

check, bank draft, or postal money order. Your payment can be mailed to: Food and Drug Administration, P.O. Box 70963, Charlotte, NC 28272-0963.

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: Wachovia Bank, Attn: Food and Drug Administration Lockbox 70963, 1525 West WT Harris Blvd., rm. NC0810, Charlotte, NC 28262. (Note: This Wachovia Bank address is for courier delivery only.)

Please make sure that the FDA post office box number (P.O. Box 70963) is written on the check, bank draft, or postal money order.

Wire transfer payment may also be used. Please reference your unique user fee ID number when completing your transfer. The originating financial institution usually charges a wire transfer fee between \$15.00 and \$35.00. Please ask your financial institution about the fee and include it with your payment to ensure that your fee is fully paid. The account information is as follows: New York Federal Reserve Bank, US Dept of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 5600 Fishers Lane, Rockville, MD 20857.

Application fees can also be paid online with an electronic check (ACH). FDA has partnered with the U.S. Department of the Treasury to utilize Pay.gov, a Web-based payment application, for online electronic payment. The Pay.gov feature is available on the FDA Web site after the user fee ID number is generated.

The tax identification number of the Food and Drug Administration is 53-0196965.

B. Establishment and Product Fees

FDA will issue invoices for establishment and product fees for FY 2010 under the new fee schedule in August 2009. Payment will be due on October 1, 2009. FDA will issue invoices in November 2010 for any products and establishments subject to fees for FY 2010 that qualify for fees after the August 2009 billing.

Dated: July 28, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Privacy Act of 1974; Report of Altered Systems of Records

AGENCY: Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA).

ACTION: Notice of Altered Systems of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, the Health Resources and Services Administration (HRSA) is proposing to alter four existing systems of records (SORs) for the reasons indicated below:

09-15-0002: Records of Patient's Personal Valuables and Monies, HHS/HRSA/BPHC

HRSA is updating the system location, categories of individuals covered by the system, storage, retrievability, safeguards, retention and disposal, system manager, and notification procedure. HRSA is also adding a new routine use, number 3 (breach notification language).

09-15-0003: Contract Physicians and Consultants, HHS/HRSA/BPHC

HRSA is updating the system location, categories of individuals covered by the system, categories of records in the system, authority for maintenance of the system, retention and disposal, and system manager. HRSA is also adding a new routine use, number 6 (breach notification language).

09-15-0007: Patient's Medical Record System Public Health Service Hospitals, HHS/HRSA/BPHC

HRSA is updating the system location (Appendix 2—Federal Records Centers), categories of individuals covered by the system, categories of records in the system, authority for maintenance of the system, purpose of the system, physical safeguards, retention and disposal, system manager, and notification procedure. HRSA is deleting four routine uses, numbers 6 (Bureau of Prisons (BP) to report results of examination and treatment of patients examined and/or treated for and on behalf of the BP), 7 (Federal, state or private health benefit plans for billing purposes), 14 (Disclosure may be made to a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. The contractor is required to maintain Privacy Act safeguards with respect to such records), and 19 (To

organizations or individuals with agreements to provide photocopying or medical record data abstracting services. (a) PBS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances:

1. The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors;

2. The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s);

3. The PBS employee or contractor 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

4. 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. (b) PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has, notified such sexual or needle-sharing partner(s). HRSA is also adding one new routine use, number 16 (breach notification language).

09-15-0028: Public Health Service Clinical Affiliation Trainee Records, HHS/HRSA/BPHC

HRSA is updating the system location, authority for maintenance of the system, retrievability, safeguards, retention and disposal, and system manager. HRSA is also deleting one routine use, number 2 (to representatives of medical/allied health training program accreditation of PHS Training Programs), and adding a new routine use, number 6 (breach notification language).

DATES: HRSA filed an altered system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Homeland Security and Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on *July 23, 2009*. To ensure all parties have adequate time in which to comment, the altered systems, including the routine uses, will become effective 30 days from

the publication of the notice or 40 days from the date it was submitted to OMB and Congress, whichever is later, unless HRSA receives comments that require alterations to this notice.

ADDRESSES: Please address comments to Associate Administrator, Health Resources and Services Administration, 5600 Fishers Lane, Room 17-105, Rockville, Maryland 20857. Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m. (Eastern Standard Time Zone), Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Renee Painter, Administrative Officer, National Hansen's Disease Program, Bureau of Primary Health Care, 1770 Physician's Park Drive, Room 113, Baton Rouge, Louisiana 70816; Telephone (225) 756-3773. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: HRSA's Bureau of Primary Health Care's National Hansen's Disease Program (NHDP) (formerly Gillis W. Long Hansen's Disease Center) relocated from Carville, Louisiana, to Baton Rouge, Louisiana. The proposed changes to the systems of records maintained at the NHDP are to update the system location, categories of individuals covered by the systems, categories of records in the systems, authority for maintenance of the systems, routine uses, retrievability, storage, safeguards, retention and disposal, system managers, and notification procedures.

Dated: July 9, 2009.

Mary K. Wakefield,
Administrator.

SYSTEM NUMBER:

09-15-0002.

SYSTEM NAME:

Record of Patients' Personal Valuables and Monies, HHS/HRSA/BPHC.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Hansen's Disease Program, 1770 Physician's Park Drive, Baton Rouge, Louisiana 70816.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals admitted to the National Hansen's Disease Program (NHDP).

CATEGORIES OF RECORDS IN THE SYSTEM:

Information regarding personal valuables such as watches or rings, and monies checked in by the patients for safe-keeping.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 321 of the Public Health Service Act.

PURPOSE(S):

The purpose of the system is to provide for the safekeeping of patients' valuables. Records may also be used by the HHS Audit Agency for audit purposes.

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

1. Disclosure may be made 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.

2. The Department may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when

a. HHS, or any component thereof; or
b. Any HHS employee in his or her official capacity; or

c. Any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or

d. The United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, the court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

3. To appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and necessary for that assistance.

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

• Storage: Valuables and monies (contents verified by the patient and a witness) are placed in an envelope by the patient. Name, hospital number, and list of contents are written on the envelope and on flap. It is sealed and receipt flap is given to the patient. The envelope is then placed in locked

cabinet or safe. Actions are documented in the patient's medical record.

• Retrievability: Presentation of receipt flap, name, and hospital number. Return of valuables is documented in the medical record.

• Safeguards:

1. Authorized Users: DNHDP personnel responsible for the security of valuables and monies.

2. Physical Safeguards: All documents are protected during lunch hours and nonworking hours in locked file cabinets or locked storage areas.

3. Procedural Safeguards: All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. Access to records is strictly limited to those staff members trained in accordance with the DHHS Chapter 45-13 and Chapter PHS.hf: 45-13 of the General Administration Manual.

RETENTION AND DISPOSAL:

Documentation within the medical record is retained indefinitely until authority to destroy medical records is received.

HOW DESTROYED:

Incinerator or shredding.

SYSTEM MANAGER(S) AND ADDRESS:

Medical Records Coordinator, National Hansen's Disease Program, 1770 Physician's Park Drive, Baton Rouge, Louisiana 70816.

NOTIFICATION PROCEDURE:

Write to the National Hansen's Disease Program, Medical Records Coordinator, 1770 Physician's Park Drive, Baton Rouge, Louisiana 70816. Individual must provide positive identification such as driver's license, passport, voter registration card, union card, or a written certification verifying his or her identity. Requesters should also reasonably specify the record contents being sought.

RECORD ACCESS PROCEDURES:

Same as notification procedures.

CONTESTING RECORD PROCEDURES:

Write to the official at the address specified in the notification procedures above, and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

RECORD SOURCE CATEGORIES:

Patient and admission record.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

SYSTEM NUMBER:

09–15–0003

SYSTEM NAME:Contract Physicians and Consultants,
HHS/HRSA/BPHC.**SECURITY CLASSIFICATION:**

None.

SYSTEM LOCATION:National Hansen's Disease Program,
1770 Physician's Park Drive, Baton
Rouge, Louisiana 70816.**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Medical and allied health professionals (*e.g.*, physicians, nurses, physical therapists, and dentists) who have contracted with the National Hansen's Disease Program to provide services to beneficiaries.

CATEGORIES OF RECORDS IN THE SYSTEM:

Duplicate of original contract and personal data qualifications. Original contracts developed by the National Hansen's Disease Program.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 320 of the Public Health Service Act, as amended (42 U.S.C. 247e), the National Hansen's Disease Program; section 321 of the Public Health Service Act, as amended (42 U.S.C. 248), Control and Management of Hospitals; and section 326 of the Public Health Service Act, as amended (42 U.S.C. 253), Medical services to Coast Guard, National Oceanic and Atmospheric Administration, and the Public Health Service.

PURPOSE(S):

To monitor contract negotiations and compliance, to review credentials, and to collect statistical data required to manage the program.

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

1. Disclosure may be made 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.
2. In the event that a system of records maintained by this agency 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, as a routine use, to the appropriate agency,

whether Federal, State or local, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

3. Where a contract between a component of the Department and a labor organization recognized under E.O. 11491 provides that the agency will disclose personal records relevant to the organization's mission, records in this system of records may be disclosed to such organization.

4. The Department may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) Any HHS employee in his or her official capacity; or (c) Any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) The United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, the court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

5. Disclosure may be made to State Boards of Medical Examiners and to equivalent State licensing boards of professional review actions which adversely affect the clinical privileges of health care professionals who either:

1. Are or were employed by the Federal Government;
2. Provide or have provided health care service under a fee-for-service contract with the Federal Government; or

3. Provide or have provided health care services on behalf of the Federal Government as a volunteer or as a visiting fellow.

Boards of Medical Examiners and equivalent State licensing boards are required by the Health Care Quality Improvement Act of 1986 and by the Medicare and Medicaid Patient and Program Protection Act of 1987 to report this information to the National Practitioner Data Bank.

6. To appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or

confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and necessary for that assistance.

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

- Storage: File folders.
- Retrievability: Name and contract number.
- Safeguards:
 1. Authorized Users: HHS medical and financial management staff and contracting personnel.
 2. Physical Safeguards: All documents are protected during lunch hours and nonworking hours in locked file cabinets or locked storage areas.
 3. Procedural Safeguards: All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. Access to records is strictly limited to those staff members trained in accordance with DHHS Chapter 45–13 and Chapter PHS.hf: 45–13 of the General Administration Manual.

RETENTION AND DISPOSAL:

Duplicate contracts: Held 1–3 years dependent upon renewal. Destroyed per authority General Records Schedule 5 and 7.

ORIGINAL CONTRACTS:

1. Transactions of more than 10,000: Destroy 6 years and 3 months after final payment.
2. Transactions of 10,000 or less: Destroy 3 years after final payment.

SYSTEM MANAGER(S) AND ADDRESS:

Contracting Officer, National Hansen's Disease Program, 1770 Physician's Park Drive, Baton Rouge, Louisiana 70816.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the System Manager at the address above. The individual must provide positive identification, such as driver's license, passport, voter registration card, or written certification verifying his or her identity. Requesters should also reasonably specify the record contents being sought.

RECORD ACCESS PROCEDURES:

Same as notification procedures.

CONTESTING RECORD PROCEDURES:

Write to the System Manager at the address specified above, and reasonably identify the record, specify the

information to be contested, and state the corrective action sought, with supporting justification.

RECORD SOURCE CATEGORIES:

Medical, allied health professionals and dentists.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

SYSTEM NUMBER:

09-15-0007

SYSTEM NAME:

Patients Medical Record System
Public Health Service Hospitals, HHS/
HRSA/BPHC.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

See Appendices 1 and 2. A list of sites where individually identifiable data is currently located is available upon request to the System Manager.

Appendix 1

A. Public Health Service Facilities:
Director, Public Health Service Health Data Center, 1770 Physicians Park Drive, Baton Rouge, Louisiana 70816.
B. Successor Organizations: Director, Johns Hopkins Medical Service, 3100 Wyman Park Drive, Baltimore, Maryland 21211. Administrator, Lutheran Medical Center, 2609 Franklin Boulevard, Cleveland, Ohio 44114. Administrator, Martins Point Health Center, 331 Veranda Street, Portland, Maine 04103. Director, Pacific Medical Center, 1200 12th Avenue South, Seattle, Washington 98144.

Appendix 2—Federal Records Centers

- Area served: Buffalo, New York OutPatient Clinic, San Juan, and Staten Island. Central Plains Federal Records Center, 200 Space Center Drive, Lee's Summit, Missouri 64064-1182.
- Area served: Chicago and Detroit. Federal Records Center, 7358 S. Pulaski Road, Chicago, Illinois 60629-5898.
- Area served: Cincinnati and Detroit. Federal Records Center, 3150 Springboro Road, Dayton, Ohio 45439-1883.
- Area served: Atlanta, Charleston, Jacksonville, Memphis, Miami, Mobile, Savannah and Tampa. Federal Records Center, 4712 Southpark Boulevard, Ellenwood, Georgia 30294.
- Area served: 090 section of Houston, New Orleans, Galveston and Nassau Bay. Federal Records Center, P.O. Box 6216, Fort Worth, Texas 76115.
- Area served: 512 section of Houston, New Orleans, Galveston/ Nassau Bay. Federal Records Center, 17501 W. 98th Street, Suite 47-48, Lenexa, Kansas 66219.

- Area served: San Diego and San Pedro. Federal Records Center, P.O. Box 6719, 23123 Cajalco Road, Perris, California 92570-7298.

- Area served: Philadelphia and Pittsburg. Federal Records Center, 14700 Townsend Road, Philadelphia, Pennsylvania 19154-1096.

- Area served: San Francisco and Honolulu. Federal Records Center, 1000 Commodore Drive, San Bruno, California 94066-2350.

- Area served: Honolulu and Portland, Oregon. Federal Records Center, 6125 Sand Point Way, NE., Seattle, Washington 98115-7999.

- Area served: Buffalo, DC, Norfolk, Port Arthur, St. Louis Space Park Memorial, Seattle, New Orleans, Tampa, San Francisco, Galveston, Seattle and Maryland. Washington National Records Center, 4205 Suitland Road, Suitland, Maryland 20746.

- Area served: Boston, Maine, Massachusetts, Kentucky and Indiana. Federal Records Center, 380 Trapelo Road, Waltham, Massachusetts 02154-6399.

- Area served: Individuals with Hansen's disease, examined and/or treated at the National Hansen's Disease Program (formerly Public Health Service Hospital), National Hansen's Disease Programs, 1770 Physician's Park Drive, Baton Rouge, Louisiana 70816.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Uniformed and non-uniformed individuals treated as inpatients in Public Health Service Hospitals.

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical examination, diagnostic and treatment data; information for proof of eligibility; social data such as address and birth date; disease registers, such as Hansen's disease and tumor and surgical procedure registers; treatment logs, medical summaries and correspondence (for example, family to doctor, doctor to doctor, doctor to clinic).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 320 of the Public Health Service Act, as amended (42 U.S.C. 247e), the National Hansen's Disease Program; and section 326 of the Public Health Service Act, as amended (42 U.S.C. 253), Medical Services to Coast Guard, National Oceanic and Atmospheric Administration, and Public Health Service.

PURPOSE(S):

The purposes of this system are:
1. To serve as a basis for planning patient care and for continuity in the evaluation of the patient's condition and

treatment to furnish documentary evidence of the course of the patient's medical evaluation, treatment and change in condition during the hospital stay, ambulatory care or emergency visit, or while being followed in a facility-based home care program;

2. To document communications between the responsible practitioner and any other health professional's contribution to the patient's care and treatment in order to assist in protecting the legal interests of the patient, the hospital or clinic, and responsible practitioners;

3. To provide data for use in facility management, continuing education, Department initiatives, quality assurance activities and research at the National Hansen's Disease Program, Baton Rouge, Louisiana.

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

Disclosure may be made to:

1. Any community health organization, government agency, private physician and/or company which has requested or arranged for an examination, treatment or care of an individual.

2. Army, Navy, Air Force to report results of examination or treatment of their uniformed service personnel.

3. Department of Transportation to report results of examination/treatment of their uniformed services personnel found to be suffering from conditions that render them hazardous to themselves or to others.

4. Department of Commerce to report results of examination/treatment of uniformed services and other personnel of that agency.

5. Immigration and Customs Enforcements (ICE) to report results of examination/treatment of aliens examined and treated for and in behalf of that agency.

6. U.S. Department of Labor, Office of Workers' Compensation Programs for persons claiming compensation benefits due to personal injury while employed by the Government.

7. Organizations such as Joint Commission on Accreditation of Hospitals for accreditation of hospitals and clinics, and American Medical Association for accreditation of resident training programs. Medical records are used to document quality of service by health care providers.

8. Health professions students serving an affiliation at the institution and their parent education program; students provide patient care and use medical records in performance of their duties.

9. Non-agency physicians providing continuing care to current and former

Public Health Service Beneficiaries, laboratories performing tests for the continuing care of these patients, and successor organizations providing health care in former Public Health Service hospitals and clinics.

10. Veterans Administration to assist uniformed service personnel, retirees and veterans to obtain medical care or benefits.

11. Disclosure may be made 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.

12. A record may be disclosed for a research purpose, when the Department: (a) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (b) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (c) has required the recipient to—(1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, and (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except—(A) in emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law; (d) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

13. Organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

14. Information regarding the commission of crimes or the reporting or occurrence of communicable diseases, tumors, child abuse, births, deaths, alcohol or drug abuse, etc. as

may be required by health providers and facilities, by state law, or regulation of the department of health or other agency of the state or its subdivision in which the facility is located. Disclosure may be made to organizations as specified by the state law or regulation such as birth and deaths to vital statistics agencies and crimes to law enforcement agencies. Disclosure of the contents of records which pertain to patient identity, diagnosis, prognosis or treatment of alcohol or drug abuse is restricted under the provisions of the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations 42 CFR part 2 as authorized by 21 U.S.C. 1175 and 42 U.S.C. 4582, as amended by Public Law 93–283. To the extent possible, identical restrictions are applied to the disclosure of the contents of records pertaining to individuals with other programs who are participating in employee counseling programs.

15. In the event of litigation where the defendant is

a. The Department, any component of the Department, or any employee of the Department in his or her official capacity;

b. The United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or

c. Any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending a claim against the Public Health Service based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual. Disclosure may be made to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

16. To appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and necessary for that assistance.

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

- Storage: File folders, magnetic tape, disk or laser optical media, punch cards, and microfilm.

- Retrievability: Indexed by name, register number, number control register, disease and operation, and uniformed services service number (which is the Social Security number (SSN)). Those records indexed by SSN are retrieved in accordance with section 7(a)(2)(B) of the Privacy Act.

- Safeguards:

1. Authorized Users: Health care practitioners, and other allied health personnel, medical and allied health students and administrative personnel for determination of eligibility for care and facility management; qualified research personnel with approved protocol; Public Health Service Commissioned Personnel Operations Division; and Public Health Service Claims Officer.

2. Physical Safeguards: Magnetic tapes, discs, other computer equipment and other forms of personal data are stored in areas where fire and life safety codes are strictly enforced. All documents are protected during lunch hours and nonworking hours in locked file cabinets in double-locked storage areas.

3. Procedural Safeguards: A password is required to access the terminal and a data set name controls the release of data only to authorized users. All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. Access to records is strictly limited to those staff members trained in accordance with Privacy Act safeguards. The contractor is required to maintain confidentiality safeguards with respect to these records. These safeguards are in accordance with DHHS Chapter 45–13 and supplementary Chapter PHS.hf: 45–13 of the General Administration Manual, and Part 6 of the DHHS Information Resources Management Manual. The Memorandums of Agreement between the successor organizations and the Public Health Service require the successor organizations to comply with the Privacy Act. Public Health Service and HHS guidelines have been provided to each successor organization.

RETENTION AND DISPOSAL:

1. Former Public Health Service Hospitals/Clinics: Destroyed 50 years after date of last treatment, inactive medical records for active duty uniformed service personnel and non-uniformed service personnel.

2. National Hansen's Disease Program: Retained at facility—not transferred to a Federal Records Center. Destroyed, as appropriate, after 50 years, or when no

longer needed for research purposes, as determined by the project leader or principal investigator.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Public Health Service Health Data Center, National Hansen's Disease Program, 1770 Physician's Park Drive, Baton Rouge, Louisiana 70816.

NOTIFICATION PROCEDURE:

To determine the existence of a record, write to: Public Health Service Health Data Center, National Hansen's Disease Program, 1770 Physician's Park Drive, Baton Rouge, Louisiana 70816.

If requesting records by mail, a written certification verifying identity must be provided. If appearing in person at the National Hansen's Disease Program, Baton Rouge, Louisiana, positive identification such as a driver's license, passport, or voter's registration card must be provided. An individual who requests access to a medical/dental record shall designate in writing, at the time the request is made, a responsible representative who will be willing to review the record and inform the subject individual of its contents. Finally, a parent or guardian who requests notification of access to a child's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own identity.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

CONTESTING RECORD PROCEDURES:

Contact the official at the address specified in the notification procedures above, and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

RECORD SOURCE CATEGORIES:

Individual, health care personnel, other hospitals and physicians, employers, social agencies, maritime unions, shipping companies.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

SYSTEM NUMBER:

09-15-0028

SYSTEM NAME:

Public Health Service Clinical Affiliation Trainee Records, HHS/HRSA/BPHC.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Hansen's Disease Program, 1770 Physicians Park Drive, Baton Rouge, Louisiana 70816.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Students in Public Health Service training programs or serving clinical affiliation in National Hansen's Disease Program.

CATEGORIES OF RECORDS IN THE SYSTEM:

Transcripts of past education, application for training, training program staff and clinical supervisor evaluations and progress reports, course grades and evidence of completion of training requirements.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 320 of the Public Health Service Act, as amended (42 U.S.C. 247e), the National Hansen's Disease Program; and section 327A of the Public Health Service Act, as amended (42 U.S.C. 254), Interdepartmental Work.

PURPOSE(S):

To provide communication between educational and supervisory staff for evaluation of trainees.

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

Disclosure may be made:
To Educational Program staff of affiliated college/university to provide reports of student trainee's progress in training;

1. To prospective employers for professional reference;
2. To professional boards or associations to certify the student's progress in or completion of training as required for professional license, registration certification, etc.
3. 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.

4. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when

- a. HHS, or any component thereof; or
- b. Any HHS employee in his or her official capacity; or
- c. Any HHS employee in his or her individual capacity where the

Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or

d. The United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, the court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

5. To appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and necessary for that assistance.

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

- Storage: File folders.
- Retrieval: By year of training and alphabetically by last name.
- Safeguards:
 - Authorized Users: Rehabilitation and Educational Services Coordinator, National Hansen's Disease Program, work and staff supervisors and administrative personnel.
 - Physical Safeguards: All documents are protected during lunch hours and nonworking hours in locked file cabinets and locked storage areas.
 - Procedural Safeguards: All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. Access to records is strictly limited to those staff members trained in accordance with DHHS Chapter 45-13 and Chapter PHS.hf: 45-13 of the General Administration Manual.

RETENTION AND DISPOSAL:

Retained 5 years, then destroyed per authority of General Records Schedule 1.29.

SYSTEM MANAGER(S) AND ADDRESS:

Rehabilitation and Educational Services Coordinator, National Hansen's Disease Program, 1770 Physician's Park Drive, Baton Rouge, Louisiana 70816.

NOTIFICATION PROCEDURE:

The individual should contact the Director, National Hansen's Disease Program, 1770 Physicians Park Drive, Baton Rouge, Louisiana 70816, and provide name, date of birth and approximate dates of training to allow positive identification of the record.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

CONTESTING RECORD PROCEDURES:

Contact the facility mentioned at the address specified in the notification procedures above, and reasonably identify the record, specify the information to be contested, and state corrective action sought, with supporting justification.

RECORD SOURCE CATEGORIES:

Individuals, clinical supervisors, instructors, training program staff and administrative personnel of facility and affiliated college/university.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

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BILLING CODE 4160-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0351]

Seafood Hazard Analysis and Critical Control Points Alliance for Education and Training (U18)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to receive and consider a single source application for the award of a cooperative agreement in fiscal year 2009 (FY09) to the University of Florida for the support of the Seafood Hazard Analysis and Critical Control Points (HACCP) Alliance for Education and Training. The goal of the Seafood HACCP Alliance for Education and Training is to provide partial support, periodic clerical assistance, and personnel travel to national and international events and committee meetings.

DATES: Important dates are as follows:

1. The application due date is August 24, 2009.

2. The anticipated start date is in September 2009.

3. The opening date is August 3, 2009.
4. The expiration date is August 25, 2009.

FOR FURTHER INFORMATION AND**ADDITIONAL REQUIREMENTS CONTACT:**

Center Contact: Barbara Kennedy, Center for Food Safety and Applied Nutrition (HFS-669), 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2056, e-mail: Barbara.Kennedy@fda.hhs.gov.

Scientific/Programmatic Contact: Stanley Serfling, Center for Food Safety and Applied Nutrition (HFS-325), 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2320, e-mail: stanley.serfling@fda.hhs.gov.

Grants Management Contact: Camille Peake, Division of Acquisition Support and Grants (HFA-500), Food and Drug Administration, 5630 Fishers Lane, rm. 2139, Rockville, MD 20857, 301-827-7175, FAX: 301-827-7101, e-mail: Camille.Peake@fda.hhs.gov.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at <http://www.cfsan.fda.gov>.

SUPPLEMENTARY INFORMATION:**I. Funding Opportunity Description**

RFA-FD-09-014

Catalog of Federal Domestic Assistance Number: 93.103

A. Background

This FOA issued by the Office of Food Safety is soliciting a sole source grant application from University of Florida that proposes to provide funding in support of the Seafood HACCP Alliance for Education and Training. The Seafood HACCP Alliance remains the primary training and educational program supporting both regulatory and commercial governance of seafood and aquaculture product safety in the U.S.A. FDA actively participates with the Alliance and values their educational programs, which are essential and consistent with the prevailing federal mandates for HACCP education and training for commercial interests and inspectors in state and federal agencies. Our funds will provide partial support, periodic clerical assistance, and personnel travel to national and international events and committee meetings. These are pertinent to the Alliance Steering Committee objectives: Related supplies for communications and educational programs, telecommunication and computer

equipment for communications and production of educational materials, and possible part-time student labor for temporary assignments.

B. Research Objectives

The Seafood HACCP Alliance remains the primary training and educational program supporting both regulatory and commercial governance of seafood and aquaculture product safety in the U.S.A.

Leadership for the Alliance has been anchored in the Florida Sea Grant College Program based at the University of Florida since its beginning in 1994. The Alliance continues to function under the structure of a formal Steering Committee, which is built on a backbone of cooperative extension services aligned with representation from every pertinent federal agency, i.e., the U.S. Department of Agriculture, FDA, and the U.S. Department of Commerce, and the leading national seafood trade associations, i.e., National Fisheries Institute and the National Food Processors Association (recently changed to the Seafood Processors Association). This is a large, complex, and multifaceted effort that involves every pertinent state regulatory agency in the nation with protocols established through the Association of Food & Drug Officials (AFDO) and the six regional AFDO affiliates. The protocols include standards for approving training materials, trainers, and courses, and procedures for certifications and records for course graduates and evaluations. This organizational structure has involved every state in the nation and every cooperative extension program in the respective state universities. The Alliance is well recognized across the nation and about the world, and their educational services are expected. This network remains experienced and poised for continuing services.

In addition, FDA will support the general management of the Seafood HACCP Alliance as positioned in the Florida Sea Grant College Program at the University of Florida. The activities associated with Alliance Steering Committee objectives are multifaceted and involve numerous individuals about the nation working through the wide variety of programs. These working arrangements have been in operation and productive for well over 10 years.

This cooperative agreement will enable the University of Florida to continue and strengthen the valued utility and proven impacts of the existing Seafood HACCP Alliance for Education and Training through updates, additions, and new programs that address the changes in seafood