

where appropriate, coordinate services to individual women, children, and families.

Nurse Practitioner means a registered nurse who has successfully completed a formal program of study designed to prepare registered nurses to deliver primary health care, involving independent and interdependent decision making and direct accountability for clinical judgment, including the abilities to:

- Assess the health status of individuals and families through health and medical history taking, physical examination, ordering and interpreting diagnostic tests and making diagnoses;
- Institute and provide continuity of primary health care to individuals and families; and refer to other health care providers when appropriate;
- Prescribe treatments including pharmacological and non-pharmacological therapeutics, consistent with current standards of care;
- Provide instruction and counseling to individuals, families, and groups in the areas of promotion and maintenance of health and disease prevention, including involving such persons in planning for their health care; and
- Collaborate with other health care providers and agencies to provide, and where appropriate, coordinate services to individuals and families.

Nurse Practitioner or Nurse-Midwifery Program means a full-time educational program of study, as defined by the institution, (although students may be progressing through the program on a full-time or part-time basis), which meets the Guidelines prescribed herein. The program's objective is the education of nurses who will, upon completion of their studies in the program, be qualified to effectively provide primary health care in a variety of settings, including in homes, ambulatory care facilities, long-term care facilities, acute care, and other health care settings.

Post-Nursing Master's Certificate Program means a formal, post-graduate program for Registered Nurses with master's degrees that awards a certificate and academic credit for completion of the program of study as a Nurse Practitioner or Nurse-Midwife.

Preceptorship means a clinical learning experience in which the student is assigned to a faculty member or with oversight by program faculty to a designated preceptor who is a nurse practitioner or nurse-midwife or other health professional for specific aspects of the clinical learning experience. The preceptorship provides the student with practice experiences conducive to meeting the defined goals and objectives

of the particular clinical course. The preceptor is responsible for the daily teaching and assignment of individuals to be cared for, supervision, and participation in the evaluation of the nurse practitioner or nurse-midwifery student. The preceptor teaches, supervises, and evaluates the student and provides the student with an environment that permits observation, active participation, and management of primary health care. Before and during this preceptorship program faculty visits and assesses clinical learning sites and prepares clinical faculty/preceptors for teaching their students.

Primary Care means the provision of integrated, accessible health care services by clinicians, including nurse practitioners and nurse-midwives, who are accountable for addressing a large majority of personal health care needs within their scopes of practice, developing a sustained partnership with clients, and practicing in the context of family and communities. Critical elements also include accountability of clinicians and systems for quality of care, consumer satisfaction, efficient use of resources, and ethical behavior. Clients have direct access to an appropriate source of care, which continues over time for a variety of problems and includes needs for preventive services. Primary care and Primary Health Care are used interchangeably in this document. (Definition adapted from Barbara Starfield, *Primary Care Concept, Evaluation, and Policy*, Oxford University Press, New York, 1992 p. 4 and Institute of Medicine:

Moila S. Donaldson, Karl D. Yordy, Kathleen N., and Neal A. Vanselow, Editors, Committee on the Future of Primary Care, Division of Health Care Services, *Primary Care: America's Health in a New Era, Summary*, National Academy Press, Washington, DC, 1996, p. 23.)

Dated: October 27, 2003.

Elizabeth M. Duke,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Privacy Act of 1974; New System of Records

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notification of new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act, the Health Resources and Services Administration (HRSA) is publishing notice of a proposal to add a new system of records. The Smallpox Vaccine Injury Compensation Act of 2003 ("the Act"), amended title II of the Public Health Service Act (42 U.S.C. 202 *et seq.*) to provide benefits and other compensation for certain individuals with injuries resulting from the administration of smallpox countermeasures or as a result of vaccinia contracted through accidental vaccinia inoculation. The Act directs the Secretary, HHS, to establish administrative procedures to compensate certain individuals who sustained a covered injury as the direct result of the administration of smallpox vaccine, and certain individuals who sustained a covered injury as a direct result of accidental vaccinia inoculation through contact with the foregoing persons or with individuals accidentally inoculated by them. This system of records is required to comply with the implementation directives of the Act, Public Law 108-20. The records will be used for the Smallpox Vaccine Injury Compensation Program's (SVICP) planning, implementation, payment, evaluation, monitoring, and document storage purposes.

DATES: HRSA invites interested parties to submit comments on the proposed New System of Records on or before December 15, 2003. As of the date of the publication of this Notice, HRSA has sent a Report of New System of Records to Congress and to the Office of Management and Budget (OMB). The New System of Records will be effective 40 days from the date submitted to OMB unless HRSA receives comments that would result in a contrary determination.

ADDRESSES: Please address comments to Health Resources and Services Administration (HRSA) Privacy Act Officer, 5600 Fishers Lane, Room 14A-20, Rockville, Maryland 20857; telephone (301) 443-3780. This is not a toll-free number. Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Director, Office of Special Programs, Health Resources and Services Administration, 5600 Fishers Lane, Room 16C-17, Rockville, Maryland 20857; telephone (301) 443-3300. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: The Health Resources and Services Administration (HRSA) proposes to establish a new system of records: "The Smallpox Vaccine Injury Compensation Program, HHS/HRSA/OSP." The Act authorizes the creation of a Smallpox Vaccine Injury Compensation Program ("the Program") by directing the Secretary, HHS, to establish administrative procedures designed to provide benefits and other compensation to certain individuals who sustained a covered injury as the direct result of the administration of smallpox countermeasures, and certain individuals who sustained a covered injury as a direct result of accidental vaccinia inoculation through contact with the foregoing persons or with individuals accidentally inoculated by them. The Secretary will issue regulations implementing the Program. Individuals eligible to be considered for benefits and other compensation are:

1. (a) Health care workers, law enforcement officers, firefighters, security personnel, emergency medical personnel, other public safety personnel, or support personnel for such occupational specialties;

(b) Who are or will be functioning in a role identified in a State, local, or HHS smallpox emergency response plan approved by the Secretary;

(c) Who have volunteered for, and been selected to be members of, a smallpox emergency response plan prior to the time at which the Secretary publicly announces that an active case of smallpox has been identified either within or outside of the United States;

(d) To whom a smallpox vaccine is administered pursuant to such an approved plan during the effective period of the Declaration Regarding Administration of Smallpox Countermeasures ("the Declaration") issued by the Secretary, HHS, on January 24, 2003, and published in the **Federal Register** on January 28, 2003 (68 FR 4212); and

(e) Who sustain a covered injury, disability, illness, condition, or death as a direct result of receiving a covered countermeasure, including the smallpox vaccine, during the effective period of the Declaration; or

2. Certain individuals who sustain a covered injury, disability, illness, condition, or death as a direct result of vaccinia contracted through contact with one or more of the individuals described above or through contact with individuals accidentally inoculated by those individuals, during the specified time frame.

Subject to certain provisions, the Act authorizes benefits and other

compensatory payments, generally secondary to other available coverage, for the following:

(1) Reasonable and appropriate medical items and services to treat a covered injury.

(2) Lost employment income incurred as a result of a covered injury beyond the first five days of work missed unless the loss of employment extends beyond nine days, to a maximum of \$50,000 for any given year with a limited exception for persons with a permanent and total disability, through the age of 65.

(3) Death payment to survivors in circumstances in which death is determined to have resulted from a covered injury.

This system of records is required to comply with the implementation directive set forth in the Act. It will be used for Program planning, implementation, payment, evaluation, monitoring, and document storage purposes.

HRSA permits disclosure of the records to third parties pursuant to the following routine uses: The first routine use permits disclosure to a congressional office to allow subject individuals to obtain assistance from their representatives in Congress, if they wish to do so. The second routine use allows disclosure to Federal, State or local Government entities or to private entities for the purpose of their providing information relevant to medical or legal documentation required for determinations of eligibility or payment. The third routine use allows disclosure of records to contractors engaged by the Department who need access to the records in order to assist the Department, *e.g.*, expert consultants providing advice on requesters' eligibility for benefits and/or compensation. The fourth routine use allows disclosure of records to individuals and/or entities as necessary for the purposes of obtaining financial advice and providing benefits and other compensation to requesters approved for payment under the Program. The fifth routine use allows disclosure to a Federal agency administering aspects of the Program under a Memorandum of Agreement or assisting in the accomplishment of a Departmental function related to the purposes of the Program. The sixth routine use allows disclosure of records to the Department of Justice or a court, in the event of litigation. The seventh routine use allows disclosure to the appropriate Federal, State or local agency in the event of a violation of law. The eighth routine use allows disclosure of records for certain medical research purposes.

The following notice is written in the present tense, rather than the future tense, in order to avoid the unnecessary expenditure of public funds to republish the notice after the system becomes effective.

Dated: October 28, 2003.

Elizabeth M. Duke,
Administrator, Health Resources and Services Administration.

09-15-0065

SYSTEM NAME:

Smallpox Vaccine Injury Compensation Program, HHS/HRSA/OSP.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Office of Special Programs, Health Resources and Services Administration, 4350 East-West Highway, 10th Floor, Bethesda, Maryland 20814.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by the system are requesters and/or their representatives filing for benefits and other compensation under the Smallpox Vaccine Injury Compensation Program.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records consist of documents that may include general or congressional correspondence, requests, case number assignment, HHS responses, medical and legal documentation, employment documentation, documentation concerning services or benefits available from the United States or any third party (including any State or local governmental entity, private insurance carrier, or employer), payment information, and other related case processing documents.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Management of the system is authorized by Pub. L. 108-20, the Smallpox Emergency Personnel Protection Act of 2003, enacted April 30, 2003 (42 U.S.C. 239 *et seq.*).

PURPOSE(S):

The purpose of the system is to provide for benefits and other compensatory payments to certain individuals who sustained a covered injury as the direct result of the administration of smallpox countermeasures, and certain individuals who sustained a covered injury as a direct result of accidental vaccinia inoculation through contact with the foregoing persons or with individuals accidentally inoculated by them, during a specified time period.

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 a subject individual, in response to an inquiry from the congressional office made at the written request of that individual or his/her representative.
2. Disclosure may be made to Federal, State or local Government entities or to private entities for the purpose of their providing information relevant to medical or legal documentation required for determinations of eligibility or payment, provided that such disclosure is compatible with the purpose for which the records were collected.
3. Disclosure of records may be made to contractors engaged by the Department who need access to the records in order to assist the Department, *e.g.*, expert consultants providing advice on requesters' eligibility for benefits and/or compensation. All such individuals shall be required to maintain Privacy Act safeguards with respect to such records and return all records to HRSA.
4. Disclosure of records may be made to individuals and/or entities as necessary for the purposes of obtaining financial advice and providing benefits and other compensation to requestors approved for payment under the Program. All individuals and/or entities permitted disclosure for this use shall be required to maintain Privacy Act safeguards with respect to such records and return all records to HRSA.
5. Disclosure of records may be made to a Federal agency administering aspects of the Program, as authorized by a Memorandum of Agreement between the Secretary and the head of the Federal agency, or to another Federal agency assisting in the accomplishment of a Departmental function relating to the purposes of this system of records, provided that such disclosure is compatible with the purposes for which the records are collected.
6. Disclosure of records may be made 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 action, if successful, is likely to affect directly the operation of the Department or any of its components; or
 - (c) Any Department employee in his or her individual capacity where the Department of Justice (DoJ) has agreed to represent such employee, for

example, in defending an action against the Department in connection with such individual, disclosure may be made to DoJ to enable DoJ to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

7. Disclosure may be made 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, regulation, rule, or order issued pursuant thereto, the relevant records in the system of records may be referred to the appropriate agency, whether Federal, State or local, charged with the responsibility of investigating or prosecuting such violation, or charged with enforcing or implementing the statute, rule, regulation or order issued pursuant thereto, provided that such disclosure is compatible with the purpose for which the records were collected.

8. A record may be disclosed for a medical research purpose, only when the Department has determined:

- (a) That the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained;
- (b) That the research purpose is consistent with the purpose for which the Program was formed;
- (c) That the proposed research is scientifically sound in its methods and analyses and is likely to answer the proposed research question;
- (d) That the information sought is not available from any other source; and
- (e) That the record made available for medical research is redacted of all personal identifiers regarding injured individuals, health care practitioners and employers that are not essential for the accomplishment of the approved research purpose.

(f) The recipient must:

- (1) Establish strict limitations acceptable to the Department concerning the receipt and use of any patient-identifiable data;
- (2) Establish reasonable administrative, technical, and physical safeguards and/or protocols acceptable to the Department to protect the confidentiality of the data and to prevent the unauthorized use or disclosure of the record;
- (3) Remove or destroy the information that identifies an individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project; and

(4) Make no further use or disclosure of the record except when required by law.

(a) Further, the Department must secure and approve a written statement attesting to the recipient's understanding of, and agreement to abide by, these conditions of disclosure. Violation of these provisions is subject to penalties set forth under 5 U.S.C. 552a(i)(3) and any other applicable Federal law.

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

Records are maintained in file folders, on computer hard drives and/or disk packs, or in electronic media storage.

RETRIEVABILITY:

Retrievability is by name of the requester, and by case number assigned based on the order in which a request form is filed.

SAFEGUARDS:

1. Assign Responsibility for Security: Responsibility is assigned to a management official knowledgeable in the nature of the information and process supported by the Smallpox Vaccine Injury Compensation Program (SVICP) request and in the management, personnel, operational, and technical controls used to protect it.
2. Perform Risk Assessment: A risk assessment is to be conducted in conjunction with the development of, and prior to the approval of, the system design and will ensure that vulnerabilities, risks, and other security concerns are identified and addressed in the system design and throughout the life cycle of the project. This is consistent with the HHS Automated Information Systems Security Program Handbook (in particular Chapters V and X).
3. Develop SVICP Request Security Plan: Plan for the adequate security of the SVICP request, taking into account the security of all systems in which the request will operate. SVICP request security plans shall address request rules, training on use of the system, personnel security, contingency planning, technical controls, information sharing, and public access controls.
4. Review SVICP Request Controls: Perform an independent review or audit of the SVICP request security control in accordance with applicable Federal requirements and/or guidelines.
5. Authorize Processing: Ensure that a management official authorizes, in writing, confirmation that the security plan as implemented adequately secures

the SVICP request. The SVICP request must be authorized prior to operating and reauthorized in accordance with applicable Federal requirements and/or guidelines.

6. Implementation Guidelines: DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 of the General Administration Manual; the DHHS Automated Information Systems Security Program Handbook; and Appendix III to OMB Circular No. A-130; Appendix I, "Federal Agency Responsibilities for Maintaining Records About Individuals."

RETENTION AND DISPOSAL:

Records will be retained and disposed of in accordance with the Records Control Schedule of the Health Resources and Services Administration.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Special Programs, Health Resources and Services Administration, 5600 Fishers Lane, Room 16C-17, Rockville, Maryland 20857, or the Director's designee.

NOTIFICATION PROCEDURE:

Requests must be made to the System Manager.

Requests by mail: Requests for information and/or access to records received by mail must contain information providing the identity of the writer, and a reasonable description of the record desired, and whom it concerns. Written requests must contain the name and address of the requester, his/her date of birth and his/her signature for comparison purposes. Requests must be notarized to verify the identity of the requester, or the requester must certify that (s)he is the individual who (s)he claims to be and that (s)he understands that to knowingly and willfully request or acquire a record pertaining to another individual under false pretenses is a criminal offense under the Privacy Act subject to a \$5,000 fine (45 CFR 5b.5(b)(2)(ii)).

Requests in person or by telephone, electronic mail or facsimile cannot be honored.

RECORD ACCESS PROCEDURES:

Record access procedures are the same as notification procedures. Requesters should also provide a reasonable description of the contents of the record being sought. A parent or guardian who requests notification of, or access to, a minor's/incompetent person's medical 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 minor/incompetent person as well as his/her own identity. Records will be mailed only to the requester's address that is on file, unless a different address is demonstrated by official documentation.

CONTESTING RECORDS PROCEDURES:

To contest a record in the system, contact the System Manager at the address specified above and reasonably identify the record, specify the information being contested, and state the corrective action sought and the reason(s) for requesting the correction, along with supporting documentation to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Sources of records include, but are not limited to, requesters and/or their representatives under the Smallpox Vaccine Injury Compensation Program, and any other sources of information or documentation submitted by any other person or entity for inclusion in a request for the purpose of determining medical or legal eligibility for, or amount of benefits and/or compensation under, the Program (e.g., Federal, State, or local government or private health care entities participating in the administration of covered countermeasures under the Declaration).

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Proposed Collection; Comment Request; Customer Satisfaction Surveys

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for the opportunity for public comment on the proposed data collection projects, the Center for Scientific Review (CSR), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Customer Satisfaction Surveys.

Type of Information Collection

Request: Reinstatement.

Need and Use of Information

Collection: The information collected in

these surveys will be used by the Center for Scientific Review management and personnel: (1) To assess the quality of the modified operations and processes now used by CSR to review grant applications; (2) To assess the quality of service provided by CSR to our customers; (3) To examine and assess the effectiveness of the reorganization and reconfiguration of the peer review study committees based on customer input; (4) To develop new modes of operation based on customer need and customer feedback about the efficacy of implemented modifications. These surveys will almost certainly lead to quality improvement activities that will enhance and/or streamline CSR's operations. The major mechanism by which CSR will request input is through surveys. The survey for customers, i.e., past and present grant applicants, is generic, but will have slight variations tailored to the scientific subject category of each major Integrated Review Group (IRG). The next major reorganized IRGs to be evaluated consist of the Behavioral and Social Sciences peer review study sections. Surveys will be collected via Internet. Information gathered from these surveys will be presented to, and used directly by, CSR management to enhance the operations, processes, organization of, and services provided by the Center. Frequency of Response: The participants will respond once, unless there is a compelling reason for a subsequent survey.

Affected public: Universities, not-for-profit institutions, business or other for-profit, small businesses and organizations, and individuals.

Type of Respondents: Adult scientific professionals.

The annual reporting burden is as follows: It is estimated that the survey form will take 20 minutes to complete. The annual hour burden is, therefore, estimated to be 600 hours for approximately 1,800 respondents in FY 2004, 600 hours for approximately 1,800 respondents in FY 2005, 600 hours for approximately 1,800 respondents in FY 2006. Estimated costs to the respondents consist entirely of their time. Costs for time were estimated using a rate of \$40.00 per hour for principal investigators/grant applicants. The estimated annual cost burden for respondents for each year for which the generic clearance is requested is \$24,000 for FY 2004, \$24,000 for FY 2005, \$24,000 for FY 2006. No additional costs should be incurred by respondents. There will be dissemination and analysis costs for the survey originators.

Requests for Comments: Written comments and/or suggestions from the