DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration/Industry Exchange Conference and Workshop on Clinical Trial Requirements; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of the Commissioner, Office of Regulatory Affairs, Center for Drug Evaluation and Research, Center for Biologic Evaluation and Research, and Center for Devices and Radiological Health, in cooperation with the Pharmaceutical Quality Institute (PQI) is announcing a conference entitled ''Clinical Trials 2000.'' The conference concerns FDA's requirements for the conduct of clinical trials in support of new drug applications, abbreviated new drug applications, biologics license applications, premarket approval applications, and 510(k) product marketing applications. The conference is targeted towards those individuals engaged in patient recruitment for clinical trials; and those conducting, recording, reporting, and overseeing clinical trials including clinical investigators, supporting medical staff, institutional review board members, testing laboratories, software developers, sponsors, monitors, and contract research organizations.

Date and Time: Thursday, October 5, 2000, 8:30 a.m. to 4:45 p.m. and Friday, October 6, 2000, 8:30 a.m. to 12 noon.

Location: Doubletree Hotel, 1750 Rockville Pike, Rockville, MD.

Contact:

For information regarding this notice, workshop content, and who should attend: Diann Shaffer, Food and Drug Administration, Baltimore District, 900 Madison Ave., Baltimore, MD 21201–2199, 410–962–3590, FAX 410–962–2219 or e-mail: dshaffer@ora.fda.gov.

For registration information: Satish K. Laroia, Registrar, PQI, 33 Aspen Circle, Edison, NJ 08820, 973–812–9033, FAX 732–549–7487. As an alternative, the registration form and agenda can also be obtained from the Internet at www.fda.gov/cder/calendar/meeting/Clintrials2000.

Registration: The full conference and workshop registration fee is $349, or $325 each for three or more from the same affiliation registering at the same time. The fee includes breakfast on both days, all refreshment breaks, and lunch on the first day, and conference materials. One-day registration is also available (see registration form for details). For registration forms and other registration details contact Satish K. Laroia (address above). As an alternative, the registration form and agenda can be obtained from the Internet at www.fda.gov/cder/calendar. Registration is due by September 25, 2000. Space is limited, therefore, interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration. Persons needing hotel rooms at the Doubletree Hotel should call 301–468–1100 or 800–222–TREE and mention that they are attending the FDA/PQI workshop. A special rate is available until September 13, 2000, or until the room block is exhausted, whichever comes first.

If you need special accommodations due to a disability, please contact PQI at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The workshops are designed to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393) and discussed in the FDA Plan for Statutory Compliance, which include working more closely with stakeholders; maximizing the availability of, and clarifying information about the process for generating data for review and submissions; and ensuring access to needed scientific and technical expertise.

The workshops also are consistent with the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121), as outreach activities by Government agencies directed to small businesses.

The topics to be discussed include the following: (1) Overview and direction of FDA programs for regulating clinical research involving human drugs, biologics, and medical devices; (2) Anatomy of an FDA clinical investigator inspection; (3) What happens after an FDA inspection; (4) Clinical equipoise and recruitment for clinical trials; (5) Human subject protection; (6) Institutional review boards; (7) Special requirements for the Department of Health and Human Services funded studies; (8) Modification of FDA's Privacy Act systems notice; (9) Effective contract research organization-sponsor partnerships; (10) Industry perspective in case studies on contract research organization—sponsor partnerships; (11) Gene therapy products; (12) Cellular product studies; (13) Fraud within clinical trials; (14) Preparing for an FDA audit; (15) Computerized systems used in clinical trials; and (16) Providing regulatory submissions in electronic format.

Dated: August 11, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–21010 Filed 8–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Privacy Act of 1974; Report of New System

AGENCY: Department of Health and Human Services (HHS), Health Care Financing Administration (HCFA).

ACTION: Notice of New System of Records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system of records. The proposed system is titled ''Links of Social Security Administration (SSA) and Health Care Financing Administration (HCFA) Data (LOD), HHS/HCFA/OSP, 09–70–0069.'' HCFA proposes to establish a new system of records containing benefit information derived from Social Security Administration and HCFA records for samples of the United States population served by programs administered by both agencies.

The primary purpose of this system of records is to provide information that will be used to conduct research, perform policy analysis, and improve program management for populations served by both SSA and HCFA. Information in this system will support: research, evaluation, or epidemiological projects; special projects and activities performed within the agency or by a contractor or consultant; constituent requests made to a congressional representative; and litigation involving the agency.

We have provided background information about the proposed system in the ''Supplementary Information'' section below. Although the Privacy Act requires only that the ''routine use'' portion of the system be published for comment, HCFA invites comments on all portions of this notice. See **EFFECTIVE DATES** section for comment period.

EFFECTIVE DATES: HCFA filed a new system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the

Senate Committee on Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on August 4, 2000. To ensure that all parties have adequate time in which to comment, the new system of records, including routine uses, will become effective 40 days from the publication of the notice, or from the date it was submitted to OMB and the congress, whichever is later, unless HCFA receives comments that require alterations to this notice.

ADDRESSES: The public should address comments to: Director, Division of Data Liaison and Distribution (DDLD), HCFA, Room N2–04–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9:00 a.m.–3:00 p.m., eastern time zone.

FOR FURTHER INFORMATION CONTACT: Dave Baugh, Office of Strategic Planning, HCFA, Room C3–19–07, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. The telephone number is 410–786–7716.

SUPPLEMENTARY INFORMATION:

I. Description of the New System of Records

Statutory and Regulatory Basis for System of Records

Under section 1875(a) of the Social Security Act, (the Act) [42 U.S.C. 1395ii(a) and section 1110 of the Social Security Act (42 U.S.C. 1310), HCFA and SSA programs are inextricably linked as they were created under Federal law. Eligibility for Medicare is based on meeting minimum standards for covered employment for Social Security. In particular, Medicare disability coverage is directly linked to SSA determinations of eligibility for income payments under the Social Security Disability Income program. Likewise, for most States, a person's Medicaid eligibility is determined by their eligibility for SSA's Supplemental Security Income (SSI) program. Because of the interrelationship between these SSA and HCFA programs, information on program beneficiaries is housed in both agencies. Some information, such as reason for disability (for disabled enrollees) is housed only in SSA files. Other information, such as utilization and expenditures for health care services, is housed only in HCFA files. Therefore, some of the research, evaluation, policy analysis and program management activities can only be conducted if data are linked from the two agencies. In summary, the purpose of this notice is to allow disclosure of the linked data in this system only where these data are required to meet the research objectives. Examples of current research objectives include:

(A) Evaluations of the impact of the Federal welfare reform law, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA) on program enrollment and spending in HCFA and SSA.

(B) Studies of utilization and spending in Medicare and Medicaid for disabled enrollees based on their reason for disability.

(C) Studies to improve the quality of care delivered to Medicare disabled beneficiaries.

(D) Studies to promote the efficiency and effectiveness of acute and long-term care services received by persons eligible for both Medicare and Medicaid (the dual eligibles) including the development of improved risk-adjusted payment methods for dual eligibles.

II. Collection and Maintenance of Data in the System

A. Scope of the Data Collected

The system includes samples of the United States population served by HCFA and SSA programs and the following information for each: name, social security number, Medicaid identification number, health insurance claim number, eligibility for SSA and HCFA programs, and benefit record information.

B. Agency Policies, Procedures, and Restrictions on the Routine Use

The Privacy Act permits us to disclose information without an individual's consent if the information is to be used for a purpose, which is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a ''routine use.'' The government will only release LOD information that can be associated with an individual as provided for under ''Section III. Entities Who May Receive Disclosures Under Routine Use.'' Both identifiable and non-identifiable data may be disclosed under a routine use. Identifiable data includes individual records with LOD information and identifiers. Non-identifiable data includes individual records with LOD information and masked identifiers or LOD information with identifiers stripped out of the file.

Data may only be used under these routine uses for those projects approved in writing by both SSA and HCFA. We will only disclose the minimum personal data necessary to achieve the purpose of LOD. HCFA has the following policies and procedures concerning disclosures of information, which will be maintained in the system. In general, disclosure of information from the system of records will be approved only for the minimum information necessary to accomplish the purpose of the disclosure after HCFA:

(a) Determines that the use or disclosure is consistent with the reason that the data is being collected, *e.g.*, used to conduct research, perform policy analysis, and improve program management for populations served by SSA and HCFA.

(b) Determines:

(1) That the purpose for which the disclosure is to be made can only be accomplished if the record is provided in individually identifiable form;

(2) That the purpose for which the disclosure is to be made is of sufficient importance to warrant the effect and/or risk on the privacy of the individual that additional exposure of the record might bring; and

(3) That there is a strong probability that the proposed use of the data would in fact accomplish the stated purpose(s).

(c) Requires the information recipient to:

(1) Establish administrative, technical, and physical safeguards to prevent unauthorized use of disclosure of the record;

(2) Remove or destroy at the earliest time all individually-identifiable information; and

(3) Agree to not use or disclose the information for any purpose other than the stated purpose under which the information was disclosed.

(d) Determines that the data are valid and reliable.

III. Proposed Routine Use Disclosures of Data in the System

Entities Who May Receive Disclosures Under Routine Use

The routine use disclosures in this system may occur only to the following four (4) categories of entities (*i.e.*, the entities, which can get identifiable data only if we apply the policies and procedures in Section II. B. above). In addition, our policy will be to prohibit release even of non-identifiable data, beyond the four listed categories, if there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the population is so small that individuals who are familiar with the population could, because of the small size, use this information to deduce the identity). Disclosures may be made:

1. To an individual or organization for research, evaluation, or epidemiological

projects related to the prevention of disease or disability, or the restoration or maintenance of health, and for payment related projects.

We contemplate disclosing information under this routine use only in situations in which HCFA may enter into a contract, grant or cooperative agreement with project directors, contractors, grantees, or awardees of cooperative agreements to assist in accomplishing activities relating to purposes for this system of records.

2. To agency contractors, or consultants who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity.

We contemplate disclosing information under this routine use only in situations in which HCFA may enter into a contract or similar agreement with a contractor or consultant to assist in accomplishing activities relating to purposes for this system of records.

HCFA occasionally contracts out certain of its functions when this would contribute to effective and efficient operations. HCFA must be able to give a contractor and/or consultant whatever information is necessary for the contractor and/or consultant to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor and/or consultant from using or disclosing the information for any purpose other than that described in the contract and to return or destroy all information at the completion of the contract.

3. To a member of Congress or to a congressional staff member in response to an inquiry of the Congressional Office made at the written request of the constituent about whom the record is maintained.

Beneficiaries sometimes request the help of a Member of congress in resolving some issue relating to a matter before HCFA. The Member of congress then writes HCFA, and HCFA must be able to give sufficient information to be responsive to the inquiry.

4. To the Department of Justice (DOJ), court or adjudicatory body when:

(a) The agency or any component thereof, or

(b) Any employee of the agency in his or her official capacity, or

(c) Any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee, or

(d) The United States Government is a party to litigation or has an interest in such litigation, and by careful review, HCFA determines that the records are both relevant and necessary to the litigation.

Whenever HCFA is involved in litigation, or occasionally when another party is involved in litigation and HCFA's policies or operations could be affected by the outcome of the litigation, HCFA would be able to disclose information to the DOJ, court or adjudicatory body involved. A determination would be made in each instance that, under the circumstances involved, the purposes served by the use of the information in the particular litigation is compatible with a purpose for which HCFA collects the information.

IV. Safeguards

A. Authorized users: Personnel having access to the system have been trained in Privacy Act requirements. Employees who maintain records in the system are instructed not to release any data until the intended recipient agrees to implement appropriate administrative, technical, procedural, and physical safeguards sufficient to protect the confidentiality of the data and to prevent unauthorized access to the data. Records are used in a designated work area or work station and the system location is attended at all times during working hours.

To ensure security of the data, the proper level of class user is assigned for each individual user. This prevents unauthorized users from accessing and modifying critical data. The system database configuration includes five classes of database users:

- Database Administrator class owns the database objects, *e.g.,* tables, triggers, indexes, stored procedures, packages, and has database administration privileges to these objects,
- Quality Control Administrator class has read and write access to key fields in the database;
- Quality Indicator Report Generator class has read-only access to all fields and tables;
- Policy Research class has query access to tables, but are not allowed to access confidential patient identification information; and
- Submitter class has read and write access to database objects, but no database administration privileges.

B. Physical Safeguards: All server sites have implemented the following minimum requirements to assist in reducing the exposure of computer equipment and thus achieve an optimum level of protection and security for the LOD data:

Access to different areas on the Windows NT server is maintained through the use of file, directory and share level permissions. These different levels of access control provide security that is managed at the user and group level within the NT domain. The file and directory level access controls rely on the presence of an NT File System (NTFS) hard drive partition. This provides the most robust security and is tied directly to the file system. Windows NT security is applied at both the workstation and NT server levels.

C. Procedural Safeguards: All automated systems must comply with Federal laws, guidance, and policies for information systems security. These include, but are not limited to: the Privacy Act of 1974; the Computer Security Act of 1987; OMB Circular A–130, revised; HHS, Information Resource Management (IRM) Circular #10; HHS Automated Information Systems Security Program; the HCFA Information Systems Security Policy and Program Handbook, and other HCFA systems security policies. Each automated information system should ensure a level of security commensurate with the level of sensitivity of the data, risk, and magnitude of the harm that may result from the loss, misuse, disclosure, or modification of the information contained in the system.

V. Effect of the Proposed System of Records on Individual Rights

HCFA proposes to establish this system in accordance with the principles and requirements of the Privacy Act and will collect, use, and disseminate information only as prescribed therein. Data in this system will be subject to the authorized releases in accordance with the routine uses identified in this system of records.

HCFA will monitor the collection and reporting of LOD data. LOD information on all projects is completed and submitted to HCFA through standard systems located at the HCFA Data Center. HCFA will utilize a variety of onsite and offsite edits and audits to increase the accuracy of LOD data.

HCFA will take precautionary measures (see item IV. above) to minimize the risks of unauthorized access to the records and the potential harm to individual privacy or other personal or property rights. HCFA will collect only that information necessary to perform the system's functions. In addition, HCFA will make disclosure from the proposed system only with consent of the subject individual, or his/her legal representative, or in accordance with an applicable exception provision of the Privacy Act.

HCFA, therefore, does not anticipate an unfavorable effect on individual

privacy as a result of the disclosure of information relating to individuals.

Dated: August 4, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

09–70–0069

SYSTEM NAME:

''Links of Social Security Administration (SSA) and Health Care Financing Administration (HCFA) Data (LOD), HHS/HCFA/OSP, 09–70–0069.''

SECURITY CLASSIFICATION:

Level 3, Privacy Act Sensitive Data

SYSTEM LOCATION:

HCFA Data Center, 7500 Security Boulevard, North Building, First Floor, and Baltimore, Maryland 21244–1850.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Samples of the United States population served by programs administered by HCFA and SSA.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system includes the following information for each: name, social security number, Medicaid identification number, health insurance claim number, eligibility for SSA and HCFA programs, and benefit record information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 1875(a) of the Social Security Act [42 U.S.C. 1395ii(a)] and section 1110 of the Social Security Act [42 U.S.C. 1310].

PURPOSE (S) OF THE SYSTEM:

The primary purpose of this system of records is to provide information that will be used to conduct research, perform policy analysis, and improve program management for populations served by both SSA and HCFA. Information in this system will support research, evaluation, or epidemiological projects; special projects and activities performed within the agency or by a contractor or consultant; support constituent requests made to a congressional representative; and support litigation involving the agency.

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

The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose, which is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a ''routine use.'' The proposed routine use in this system meets the compatibility requirement of the Privacy Act. We are proposing to establish the following routine use disclosures of information, which will be maintained in the system:

1. To an individual or organization for research, evaluation, or epidemiological projects related to the prevention of disease or disability, or the restoration or maintenance of health, and for payment related projects.

2. To agency contractors, or consultants who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity.

3. To a member of congress or to a congressional staff member in response to an inquiry of the congressional office made at the written request of the constituent about whom the record is maintained.

4. To the Department of Justice (DOJ), court or adjudicatory body when:

(a) The agency or any component thereof, or

(b) Any employee of the agency in his or her official capacity, or

(c) Any employee of the agency in his or her individual capacity where the DOJ has

(d) Agreed to represent the employee, or the United States Government is,

a party to litigation or has an interest in such litigation, and by careful review, HCFA determines that the records are both relevant and necessary to the litigation.

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

STORAGE:

Computer diskette and on magnetic storage media.

RETRIEVABILITY:

Information can be retrieved by the social security number, Medicaid identification number, health insurance claim number and by name.

SAFEGUARDS:

HCFA has safeguards for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and systems security requirements. Employees who maintain records in the system are instructed not to release any data until the intended recipient agrees to implement appropriate administrative, technical, procedural, and physical safeguards sufficient to protect the confidentiality of the data and to prevent unauthorized access to the data.

In addition, HCFA has physical safeguards in place to reduce the exposure of computer equipment and thus achieve an optimum level of protection and security for the LOD system. For computerized records, safeguards have been established in accordance with HHS standards and National Institute of Standards and Technology guidelines, e.g., security codes will be used, limiting access to authorized personnel. System securities are established in accordance with HHS, Information Resource Management (IRM) Circular #10, Automated Information Systems Security Program; HCFA Automated Information Systems (AIS) Guide, Systems Securities Policies, and OMB Circular No. A–130 (revised), Appendix III.

RETENTION AND DISPOSAL:

Records are maintained in a secure storage area with identifiers. Records will be retained for 15 years.

SYSTEM MANAGER AND ADDRESS:

Director, Office of Strategic Planning, HCFA, Room C3–20–11, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. The telephone number is 410–786–7932.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, Medicaid identification number, health insurance claim number, address, date of birth, sex, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), and social security number (SSN). Furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay.

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2)).

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORD SOURCE CATEGORIES:

Sources of information contained in this records system include data collected from SSA systems of records, *e.g.*, Supplemental Security Record (09–60–0103), Master Beneficiary Record (09–60–0090), Disability Determination Files (09–60–0044), and Social Security Account Number Identification File (09–60–0058) and HCFA systems of records, *e.g.*, Medicaid Statistical Information System (09–70–6001), Current Beneficiary Survey (09–70–6002), Common Working Files (09–70–0526), National Claims History Files (09–70–0005) and Enrollment Data Base (09–70–0502).

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 00–21060 Filed 8–17–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Privacy Act of 1974; Report of New System

AGENCY: Department of Health and Human Services (HHS), Health Care Financing Administration (HCFA).

ACTION: Notice of New System of Records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system of records, ''Medicare Provider Analysis and Review (MEDPAR), HHS/HCFA/OIS, 09–70–0009.'' The MEDPAR will contain a summary of all services rendered to a Medicare beneficiary, from the time of admission through discharge, for a stay in an inpatient hospital and/or skilled nursing facility (SNF), Supplemental Security Income (SSI) eligibility information which HCFA receives from the Social Security Administration on Medicare beneficiaries who have had stays at inpatient hospitals and SNF, and enrollment data on Medicare beneficiaries.

The primary purpose of the system of records is to collect and maintain information for all services rendered during a stay at an inpatient hospital and/or SNF of Medicare beneficiaries, so as to enable HCFA and its contractors to facilitate research on the quality and effectiveness of care provided, update annual hospital Prospective Payment System (PPS) rates, and to recalculate Supplemental Security Income (SSI) ratios for hospitals that are paid under the PPS and serve a disproportionate share of low-income patients may be entitled to increased reimbursement under Part A of the Medicare program. Information retrieved from this system of records will also be disclosed to: support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant, provide system data to a hospital that has an appeal properly pending before the Provider Reimbursement Review Board (PRRB), or before an intermediary, assist another federal or state agency with information to enable such agency to administer a federal health benefits program, or to enable such agency to fulfill a requirement of a federal statute or regulation that implements a health benefits program funded in whole or in part with federal funds, support constituent requests made to a congressional representative, support litigation involving the agency, facilitate research on the quality and effectiveness of care provided, and, combat fraud and abuse in certain health benefits programs. We have provided background information about the modified system in the **SUPPLEMENTARY INFORMATION** section below. Although the Privacy Act requires only that HCFA provide an opportunity for interested persons to comment on the proposed routine uses, HCFA invites comments on all portions of this notice. See **EFFECTIVE DATES** section for comment period.

EFFECTIVE DATES: HCFA filed a new system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on August 14, 2000. To ensure that all parties have adequate time in which to comment, the new system of records, including routine uses, will become effective 40 days from the publication of the notice, or from the date it was submitted to OMB and the congress, whichever is later, unless HCFA receives comments that require alterations to this notice.

ADDRESSES: The public should address comments to: Director, Division of Data Liaison and Distribution (DDLD), HCFA, Room N2–04–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.–3 p.m., eastern time zone.

FOR FURTHER INFORMATION CONTACT: Anne Rudolph, Division of Acute Care, Plan and Providers Purchasing Policy Group (PPPPG), Center for Health Plans and Providers (CHPP), HCFA, Room C4–07–07, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. The telephone number is (410) 786–4546.

SUPPLEMENTARY INFORMATION:

I. Description of the Proposed System of Records

A. Statutory and Regulatory Basis For System of Records

Authority for maintainance of this system is given under sections 1102(a), 1871, and 1886(d)(5)(F) of the Social Security Act, (Title 42 United States Code (USC) sections 1302(a), 1395hh, and 1395ww(d)(5)(F)). Under section 1886 (d)(5)(F)(vi)(I) of the Social Security Act (the Act), 42 USC 1395ww (d)(5)(F)(vi)(I), hospitals that are paid under the PPS and serve a disproportionate share of low-income patients may be entitled to increased reimbursement under Part A of the Medicare program. Such disproportionate share hospital payments, which became effective for discharges occurring on or after May 1, 1986, depend in part on a hospital's ''SSI ratio.'' HCFA determines a hospital's SSI ratio by comparing, for the same period, (1) the hospital's total number of its Medicare inpatient days to (2) the hospital's ''Medicare/SSI days,'' *i.e.,* inpatient days attributable to Medicare patients who for such days were eligible for SSI payments under Title XVI of the Act. In determining a hospital's SSI ratio, HCFA uses information from the National Claims History (NCH), (HHS/HCFA/OIS 09–70–0005), in conjunction with SSI eligibility information that HCFA receives from the Social Security Administration. HCFA notifies each hospital of the total number of its Medicare/SSI days for a given federal fiscal year, or cost reporting period, but does not identify which of the hospital's Medicare patients had Medicare/SSI days.

II. Collection and Maintenance of Data in the System

A. Scope of the Data Collected

The MEDPAR contains information necessary for appropriate Medicare claim processing. It contains the Medicare health insurance claim (HIC) number, sex, race, age (no date of birth), zip code, state and county for Medicare beneficiaries who have received inpatient hospital and SNF services.