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Calculi in Patients with Ileal Conduit Urinary Diversion," *Journal of Urology*, 123:345-347, 1980; Newhouse, J. H. and R. C. Pfister, "Therapy for Renal Calculi via Percutaneous Nephrostomy: Dissolution and Extraction," *Urology and Radiology*, 2:165-170, 1981; Klein, R. S., et al., "Hemiacidrin Renal Irrigation: Complications and Successful Management," *Journal of Urology*, 128:241-242, 1982.

Copies of the references cited above are on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen in that office between 9 a.m. and 4 p.m., Monday through Friday.

A Sponsor should submit an NDA in the usual format as described in 21 CFR 314.1, with particular attention to:

1. Manufacturing controls information, including stability of the solution.
2. A detailed summary and analysis of the published medical literature pertinent to the safety and effectiveness of the drug for the indications listed in the labeling.

3. Any other information the applicant has that bears on safety and effectiveness and appropriate directions for use.

4. Labeling that includes the indications for which FDA has found the drug safe and effective and that gives detailed directions on safe administration of the drug product.

Because the product is delivered directly to the site of action, bioavailability studies are not needed. Moreover, the extensive clinical experience obviates the need for animal toxicology studies other than those described in the published literature (included in the list of references provided in this notice).

FDA will be pleased to meet with potential sponsors to discuss the data and requirements. Manufacturers interested in submitting an NDA should contact Roger Gregorio at the address given above.

Dated: October 21 1983.

Marion J. Finkel,

Director, Orphan Products Development.

[FR Doc. 83-30510 Filed 11-9-83; 8:45 am]

BILLING CODE 4160-01-M

Social Security Administration

Privacy Act of 1974; Report of New System of Records

AGENCY: Social Security Administration (SSA), HHS.

ACTION: Notification of new system of records.

SUMMARY: In accordance with the Privacy Act (5 U.S.C. 552a(e)(4)), we are issuing public notice of our intent to establish a new system of records, the Beneficiary, Family, and Household Surveys, Records and Extracts System (Statistics), HHS/SSA/OP, 09-60-0211. We also are proposing routine uses of information that we will maintain in the system in accordance with 5 U.S.C. 552a(e)(11). We invite public comments on the proposed routine uses. The routine uses are discussed below.

DATES: We filed a report of new system of records with the President of the Senate, the Speaker of the House of Representatives, and the Director, Office of Management and Budget on October 27, 1983. The proposed system and the proposed routine uses will become effective as proposed without further notice on December 26, 1983, unless we receive comments on or before that date which would result in a contrary determination.

ADDRESSES: Interested individuals may comment on this proposal by writing to the SSA Privacy Officer, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235. All comments received will be available for public inspection at 3-F-1 Operations Building, at the above address.

FOR FURTHER INFORMATION CONTACT:

Ms. Emily Andrews, Special Assistant to the Director, Office of Research, Statistics and International Policy, Social Security Administration, Room 1121, Universal North Building, 1875 Connecticut Avenue, Washington, D.C. 20009, telephone: 202/673-5627.

SUPPLEMENTARY INFORMATION: We are proposing to establish this system so that we may collect, compile, and analyze data for use in program planning and evaluation, cost estimation, and production of general economic and program statistics for individuals, families, and households. The proposed system also will provide a base for validating other data sources which we currently use in policy analysis, and estimating the impact of proposed changes affecting the Social Security programs.

The major part of the system will consist of the New Beneficiary Survey (NBS) and other surveys of beneficiaries planned to be conducted under contract with SSA or another agency. The NBS will provide in-depth information on the sample of new participants in the Retirement, Survivors, and Disability Insurance (RSDI) components of the Social Security program. The interviews will collect information on the

beneficiaries' employment histories, income and assets, health conditions, program knowledge, marital and childcare histories, and similar socioeconomic data. The survey information is needed to provide program analysts with information about the current cohort of new program beneficiaries, who most closely represent future beneficiary cohorts.

We are proposing routine uses of information that will be maintained in the system. (A routine use disclosure is disclosure without the consent of a subject individual for a purpose which is compatible with the purpose for which we collect information.) The proposed routine uses provide for disclosure to third parties under contract with SSA or other agencies to perform research and statistical activities and to the Bureau of Census when it performs as a collecting agent or data processor for research and statistical purposes. The proposed routine uses are consistent with the provisions of the Privacy Act and our disclosure regulation (20 CFR Part 401). Section 401.310 of the regulation permits us to disclose information for a routine use when necessary to administer our program. The routine uses will be used solely for that purpose; e.g., we will disclose a limited amount of information to the Bureau of the Census and to contractors to collect and process statistical data directly related to the purpose served by this proposed system. The specific statements of routine use are as follows:

Disclosure may be made to a contractor under contract with SSA (or another agency with funds provided by SSA) for the performance of research and statistical activities directly related to the purpose served by this system of records.

Disclosure may be made to another government agency (such as the Bureau of the Census) serving as a data source, collecting agent or data processor for SSA in connection with the performance of research and statistical activities directly related to the purpose served by this system of records.

We will establish and maintain security and safeguards for this proposed system in accordance with the HHS Automated Data Processing (ADP) System Manual, Part 6, ADP System Security; standards established by the Bureau of Census for protection of data collected by that Bureau under title 13, United States Code; and standards established under provisions of 26 U.S.C. 6103(p)(4) regarding safeguards applicable to Federal tax return information. This will include maintaining the data in an enclosure attended by security guards, and using

locked files and passwords. Only authorized personnel who have a need for the data in the performance of their official duties and who have the appropriate identification and clearance will be permitted in areas containing records. In compliance with section 6103 of the Internal Revenue Code, no Federal tax return information contained in the proposed system of records will be disclosed by SSA to contractors or other agencies without the express approval of the Internal Revenue Service.

We are proposing this system of records in accordance with the Privacy Act and will collect and disclose information only as discussed above. We, therefore, do not anticipate any untoward effects on the personal privacy rights of individuals.

Dated: October 27, 1983.

Lou Enoff,

Acting Deputy Commissioner for Programs and Policies.

09-60-0211

SYSTEM NAME:

Beneficiary, Family, and Household Surveys, Records and Extracts System (Statistics), HHS/SSA/OP.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Records in this system may be located at the following locations:

Office of Research, Statistics and International Policy, Social Security Administration, 1875 Connecticut Avenue, NW., Washington, D.C. 20009;

Office of Systems, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235; Datacrown/SDL, 770 Brookfield Road, Ottawa, Ontario K1B 6J5, Canada; Parklawn, 5600 Fishers Lane, Rockville, Maryland 20857;

National Institute of Health, 9000 Rockville Pike, Bethesda, Maryland 20205; and

Bureau of Census, Washington, D.C. 20857.

Records also may be maintained at contractor sites (contact the system manager at the address below to obtain contractor addresses).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Samples of United States individuals and households presently or potentially receiving benefits from the Department of Health and Human Services (HHS) or other related Federal/State programs,

and other comparison individuals and households.

CATEGORIES OR RECORDS IN THE SYSTEM:

Basic demographic characteristics; marital and childcare histories; medical and disability information; information which relates to ability to work; living conditions; attitudes; socioeconomic information; earnings and employment history; financial assets and liabilities; real and personal property; benefit and pension information; use of medical and rehabilitative services; and participation in HHS and related Federal/State welfare programs.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Sections 702 and 1110 of the Social Security Act; and 13 U.S.C. 182.

PURPOSE:

This system will enable the SSA Office of Research Statistics and International Policy to collect, compile, and analyze data through survey and record extracts. Data collected through the surveys in their developmental and operational phases will be used within ORSIP for program planning and evaluation purposes, subject to applicable restrictions of title 13, U.S. Code, regarding data supplied by the Bureau of the Census; and 26 U.S.C. 6103(p)(4) regarding Federal tax return information. In compliance with section 6103 of the Internal Revenue Code, no Federal tax return information contained in the proposed system of records will be disclosed by SSA to contractors or other agencies without the express approval of the Internal Revenue Service. Information resulting from these efforts will provide HHS with: (1) Reliable estimates of future outlays under various program alternatives; (2) a base for validation of other data sources currently used in policy analysis; and (3) an evaluation of the Retirement, Survivors and Disability Insurance program.

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

Disclosure may be made for routine uses as indicated below:

1. To a contractor under contract with SSA or another agency for the performance of research and statistical activities directly related to the purpose served by this system of records.

2. To another government agency (such as the Bureau of the Census) serving as a data source, collecting agent, or data processor for SSA in connection with research and statistical

activities directly related to the purpose served by this system of records.

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

STORAGE:

Records may be stored on hard copy forms, discs, or magnetic tape.

RETRIEVABILITY:

Records will be indexed by Social Security number (SSN) during the matching steps but identifiers will not be retained by SSA after matching is completed.

SAFEGUARDS:

Safeguards have been established in accordance with the HHS Automated Data Processing (ADP) System Manual, Part 6, ADP System Security; standards established by the Bureau of Census for protection of data collected by the Census under title 13, U.S. Code; and in accordance with 26 U.S.C. 6103(p)(4), which provides for protection of Federal tax return information, principally earnings records. These safeguards include maintaining the data in an enclosure attended by security guards, and using locked files and passwords. Only authorized personnel who have a need for the data in the performance of their official duties and have the appropriate identification and clearance will be permitted in areas containing records.

Employees having access to records will receive prior notification of criminal sanctions for unauthorized disclosure of personal information about individuals. Magnetic tape and other files with personal identifiers will be retained in secured storage areas accessible only to authorized personnel who have a need to enter the areas in the performance of their official duties. Microdata files prepared for purposes of research and analysis will be stripped of personal identifiers and will be subject to procedural safeguards to assure anonymity.

RETENTION AND DISPOSAL:

Records with identifiers will be held in secured storage areas at SSA or at the Bureau of Census and will be disposed of as soon as they are determined to be no longer needed for analysis. Means of disposal will be appropriate to the records storage medium (e.g., erasure of tapes, shredding of printouts, etc.).

SYSTEM MANAGERS AND ADDRESS:

Director, Office of Research, Statistics, and International Policy, Social Security Administration, Room 1121 Universal North Building, 1875

Connecticut Avenue, Washington, D.C. 20009.

NOTIFICATION PROCEDURE:

This system will contain limited data selected for statistical analysis about which individuals normally would not be interested. Individuals inquiring about their records in SSA programs may wish to consult other SSA systems of records which contain more complete information.

However, if an individual wishes notification of or access to information that may be maintained in this system during processing stages, he/she should write to the system manager at the address above and provide his/her name, SSN, and a description of the information he/she is seeking. Also, to verify identity, the individual should provide his/her address and date of birth. Disclosure of the SSN is voluntary. If an individual is unable or unwilling to provide his/her SSN, he/she should provide date and place of birth and both parents' names to enable us to attempt to locate the number so that we can use it to attempt to locate any requested records.

RECORDS ACCESS PROCEDURES:

Same as notification procedures. Requesters should reasonably identify the information they are seeking. These procedures are in accordance with HHS regulations (45 CFR Part 5b).

CONTESTING RECORD PROCEDURES:

Same as notification procedures. Requesters should reasonably identify the record, specify the information they are contesting, and state the corrective action sought and the reasons for the correction with supporting justification. These procedures are in accordance with HHS regulations (45 CFR Part 5b).

RECORD SOURCE CATEGORIES:

Records in this system of records will be derived from other existing systems of records maintained by SSA for its retirement, disability, and income supplementation programs (e.g., the Master Beneficiary Record, 09-60-0090; the Supplemental Security Income Record, 09-60-0103; the Earnings Recording and Self-Employment Income System, 09-60-0059; the disability data systems, 09-60-0049 through 09-60-0051); Census survey data obtained from the Bureau of Census; Medicare records obtained from the HHS Health Care Financing Administration; and survey records from personal interviews.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 83-30428 Filed 11-9-83; 8:45 am]

BILLING CODE 4190-11-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

[Docket No. D-83-705]

**Amended Delegations of Authority—
Departmental Reorganization**

AGENCY: Office of the Secretary, HUD.

ACTION: Amended delegations of authority.

SUMMARY: On September 12, 1983, by Notice (48 FR 40958), the Secretary of Housing and Urban Development delegated to each of HUD's ten Regional Administrators all authority necessary to continue operating HUD's programs following a reorganization of HUD's Regional and Field offices which took effect beginning September 6, 1983. The Notice also authorized each Regional Administrator to redelegate, but limited the duration of such redelegations to 60 days (i.e., to November 5, 1983) in the anticipation that HUD would issue at least a preliminary revision of all Regional and Field redelegations by that time. Because such a preliminary revision has not proved necessary the 60 day limitation on Regional Administrators' redelegation is rescinded, pending the development of a permanent set of Regional and Field redelegations.

EFFECTIVE DATE: November 4, 1983.

FOR FURTHER INFORMATION CONTACT: David D. White, Assistant General Counsel for Administrative Law, Room 10254, Department of Housing and Urban Development, 451 Seventh Street, S.W., Washington, D.C. 20410. Telephone (202) 755-7137 (this is not a toll-free number).

Amendment of Delegation

The Delegation of Authority to Regional Administrators published at 48 FR 40958 (September 12, 1983) is amended by removing the second sentence of paragraph 2.

Dated: November 4, 1983.

Samuel R. Pierce, Jr.,
*Secretary of Housing and Urban
Development.*

[FR Doc. 83-30380 Filed 11-9-83; 8:45 am]

BILLING CODE 4210-32-M