, SSN, health plan name, insurance number, employment status, and other relevant claim information necessary to process and validate third-party reimbursement claims.

7. Contract Health Service (CHS) records containing name, address, date of birth, dates of care, Medicare or Medicaid claim numbers, SSN, health plan name, insurance number, employment status, and other relevant claim information necessary to determine CHS eligibility and to process CHS claims.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Departmental Regulations (5 U.S.C. 301); Privacy Act of 1974 (5 U.S.C. 552a); Federal Records Act (44 U.S.C. 2901); Section 321 of the Public Health Service Act, as amended (42 U.S.C. 248); Section 327A of the Public Health Service Act, as amended (42 U.S.C. 254a); Snyder Act (25 U.S.C. 13); Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*); and the Transfer Act of 1954 (42 U.S.C. 2001-2004).

PURPOSES:

The purposes of this system are:

1. To provide a description of an individual's diagnosis, treatment and outcome, and to plan for immediate and future care of the individual.
2. To provide statistical data to IHS officials in order to evaluate health care programs and to plan for future needs.
3. To serve as a means of communication among members of the health care team who contribute to the individual's care; e.g., to integrate information from field visits with records of treatment in IHS facilities and with non-IHS health care providers.

4. To serve as the official documentation of an individual's health care.

5. To contribute to continuing education of IHS staff to improve the delivery of health care services.

6. For disease surveillance purposes. For example:

(a) The Centers for Disease Control and Prevention (CDC) may use these records to monitor various communicable diseases;

(b) The National Institutes of Health (NIH) may use these records to review the prevalence of particular diseases (e.g., malignant neoplasms, diabetes mellitus, arthritis, metabolism, and digestive diseases) for various ethnic groups of the United States; or

(c) Those public health authorities that are authorized by law may use these records to collect or receive such information for purposes of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death and the conduct of public health surveillance, investigations, and interventions.

7. To compile and provide aggregated program statistics. Upon request of other components of the Department of Health and Human Services (DHHS), IHS will provide statistical information, from which individual/personal identifiers have been removed, such as:

(a) To the National Committee on Vital and Health Statistics (NCVHS) for its dissemination of aggregated health statistics on various ethnic groups;

(b) To the Assistant Secretary for Planning and Evaluation (ASPE), Health Policy to keep a record of the number of sterilizations provided by federal funding;

(c) To the Centers for Medicare & Medicaid Services (CMS) to document IHS health care covered by the Medicare and Medicaid programs for third-party reimbursement; or

(d) To the Office of Clinical Standards and Quality, CMS to determine the prevalence of end-stage renal disease among the American Indian and Alaska Native (AI/AN) population and to coordinate individual care.

8. To process and collect third-party claims and facilitate fiscal intermediary functions and to process debt collection activities.

9. To improve the IHS national patient care database by means of obtaining and verifying an individual's SSN with the Social Security Administration (SSA).

10. To provide information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of organs to

facilitate organ, eye, or tissue donation and transplant.

11. To provide information to individuals about treatment alternatives or other types of health-related benefits and services.

12. To provide information to the Food and Drug Administration (FDA) in connection with an FDA-regulated product or activity.

13. To provide information to correctional institutions as necessary for health and safety purposes.

14. To provide information to governmental authorities (e.g., social services or protective services agencies) on victims of abuse, neglect, sexual assault or domestic violence.

15. To provide information to the National Archives and Records Administration (NARA) in records management inspections conducted under the authority of 44 U.S.C. 2901 *et seq.*

16. To provide relevant health care information to funeral directors or representatives of funeral homes to allow necessary arrangements prior to and in anticipation of an individual's impending death.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

This system of records contains individually identifiable health information. The DHHS Privacy Act Regulations (45 CFR part 5b) and the Privacy Rule (45 CFR parts 160 and 164) issued pursuant to the Health Insurance Portability and Accountability Act (HIPAA) of 1996 apply to most health information maintained by IHS. Those regulations may place additional procedural requirements on the uses and disclosures of such information beyond those found in the Privacy Act of 1974 or mentioned in this system of records notice. An accounting of all disclosures of a record made pursuant to the following routine uses will be made and maintained by IHS for five years or for the life of the records, whichever is longer.

Note: Special requirements for alcohol and drug abuse patients: If an individual receives treatment or a referral for treatment for alcohol or drug abuse, then the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR part 2 may apply. In general, under these regulations, the only disclosures of the alcohol or drug abuse record that may be made without patient consent are: (1) To meet medical emergencies (42 CFR 2.51), (2) for research, audit, evaluation and examination (42 CFR 2.52 and 2.53), (3) pursuant to a court order (42 CFR 2.61–2.67), and (4) pursuant to a qualified service organization agreement, as defined in 42 CFR

2.11. In all other situations, written consent of the individual is usually required prior to disclosure of alcohol or drug abuse information under the routine uses listed below.

1. Records may be disclosed to Federal and non-federal (public or private) health care providers that provide health care services to IHS individuals for purposes of planning for or providing such services, or reporting results of medical examination and treatment.

2. Records may be disclosed to Federal, State, local or other authorized organizations that provide third-party reimbursement or fiscal intermediary functions for the purposes of billing or collecting third-party reimbursements. Relevant records may be disclosed to debt collection agencies under a business associate agreement arrangement directly or through a third party.

3. Records may be disclosed to state agencies or other entities acting pursuant to a contract with CMS, for fraud and abuse control efforts, to the extent required by law or under an agreement between IHS and respective state Medicaid agency or other entities.

4. Records may be disclosed to school health care programs that serve AI/AN for the purpose of student health maintenance.

5. Records may be disclosed to organizations deemed qualified by the Secretary of DHHS and under a business associate agreement to carry out quality assessment/improvement, medical audits, utilization review or to provide accreditation or certification of health care facilities or programs.

6. Records may be disclosed under a business associate agreement to individuals or authorized organizations sponsored by IHS, such as the National Indian Women's Resource Center, to conduct analytical and evaluation studies.

7. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual. No authorization, Form IHS 810, is required for the disclosure of protected health information (PHI) contained in the medical record, unless sensitive information (e.g., alcohol/drug abuse patient information, HIV/AIDS, STD, or mental health) is included.

8. Records may be disclosed for research purposes to the extent permitted by:

(a) Determining that the use(s) or disclosure(s) are met under 45 CFR 164.512(i), or

(b) Determining that the use(s) or disclosure(s) are met under 45 CFR 164.514(a) through (c) for de-identified PHI, and 5 U.S.C. 552a(b)(5), or

(c) Determining that the requirements of 45 CFR 164.514(e) for limited data sets, and 5 U.S.C. 552a(b)(5) are met.

9. Information from records, such as information concerning the commission of crimes, suspected cases of abuse (including child, elder and sexual abuse), neglect, sexual assault or domestic violence, births, deaths, alcohol or drug abuse, immunizations, cancer, or the occurrence of communicable diseases, may be disclosed to public health authorities or other appropriate government authorities, as authorized by Federal, State, tribal or local law or regulation of the jurisdiction in which the facility is located.

Note: In federally conducted or assisted alcohol or drug abuse programs, under 42 CFR part 2, disclosure of patient information for purposes of criminal investigations must be authorized by court order issued under 42 CFR 2.65, except that reports of suspected child abuse may be made to the appropriate state or local authorities under state law.

10. Information may be disclosed from these records regarding suspected cases of child abuse to:

(a) Federal, State or tribal agencies that need to know the information in the performance of their duties, and

(b) Members of community child protection teams for the purposes of investigating reports of suspected child abuse, establishing a diagnosis, formulating or monitoring a treatment plan, and making recommendations to the appropriate court. Community child protection teams are comprised of representatives of tribes, the BIA, child protection service agencies, the judicial system, law enforcement agencies and IHS.

11. IHS may disclose information from these records in litigations and/or proceedings related to an administrative claim when:

(a) IHS has determined that the use of such records is relevant and necessary to the litigation and/or proceedings related to an administrative claim and would help in the effective representation of the affected party listed in subsections (i) through (iv) below, and that such disclosure is compatible with the purpose for which the records were collected. Such disclosure may be made to the DHHS/ Office of General Counsel (OGC) and/or Department of Justice (DOJ), pursuant to an agreement between IHS and OGC, when any of the following is a party to litigation and/or proceedings related to an administrative claim or has an

interest in the litigation and/or proceedings related to an administrative claim:

(i) DHHS or any component thereof; or

(ii) Any DHHS employee in his or her official capacity; or

(iii) Any DHHS employee in his or her individual capacity where the DOJ (or DHHS, where it is authorized to do so) has agreed to represent the employee; or

(iv) The United States or any agency thereof (other than DHHS) where HHS/ OGC has determined that the litigation and/or proceedings related to an administrative claim is likely to affect DHHS or any of its components.

(b) In the litigation and/or proceedings related to an administrative claim described in subsection (a) above, information from these records may be disclosed to a court or other tribunal, or to another party before such tribunal in response to an order of a court or administrative tribunal, provided that the covered entity discloses only the information expressly authorized by such order.

12. Records may be disclosed under a business associate agreement to an IHS contractor for the purpose of computerized data entry, medical transcription, duplication services, or maintenance of records contained in this system.

13. Records may be disclosed under a personal services contract or other agreement to student volunteers, individuals working for IHS, and other individuals performing functions for IHS who do not technically have the status of agency employees, if they need the records in the performance of their agency functions.

14. Records regarding specific medical services provided to a unemancipated minor individual may be disclosed to the unemancipated minor's parent or legal guardian who previously consented to those specific medical services, to the extent permitted under 45 CFR 164.502(g).

15. Records may be disclosed to an individual having authority to act on behalf of an incompetent individual concerning health care decisions, to the extent permitted under 45 CFR 164.502(g).

16. Information may be used or disclosed from an IHS facility directory in response to an inquiry about a named individual from a member of the general public to establish the individual's presence (and location when needed for visitation purposes) or to report the individual's condition while hospitalized (e.g., satisfactory or stable), unless the individual objects to disclosure of this information. IHS may

provide the religious affiliation only to members of the clergy.

17. Information may be disclosed to a relative, a close personal friend, or any other person identified by the individual that is directly relevant to that person's involvement with the individual's care or payment for health care.

Information may also be used or disclosed in order to notify a family member, personal representative, or other person responsible for the individual's care, of the individual's location, general condition or death.

If the individual is present or otherwise available prior to use or disclosure, and is competent to make health care decisions;

(a) May use or disclose after the facility obtains the individual's consent,

(b) Provides the individual with the opportunity to object and the individual does not object, or

(c) It could reasonably infer, based on professional judgment, that the individual does not object.

If the individual is not present, or the opportunity to agree or object cannot practicably be provided due to incapacity or emergent circumstances, an IHS health care provider may determine, based on professional judgment, whether disclosure is in the individual's best interest, and if so, may disclose only what is directly relevant to the individual's health care.

18. Information concerning exposure to the HIV may be disclosed, to the extent authorized by Federal, State or tribal law, to the sexual and/or needle-sharing partner(s) of a subject individual who is infected with HIV under the following circumstances:

(a) The information has been obtained in the course of clinical activities at IHS facilities;

(b) IHS has made reasonable efforts to counsel and encourage the subject individual to provide information to the individual's sexual or needle-sharing partner(s);

(c) IHS determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and

(d) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices.

(e) IHS has advised the partner(s) to whom information is disclosed that they shall not re-disclose or use such information for a purpose other than that for which the disclosure was made.

19. Records may be disclosed to federal and non-federal protection and advocacy organizations (P&A) that serve AI/AN for the purpose of investigating incidents of abuse and neglect of individuals with developmental disabilities (including mental disabilities), as defined in 42 U.S.C. 10801-10805(a)(4) and 42 CFR 51.41-46, to the extent that such disclosure is authorized by law and the conditions of 45 CFR 1386.22(a)(2) are met.

20. Records of an individual may be disclosed to a correctional institution or a law enforcement official, during the period of time the individual is either an inmate or is otherwise in lawful custody, for the provision of health care to the individual or for health and safety purposes. Disclosure may be made upon the representation of either the institution or a law enforcement official that disclosure is necessary for the provision of health care to the individual, for the health and safety of the individual and others (e.g., other inmates, employees of the correctional facility, transport officers), and for facility administration and operations. This routine use applies only for as long as the individual remains in lawful custody, and does not apply once the individual is released on parole or placed on either probation or on supervised release, or is otherwise no longer in lawful custody.

21. Records including patient name, date of birth, SSN, gender and other identifying information may be disclosed to the SSA as is reasonably necessary for the purpose of conducting an electronic validation of the SSN(s) maintained in the record to the extent required under an agreement between IHS and SSA.

22. Disclosure of relevant health care information may be made to funeral directors or representatives of funeral homes in order to allow them to make necessary arrangements prior to and in anticipation of an individual's impending death.

23. Records may be disclosed to a public or private covered entity that is authorized by law or charter to assist in disaster relief efforts (e.g., the Red Cross and the Federal Emergency Management Administration (FEMA)), for purposes of coordinating information with other similar entities concerning an individual's health care, payment for health care, notification of the individual's whereabouts and his or her health status or death.

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

File folders, ledgers, card files, microfiche, microfilm, computer tapes, disk packs, digital photo discs, and automated, computer-based or electronic files.

RETRIEVABILITY:

Indexed by name, record number, and SSN and cross-indexed.

SAFEGUARDS:

Safeguards apply to records stored on-site and off-site.

1. *Authorized Users:* Access is limited to authorized IHS personnel, volunteers, IHS contractors, subcontractors, and other business associates in the performance of their duties. Examples of authorized personnel include: Medical records personnel, business office personnel, contract health staff, health care providers, authorized researchers, medical audit personnel, health care team members, and legal and administrative personnel on a need to know basis.

2. *Physical Safeguards:* Records are kept in locked metal filing cabinets or in a secured room or in other monitored areas accessible to authorized users at all times when not actually in use during working hours and at all times during non-working hours. Magnetic tapes, disks, other computer equipment (e.g., pc workstations) and other forms of personal data are stored in areas where fire and life safety codes are strictly enforced. Telecommunication equipment (e.g., computer terminal, servers, modems and disks) of the Resource and Patient Management System (RPMS) are maintained in locked rooms during non-working hours. Network (Internet or Intranet) access of authorized individual(s) to various automated and/or electronic programs or computers (e.g., desktop, laptop, handheld or other computer types) containing protected personal identifiers or personal health information (PHI) is reviewed periodically and controlled for authorizations, accessibility levels, expirations or denials, including passwords, encryptions or other devices to gain access. Combinations and/or electronic passcards on door locks are changed periodically and whenever an IHS employee resigns, retires or is reassigned.

3. *Procedural Safeguards:* Within each facility a list of personnel or categories of personnel having a demonstrable need for the records in the performance of their duties has been

developed and is maintained. Procedures have been developed and implemented to review one-time requests for disclosure to personnel who may not be on the authorized user list. Proper charge-out procedures are followed for the removal of all records from the area in which they are maintained. Records may not be removed from the facility except in certain circumstances, such as compliance with a valid court order or shipment to the Federal Records Center(s). Persons who have a need to know are entrusted with records from this system of records and are instructed to safeguard the confidentiality of these records. These individuals are to make no further disclosure of the records except as authorized by the system manager and permitted by the Privacy Act and the HIPAA Privacy Rule as adopted, and to destroy all copies or to return such records when the need to know has expired. Procedural instructions include the statutory penalties for noncompliance.

The following automated information systems (AIS) security procedural safeguards are in place for automated health and medical records maintained in the RPMS. A profile of automated systems security is maintained. Security clearance procedures for screening individuals, both Government and contractor personnel, prior to their participation in the design, operation, use or maintenance of IHS AIS are implemented. The use of current passwords and log-on codes are required to protect sensitive automated data from unauthorized access. Such passwords and codes are changed periodically. An automated or electronic audit trail is maintained and reviewed periodically. Only authorized IHS Division of Information Resources staff may modify automated files in batch mode. Personnel at remote terminal sites may only retrieve automated or electronic data. Such retrievals are password protected. Privacy Act requirements, HIPAA Privacy Rule and Security requirements and specified AIS security provisions are specifically included in contracts and agreements and the system manager or his/her designee oversee compliance with these contract requirements.

4. *Implementing Guidelines:* DHHS Chapter 45-10 and supplementary Chapter PHS.hf: 45-10 of the General Administration Manual; DHHS, "Automated Information Systems Security Program Handbook," as amended; DHHS IRM Policy HHS-IRM-2000-0005, "IRM Policy for IT Security for Remote Access"; OMB Circular A-130 "Management of Federal

Information Resources"; HIPAA Security Standards for the Protection of Electronic Protected Health Information, 45 CFR 164.302 through 164.318; and E-Government Act of 2002 (Public Law 107-347, 44 U.S.C. Ch 36).

RETENTION AND DISPOSAL:

Patient listings which may identify individuals are maintained in IHS Area and Program Offices permanently. Inactive records are held at the facility that provided health and billing services from three to seven years and then are transferred to the appropriate Federal Records Center. Monitoring strips and tapes (e.g., fetal monitoring strips, EEG and EKG tapes) that are not stored in the individual's official medical record are stored at the health facility for one year and are then transferred to the appropriate Federal Records Center. (See Appendix 2 for Federal Records Center addresses). In accordance with the records disposition authority approved by the Archivist of the United States, paper records are maintained for 75 years after the last episode of individual care except for billing records. The retention and disposal methods for billing records will be in accordance with the approved IHS Records Schedule. The disposal methods of paper medical and health records will be in accordance with the approved IHS Records Schedule. The electronic data consisting of the individual personal identifiers and PHI maintained in the Resource and Patient Management System (RPMS) or any subsequent revised IHS database system should be inactivated once the paper record is forwarded to the appropriate Federal Records Center.

SYSTEM MANAGER(S) AND ADDRESS:

Policy Coordinating Official: Director, Office of Clinical and Preventive Services, Indian Health Service, Reyes Building, 801 Thompson Avenue, Suite 300, Rockville, Maryland, 20852-1627. See Appendix 1. The IHS Area Office Directors, Service Unit Directors/Chief Executive Officers and Facility Directors listed in Appendix 1 are System Managers.

NOTIFICATION PROCEDURE:

General Procedure: Requests must be made to the appropriate System Manager (IHS Area, Program Office Director or Service Unit Director/Chief Executive Officer). A subject individual who requests a copy of, or access to, his or her medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents.

Such a representative may be an IHS health professional. When a subject individual is seeking to obtain information about himself/herself that may be retrieved by a different name or identifier than his/her current name or identifier, he/she shall be required to produce evidence to verify that he/she is the person whose record he/she seeks. No verification of identity shall be required where the record is one that is required to be disclosed under the Freedom of Information Act (FOIA). Where applicable, fees for copying records will be charged in accordance with the schedule set forth in 45 CFR Part 5b.

Requests In Person: Identification papers with current photographs are preferred but not required. If a subject individual has no identification but is personally known to the designated agency employee, such employee shall make a written record verifying the subject individual's identity. If the subject individual has no identification papers, the responsible system manager or designated agency official shall require that the subject individual certify in writing that he/she is the individual whom he/she claims to be and that he/she understands that the knowing and willful request or acquisition of records concerning an individual under false pretenses is a criminal offense subject to a \$5,000 fine. If an individual is unable to sign his/her name when required, he/she shall make his/her mark and have the mark verified in writing by two additional persons.

Requests By Mail: Written requests must contain the name and address of the requester, his/her date of birth and at least one other piece of information that is also contained in the subject record, and his/her signature for comparison purposes. If the written request does not contain sufficient information, the System Manager shall inform the requester in writing that additional, specified information is required to process the request.

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

Parents, Legal Guardians and Personal Representatives: Parents of minor children and legal guardians or personal representatives of legally incompetent individuals shall verify their own identification in the manner described above, as well as their relationship to the individual whose record is sought. A copy of the child's birth certificate or court order establishing legal guardianship may be required if there is any doubt regarding

the relationship of the individual to the patient.

RECORD ACCESS PROCEDURES:

Same as Notification Procedures: Requesters may write, call or visit the last IHS facility where medical care was provided. 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 record, if any.

CONTESTING RECORD PROCEDURES:

Requesters may write, call or visit the appropriate IHS Area/Program Office Director or Service Unit Director/Chief Executive Officer at his/her address specified in Appendix 1, and specify the information being contested, 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:

Individual and/or family members, IHS health care personnel, contract health care providers, State and local health care provider organizations, Medicare and Medicaid funding agencies, and the SSA.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

Appendix 1—System Managers and IHS 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, Ft. Thompson Indian Health Center, P.O. Box 200, Ft. 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 57570.

Director, Sisseton-Wahpeton Service Unit, Sisseton Indian Hospital, P.O. Box 189, Sisseton, South Dakota 57262.

Director, Standing Rock Service Unit, Fort Yates Indian Hospital, P.O. Box J, Fort Yates, North Dakota 58538.

Director, Trenton-Williston Indian Health Center, P.O. Box 210, Trenton, North Dakota 58853.

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 57577.

Director, Yankton-Wagner Service Unit, Wagner Indian Hospital, 110 Washington Street, Wagner, South Dakota 57380.

Director, Youth Regional Treatment Center, P.O. Box #68, Mobridge, South Dakota 57601.

Director, Sac & Fox Health Center, 307 Meskwaki Road, Tama, Iowa 52339.

Director, Santee Health Center, 425 Frazier Avenue, N ST Street #2, Niobrara, Nebraska 68760.

Director, Alaska Area Native Health Service, 4141 Ambassador Drive, Suite 300, Anchorage, Alaska 99508-5928.

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 6008, 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, RR5, 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 889, Ignacio, Colorado 81137.
Director, Towac Ute Health Center, Towaoc, Colorado 81334.

Director, Jicarilla Indian Health Center, P.O. Box 187, Dulce, New Mexico 87528.

Director, Mescalero Service Unit, Mescalero Indian Hospital, P.O. Box 210, Mescalero, New Mexico 88340.

Director, Taos/Picuris Indian Health Center, P.O. Box 1956, 1090 Goat Springs Road, Taos, New Mexico 87571.

Director, Zuni Service Unit, Zuni Indian Hospital, Zuni, New Mexico 87327.

Director, Pine Hill Health Center, P.O. Box 310, Pine Hill, New Mexico 87357.

Director, Bemidji Area Indian Health Service: 522 Minnesota Avenue, NW., Bemidji, Minnesota 56601.

Director, Red Lake Service Unit, PHS Indian Hospital, Highway 1, Red Lake, Minnesota 56671.

Director, Leech Lake Service Unit, PHS Indian Hospital, 425 7th Street, NW., Cass Lake, Minnesota 56633.

Director, White Earth Service Unit, PHS Indian Hospital, P.O. Box 358, White Earth, Minnesota 56591.

Director, Billings Area Indian Health Service, P.O. Box 36600, 2900 4th Avenue North, Billings, Montana 59101.

Director, Blackfeet Service Unit, Browning Indian Hospital, P.O. Box 760, Browning, Montana 59417.

Director, Heart Butte PHS Indian Health Clinic, Heart Butte, Montana 59448.

Director, Crow Service Unit, Crow Indian Hospital, Crow Agency, Montana 59022.

Director, Lodge Grass PHS Indian Health Center, Lodge Grass, Montana 59090.

Director, Pryor PHS Indian Health Clinic, P.O. Box 9, Pryor, Montana 59066.

Director, Fort Peck Service Unit, Poplar Indian Hospital, Poplar, Montana 59255.

Director, Fort Belknap Service Unit, Harlem Indian Hospital, Harlem, Montana 59526.

Director, Hays PHS Indian Health Clinic, Hays, Montana 59526.

Director, Northern Cheyenne Service Unit, Lame Deer Indian Health Center, Lame Deer, Montana 59043.

Director, Wind River Service Unit, Fort Washakie Indian Health Center, Fort Washakie, Wyoming 82514.

Director, Arapahoe Indian Health Center, Arapahoe, Wyoming 82510.

Director, Chief Redstone Indian Health Center, Wolf Point, Montana 59201.

Director, California Area Indian Health Service, John E. Moss Federal Building, 650 Capitol Mall, Suite 7-100, Sacramento, California 95814.

Director, Nashville Area Indian Health Service, 711 Stewart's Ferry Pike, Nashville, Tennessee 37214-2634.

Director, Catawba PHS Indian Nation of South Carolina, P.O. Box 188, Catawba, South Carolina 29704.

Director, Unity Regional Youth Treatment Center, P.O. Box C-201, Cherokee, North Carolina 28719.

Director, Navajo Area Indian Health Service, P.O. Box 9020, Highway 264, Window Rock, Arizona 86515-9020.

Director, Chinle Service Unit, Chinle Comprehensive Health Care Facility, P.O. Drawer PH, Chinle, Arizona 86503.

Director, Tsaile Health Center, P.O. Box 467, Navajo Routes 64 & 12, Tsaile, Arizona 86556.

Director, Rock Point Field Clinic, c/o Tsaile Health Center, P.O. Box 647, Tsaile, Arizona 86557.

Director, Pinon Health Station, Pinon, Arizona 86510.

Director, Crownpoint Service Unit, Crownpoint Comprehensive Health Care Facility, P.O. Box 358, Crownpoint, New Mexico 87313.

Director, Pueblo Pintado Health Station, c/o Crownpoint Comprehensive Health Care Facility, P.O. Box 358, Crownpoint, New Mexico 87313.

Director, Fort Defiance Service Unit, Fort Defiance Indian Hospital, P.O. Box 649, Intersection of Navajo Routes N12 & N7, Fort Defiance, Arizona 86515.

Director, Nahata Dziil Health Center, P.O. Box 125, Sanders, Arizona 86512

Director, Gallup Service Unit, Gallup Indian Medical Center, P.O. Box 1337, Nizhoni Boulevard, Gallup, New Mexico 87305.

Director, Tohatchi Indian Health Center, P.O. Box 142, Tohatchi, New Mexico 87325.

Director, Ft. Wingate Health Station, c/o Gallup Indian Medical Center, P.O. Box 1337, Gallup, New Mexico 87305.

Director, Kayenta Service Unit, Kayenta Indian Health Center, P.O. Box 368, Kayenta, Arizona 86033.

Director, Inscription House Health Center, P.O. Box 7397, Shonto, Arizona 86054.

Director, Dennehotso Clinic, c/o Kayenta Health Center, P.O. Box 368, Kayenta, Arizona 86033.

Director, Shiprock Service Unit, Northern Navajo Medical Center, P.O. Box 160, U.S. Hwy. 491 North, Shiprock, New Mexico 87420.

Director, Dziłth-Na-O-Dith-Hle Indian Health Center, 6 Road 7586, Bloomfield, New Mexico 87413.

Director, Teecnospos Health Center, P.O. Box 103, N5114 BIA School Road, Teecnospos, Arizona 86514.

Director, Sanostee Health Station, c/o Northern Navajo Medical Center, P.O. Box 160, Shiprock, New Mexico 87420.

Director, Toadlena Health Station, c/o Northern Navajo Medical Center, P.O. Box 160, Shiprock, New Mexico 87420.

Director, Teen Life Center, c/o Northern Navajo Medical Center, P.O. Box 160, Shiprock, New Mexico 87420.

Director, Oklahoma City Area Indian Health Service, Five Corporation Plaza, 3625 NW. 56th Street, Oklahoma City, Oklahoma 73112.

Director, Claremore Service Unit, Claremore Comprehensive Indian Health Facility, West Will Rogers Boulevard and Moore, Claremore, Oklahoma 74017.

Director, Clinton Service Unit, Clinton Indian Hospital, Route 1, Box 3060, Clinton, Oklahoma 73601-9303.

Director, El Reno PHS Indian Health Clinic, 1631A 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 74058-9247.

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, Sherman Indian High School, 9010 Magnolia Avenue, Riverside, California 92503.

Director, Elko Service Unit, Newe Medical Clinic, 400 "A" Newe View, Ely, Nevada 89301.

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, Keams 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, Utah and Ouray Service Unit, Fort Duchesne Indian Health Center, P.O. Box 160, Ft. 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, Arizona 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 Center, 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. Wynecoop 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 85746-9352.

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, HCO1, 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.

Appendix 2—Federal Archives and Records Centers

District of Columbia, Maryland Except U.S. Court Records for Maryland, Washington National Records Center, 4205 Suitland Road, Suitland, Maryland 20746-8001.

Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont, Federal Archives and Records Center, Frederick C. Murphy Federal Center, 380 Trapelo Road, Waltham, Massachusetts 02452-6399.

Northeast Region, Federal Archives and Records Center, 10 Conte Drive, Pittsfield, Massachusetts 01201-8230.

Mid-Atlantic Region and Pennsylvania, Federal Archives and Records Center, 14700 Townsend Road, Philadelphia, Pennsylvania 19154-1096.

Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee, Federal Archives and Records Center, 1557 St. Joseph Avenue, East Point, Georgia 30344-2593.

Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin and U.S. Court Records for the mentioned States, Federal Archives and Records Center, 7358 South Pulaski Road, Chicago, Illinois 60629-5898.

Michigan, Except U.S. Court Records, Federal Records Center, 3150 Springboro Road, Dayton, Ohio 45439-1883.

Kansas, Iowa, Missouri and Nebraska, and U.S. Court Records for the mentioned States, Federal Archives and Records Center, 2312 East Bannister Road, Kansas City, Missouri 64131-3011.

New Jersey, New York, Puerto Rico, and the U.S. Virgin Islands, and U.S. Court Records for the mentioned States and territories, 200 Space Center Drive, Lee's Summit, Missouri 64064-1182.

Arkansas, Louisiana, Oklahoma and Texas, and U.S. Courts Records for the mentioned States, Federal Archives and Records Center, P.O. Box 6216, Ft. Worth, Texas 76115-0216.

Colorado, Wyoming, Utah, Montana, New Mexico, North Dakota, and South Dakota, and U.S. Courts Records for the mentioned States, Federal Archives and Records Center, P.O. Box 25307, Denver, Colorado 80225-0307.

Northern California Except Southern California, Hawaii, and Nevada Except Clark County, the Pacific Trust Territories, and American Samoa, and U.S. Courts Records for the mentioned States and territories, Federal Archives and Records Center, 1000 Commodore Drive, San Bruno, California 94066-2350.

Arizona, Southern California, and Clark County, Nevada, and U.S. Courts Records for the mentioned States, Federal Archives and Records Center, 23123 Cajalco Road, Perris, California 93570-7298.

Washington, Oregon, Idaho and Alaska, and U.S. Courts Records for the mentioned States, Federal Archives and Records Center, 6125 Sand Point Way NE, Seattle, Washington 98115-7999.

Dated: December 22, 2005.

Charles W. Grim,

Assistant Surgeon General, Director, Indian Health Service.

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BILLING CODE 4165-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

A Single Ribozyme To Catalyze Both Trimming and Transacting Catalysis—Potential Therapeutic for HPV Infection and Cervical Cancer

Joseph A. DiPaolo (NCI) *et al.*,

U.S. Provisional Application No. 60/675,076 filed 25 April 2005 (HHS Reference No. E-142-2005/0-US-01),

Licensing Contact: Robert M. Joynes; 301/594-6565; joynesr@mail.nih.gov.

This technology relates to a potential therapeutic for treating human papillomavirus (HPV) infection as well as cervical cancer. It is acknowledged that HPV is the primary agent associated with cervical cancer. The life cycle of HPVs progresses with epithelial differentiation and may persist for decades. The E6 and E7 oncogenes are responsible for two viral proteins that target p53 and Rb. The persistence of E6 and E7 in cervical carcinomas has led to them being recognized as the hallmark of cervical carcinomas and makes them excellent targets for therapy. Previously, we reported an engineered hairpin ribozyme (R434) that caused down-regulation of HPV-16 E6/E7 mRNA and inhibited growth of both HPV-16 immortalized cells and tumor cells. To increase efficiency of R434 we constructed a ribozyme expression