conditions of participation in the Medicaid program. This means that a state may not include costs or revenues in the DSH calculation which are attributable to services rendered in a separately licensed/certified entity, even if that entity is owned by the same institution. Such health services are not ''hospital services.''

Louisiana SPA 01–03 is not consistent with either section 1923(g)(1) of the Act or 42 CFR 440.20, because it would include as hospital services (for purposes of the DSH calculations) health services that were not within the regulatory definition of hospital services or otherwise characterized as hospital services. Therefore, the CMS Administrator, after consulting with the Secretary as required by 42 CFR 430.15, informed Louisiana that Louisiana SPA 01–03 was disapproved.

The notice to Louisiana announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Mr. David W. Hood,

Secretary, Louisiana Department of Health and Hospitals, 1201 Capitol Access Road, P.O. Box 91030, Baton Rouge, LA 70821–9030

Dear Mr. Hood: I am responding to your request for reconsideration of the decision to disapprove Louisiana State Plan Amendment (SPA) 01–03.

At issue is whether Louisiana may include in the calculation of disproportionate share hospital (DSH) payments the uncompensated costs of providing certain health care services that were not within the regulatory definition of hospital services and are not treated as hospital services for any other purpose. This amendment proposed including rural health clinic uncompensated care costs in a hospital's DSH payment calculation.

Section 1923(g)(1) of the Social Security Act (the Act) sets forth a hospital-specific limit on DSH payments and permits only the costs of ''hospital services'' furnished by a hospital to be included in calculating this limit. Medicaid outpatient hospital services are defined in Federal regulations at 42 CFR 440.20(a). This regulation requires the services to be provided by an institution that is licensed or formally approved as a hospital by an officially designated authority for state standard setting. The institution also must meet the conditions of participation in the Medicaid program. This means that a state may not include costs or revenues in the DSH calculation which are attributable to services rendered in a separately licensed/certified entity, even if that entity is owned by the same institution. Such health services are not ''hospital services.''

Louisiana SPA 01–03 is not consistent with either section 1923(g)(1) of the Act or 42 CFR 440.20 because it would include as hospital services (for purposes of the disproportionate share calculations) health services that were not within the regulatory definition of hospital services or otherwise characterized as hospital services. Therefore, the Centers for Medicare & Medicaid Services' Administrator, after consulting with the Secretary as required by 42 CFR 430.15, informed Louisiana that Louisiana SPA 01–03 was disapproved.

I am scheduling a hearing on your request for reconsideration to be held on December 19, 2001, at 10 a.m.; 1301 Young Street; Conference Room 1113; Dallas, Texas 75202.

If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed at 42 CFR, part 430.

I am designating Ms. Kathleen Scully-Hayes as the presiding officer. If these arrangements present any problems, please contact the presiding officer. In order to facilitate any communication which may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing. The presiding officer may be reached at (410) 786–2055.

Sincerely,

Thomas A. Scully,

Administrator.

(Sec. 1116 of the Social Security Act (42 U.S.C. 1316); 42 CFR 430.18)

(Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program)

Dated: November 5, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 01–28220 Filed 11–8–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of New System

AGENCY: Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) (formerly the Health Care Financing Administration).

ACTION: Notice of New System of Records (SOR).

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 ''Inpatient Rehabilitation Facilities Patient Assessment Instrument (IRF-PAI), HHS/CMS/CMSO, 09–70–1518.'' CMS proposes to establish a new system of records containing data on the physical, cognitive, functional, and psychosocial status of all patients receiving the services of Inpatient Rehabilitation Facilities (IRF) that are approved to participate in the Medicare program. Information will not be retained in this system for those individuals who have non-Medicare payment sources.

The primary purpose of the IRF system of records is to support the IRF prospective payment system (PPS) for payment of the IRF Medicare Part A fee-for-services furnished by the IRF to Medicare beneficiaries. Other purposes for the system of records are to: (1) Help validate and refine the Medicare IRF-PPS; (2) study and help ensure the quality of care provided by IRFs; (3) enable CMS and its agents to provide IRFs with data for their own quality assurance and, (4) ultimately, quality improvement activities; (5) support agencies of the State government, deeming organizations or accrediting agencies to determine, evaluate and assess overall effectiveness and quality of IRF services provided in the State; (6) provide information to consumers to allow them to make better informed selections of providers; (7) support regulatory and policy functions performed within the IRF or by a contractor or consultant; (8) support constituent requests made to a Congressional representative; (9) support litigation involving the facility; and (10) support research on the utilization and quality of inpatient rehabilitation services; as well as, evaluation, or epidemiological projects related to the prevention of disease or disability, or the restoration or maintenance of health for understanding and improving payment systems. 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, CMS invites comments on all portions of this notice. See ''Effective Dates section for comment period.

EFFECTIVE DATES: CMS 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 November 2, 2001. In any event, we will not disclose any information under a routine use until 40 days after publication. We may defer implementation of this system of records or one or more of the routine use statements listed below if we receive comments that persuade us to defer implementation.

ADDRESSES: The public should address comments to: Director, Division of Data Liaison and Distribution (DDLD), CMS, 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: Centers for Medicare & Medicaid Services (CMS), Director, Survey and Certification Group, 7500 Security Boulevard, S2–12–25, Baltimore, Maryland 21244–1850.

SUPPLEMENTARY INFORMATION:

I. Description of The New System of Records

A.Glossary of IRF–PAI Terms

1. IRF–PAI Data Set—The IRF–PAI data set is the patient assessment instrument that contains the sum of the identifiers and information.

2. Identifiers—Identifiers are the data elements that can be used to determine a patient's identity. These are: patient's name, social security number, Medicaid number, Medicare number, and patient identification number.

3. IRF–PAI Information IRF–PAI information includes the clinical items listed below and case mix adjusters.
Patient History
Social Cognition
Functional Status
Bowel/Bladder Management
Diagnoses
Medical Complexities
Pain Status
Oral/Nutrition Status
Functional Prognosis
Safety
Resources for Discharge

B. Statutory and Regulatory Basis For System of Records

Section 1886 (j) (2) (D) of the Social Security Act authorizes the Secretary to collect the data necessary to establish and administer the payment system.

C. Data/Information

The IRF–PAI information may contribute to development of the patient care plan by identifying patients at risk for adverse outcomes, such as weight loss, aspiration, or pressure ulcers, and ensure that these patients are monitored to prevent such outcomes which might negatively impact patients' likelihood of optimal rehabilitation. The data collected will generate quality indicators that would allow providers to assess their performance, and to compare it against benchmarks derived from standards of care or the performance of peers. The detection of quality of care problems will guide CMS, the State survey agencies and accrediting agencies in surveying IRFs. This information will be valuable to CMS in fulfilling its responsibility for validating surveys conducted by accrediting agencies. Also, IRF-PAI items may be useful in developing core measures that provide meaningful information on patient characteristics and outcomes across post-acute care settings. We will monitor the data obtained from the IRF-PAI to assess the effects of implementing the changes in the payment system on the quality of care provided in post-acute care settings.

The system of records will contain clinical assessment information (IRF-PAI records) for all Medicare Part A fee-for-service patients receiving the services of a Medicare approved IRF.

II. Collection and Maintenance of Data in the System

A. Scope of the Data Collected

The IRF–PAI will be completed on all Medicare Part A fee-for-service patients who receive services under Part A from an IRF. The IRF–PAI may be completed on Medicare+Choice enrollees, but it is not a requirement. The IRF–PAI data set includes identifiers and information (the specific areas have already been identified in the **SUPPLEMENTARY INFORMATION** section IA).

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 that 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 IRF–PAI information that can be associated with an individual patient 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 IRF–PAI information and identifiers. Non-identifiable data includes individual records with IRF–PAI information and masked identifiers or IRF–PAI information with identifiers stripped out of the file.

We will only disclose the minimum personal data necessary to achieve the purpose of the IRF–PAI. CMS has the following policies and procedures concerning disclosures of information that will be maintained in the system. In general, disclosure of information from the SOR will be approved only for the minimum information necessary to accomplish the purpose of the disclosure after CMS:

1. Determines that the use or disclosure is consistent with the reason that the data is being collected; e.g., developing and refining payment systems and monitoring the quality of care provided to patients.

2. Determines that:

a. The purpose for which the disclosure is to be made can only be accomplished if the record is provided in individually identifiable form;

b. 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

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

3. Requires the information recipient to:

a. Establish administrative, technical, and physical safeguards to prevent

b. Unauthorized use of disclosure of the record;

c. Remove or destroy at the earliest time all patient-identifiable information; and

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

4. Determines that the data are valid and reliable.

III. Proposed Routine Use Disclosures of Data in the System

A. Entities Who May Receive Disclosures Under Routine Use

These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974, under which CMS may release information from the IRF–PAI without the consent of the individual to whom such information pertains. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure is legally permissible, including but not limited to ensuring that the purpose of the disclosure is compatible with the purpose for which the information was collected. We are proposing to establish the following routine use disclosures of information maintained in the system:

1. To agency contractors, or consultants who have been contracted 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 CMS may enter into a contractual or similar agreement with a third party to assist in accomplishing agency business functions relating to purposes for this system of records.

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

2. To a Peer Review Organization (PRO) in order to assist the PRO to perform Title XI and Title XVIII functions relating to assessing and improving IRF quality of care. PROs will work with IRFs to implement quality improvement programs, provide consultation to CMS, its contractors, and to State agencies.

The PROs may use these data to support quality improvement activities and other PRO responsibilities as detailed in Title XI, Sections 1151–1164.

3. To another Federal or State agency:

a. To contribute to the accuracy of CMS's proper payment of Medicare benefits,

b. To enable such agency to administer a Federal health benefits program, or as necessary 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, or

c. To improve the state survey process for investigation of complaints related to health and safety or quality of care and to implement a more outcome oriented survey and certification program.

Other Federal or State agencies in their administration of a Federal health program may require IRF–PAI information in order to support evaluations and monitoring of quality of care for special populations or special care areas, including proper payment for services provided. Releases of information would be allowed if the proposed use(s) for the information proved compatible with the purpose for which CMS collects the information.

4. To an individual or organization for research on the utilization of inpatient rehabilitation services as well as evaluation or epidemiological projects related to the prevention of disease or disability, the restoration or maintenance of health, or for understanding and improving payment projects.

The IRF–PAI data will provide an opportunity for comprehensive research, evaluation and epidemiological projects regarding IRF patients. CMS anticipates that many researchers will have legitimate requests to use these data in projects that could ultimately improve the care provided to IRF patients and the policy that governs the care.

5. 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 CMS. The Member of Congress then writes CMS, and CMS must be able to give sufficient information to be responsive to the inquiry.

6. 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, CMS determines that the records are both relevant and necessary to the litigation.

Whenever CMS is involved in litigation, or occasionally when another party is involved in litigation and CMS's policies or operations could be affected by the outcome of the litigation, CMS 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 CMS collects the information.

7. To a CMS contractor (including, but not necessarily limited to fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such program.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual relationship or grant with a third party to assist in accomplishing CMS functions relating to the purpose of combating fraud and abuse.

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

8. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such programs.

Other agencies may require IRF–PAI information for the purpose of combating fraud and abuse in such Federally funded programs. Releases of information would be allowed if the proposed use(s) for the information proved compatible with the purposes of collecting the information.

9. To a national accrediting organization whose accredited facilities are presumed to meet certain Medicare requirements for inpatient hospital rehabilitation services (e.g., the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), the American Osteopathic Association (AOA) or the Commission on Accreditation of Rehabilitation Facilities (CARF)). Information will be released to these organizations only for those facilities that they accredit and that participate in Medicare.

At this time, CMS anticipates providing accrediting organizations with IRF–PAI information to enable them to target potential or identified problems during the organization's

accreditation review process of the facility.

10. To insurance companies, third party administrators (TPA), employers, self-insurers, managed care organizations, other supplemental insurers, non-coordinating insurers, multiple employer trusts, group health plans (i.e., health maintenance organizations (HMO) or a competitive medical plan (CMP)) with a Medicare contract, or a Medicare-approved health care prepayment plan (HCPP), directly or through a contractor, and other groups providing protection for their enrollees. Information to be disclosed shall be limited to Medicare entitlement data. In order to receive the information, they must agree to:

a. Certify that the individual about whom the information is being provided is one of its insured or employees, or is insured and/or employed by another entity for whom they serve as a third party administrator;utilize the information solely for the purpose of processing the individual's insurance claims; and

b. Safeguard the confidentiality of the data and prevent unauthorized access. Other insurers, CMP, HMO, and HCPP may require IRF–PAI information in order to support evaluations and monitoring of Medicare claims information of beneficiaries, including proper payment for services provided.

B. Additional Provisions Affecting Routine Use Disclosures

In addition, our policy will be to prohibit release even of non-identifiable data, except pursuant to one of the routine uses, if there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals who are familiar with the enrollees could, because of the small size, use this information to deduce the identity of the beneficiary).

This System of Records contains Protected Health Information as defined by the Department of Health and Human Services' regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, 65 FR 82462 as amended by 66 FR 12434). Disclosures of Protected Health Information authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.''

IV. Safeguards

The HHS IRF–PAI system will conform to applicable law and policy governing the privacy and security of Federal automated information systems. These include but are not limited to: the Privacy Act of 1984, Computer Security Act of 1987, the Paperwork Reduction Act of 1995, the Clinger-Cohen Act of 1996, and OMB Circular A–130, Appendix III, ''Security of Federal Automated Information Resources.'' HCFA has prepared a comprehensive system security plan as required by OMB Circular A–130, Appendix III. This plan conforms fully to guidance issued by the National Institute for Standards and Technology (NIST) in NIST Special Publication 800–18, ''Guide for Developing Security Plans for Information Technology Systems.'' Paragraphs A–C of this section highlight some of the specific methods that HCFA is using to ensure the security of this system and the information within it.

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 and 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 level. 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 Index 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 will implement 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 CMS system:

Access to all servers is to be controlled, with access limited to only those support personnel with a demonstrated need for access. Servers are to be kept in a locked room accessible only by specified management and system support personnel. Each server is to require a specific log-on process. All entrance doors are identified and marked. A log is kept of all personnel who were issued a security card, key and/or combination, which grants access to the room housing the server, and all visitors are escorted while in this room. All servers are housed in an area where appropriate environmental security controls are implemented, which include measures implemented to mitigate damage to Automated Information Systems (AIS) resources caused by fire, electricity, water and inadequate climate controls.

Protection applied to the workstations, servers and databases include:

- User Log-on—Authentication is to be performed by the Primary Domain Controller/Backup Domain Controller of the log-on domain.
- Workstation Names—Workstation naming conventions may be defined and implemented at the agency level.
- Hours of Operation—May be restricted by Windows NT. When activated all applicable processes will automatically shut down at a specific time and not be permitted to resume until the predetermined time. The appropriate hours of operation are to be determined and implemented at the agency level.
- Inactivity Lockout—Access to the NT workstation is to be automatically locked after a specified period of inactivity.
- Warnings—Legal notices and security warnings are to be displayed on all servers and workstations.
- Remote Access Security—Windows NT Remote Access Service (RAS) security handles resource access control. Access to NT resources is to be controlled for remote users in the same manner as local users, by utilizing Windows NT file and sharing permissions. Dial-in access can be granted or restricted on a user-by-user basis through the Windows NT RAS administration tool.

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; Information Resource Management (IRM) Circular #10; HHS Automated Information Systems Security Program; the CMS Information Systems Security Policy, Standards, and Guidelines Handbook; and other CMS 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. Effects of the New System on Individual Rights

CMS 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.

CMS will monitor the collection and reporting of IRF–PAI data. IRF–PAI information on patients is completed by the IRF and submitted to CMS through standard systems. Accuracy of the data is important since incorrect information could result in the wrong payment for services and a less effective process for assuring quality of services. CMS will utilize a variety of onsite and offsite edits and audits to increase the accuracy of IRF–PAI data.

CMS 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 of patients whose data is maintained in the system. CMS will collect only that information necessary to perform the system's functions. In addition, CMS 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.

CMS, therefore, does not anticipate an unfavorable effect on individual privacy as a result of maintaining this system of records.

Dated: November 2, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

09–70–1518.

SYSTEM NAME:

Inpatient Rehabilitation Facilities Patient Assessment Instrument (IRF PAI), HHS/CMS/CMSO.

SECURITY CLASSIFICATION:

Level 3, Privacy Act Sensitive.

SYSTEM LOCATION:

CMS Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244–1850 and CMS contractors and agents at various locations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system of records will contain clinical assessment information (IRF-PAI records) for all Medicare Part A fee-for-service patients receiving the services of a Medicare approved Inpatient Rehabilitation Facility (IRF). Information will be retained in the system of records only for those individuals whose payments come from Medicare.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system of records will contain individual-level demographic and identifying data, as well as clinical status data for patients with the payment source of traditional Medicare Part A fee-for-service and Medicare+Choice Enrollees.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 1886 (j) (2) (D) of the Social Security Act authorizes the Secretary to collect the data necessary to establish and administer the payments system

PURPOSE(S) OF THE SYSTEM:

The primary purpose of the IRF system of records is to support the IRF prospective payment system (PPS) for payment of the IRF Medicare Part A fee-for-services furnished by the IRF to Medicare beneficiaries. Other purposes for the system of records are to: (1) Help validate and refine the Medicare IRF-PPS; (2) study and help ensure the quality of care provided by IRFs; (3) enable CMS and its agents to provide IRFs with data for their own quality assurance and, (4) ultimately, quality improvement activities; (5) support agencies of the State government, deeming organizations or accrediting agencies to determine, evaluate and assess overall effectiveness and quality of IRF services provided in the State; (6) provide information to consumers to allow them to make better informed selections of providers; (7) support regulatory and policy functions performed within the IRF or by a contractor or consultant; (8) support constituent requests made to a Congressional representative; (9) support litigation involving the facility; and (10) support research on the utilization and quality of inpatient rehabilitation services; as well as, evaluation, or epidemiological projects related to the prevention of disease or disability, or the restoration or maintenance of health for understanding and improving payment systems.

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

These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974, under which CMS may release information from the IRF-PAI without the consent of the individual to whom such information pertains. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure is legally permissible, including but not limited to ensuring that the purpose of the disclosure is compatible with the purpose for which the information was collected. In addition, our policy will be to prohibit release even of non-identifiable data, except pursuant to one of the routine uses, if there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals who are familiar with the enrollees could, because of the small size, use this information to deduce the identity of the beneficiary). Be advised, this System of Records contains Protected Health Information as defined by the Department of Health and Human Services' regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, 65 FR 8462 as amended by 66 FR 12434). Disclosures of Protected Health Information authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.''

1. To agency contractors or consultants who have been contracted 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.

2. To a Peer Review Organization (PRO) in order to assist the PRO to

perform Title XI and Title XVIII functions relating to assessing and improving IRF quality of care. PROs will work with IRFs to implement quality improvement programs, provide consultation to CMS, its contractors, and to State agencies.

3. To another Federal or State agency:

a. To contribute to the accuracy of CMS's proper payment of Medicare benefits,

b. To enable such agency to administer a Federal health benefits program, or as necessary 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, or

c. To improve the state survey process for investigation of complaints related to health and safety or quality of care and to implement a more outcome oriented survey and certification program.

4. To an individual or organization for research on the utilization of inpatient rehabilitation services as well as evaluation or epidemiological projects related to the prevention of disease or disability, or the restoration or maintenance of health epidemiological, or for understanding and improving payment projects.

5. 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.

6. 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, CMS determines that the records are both relevant and necessary to the litigation and the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

7. To a CMS contractor (including, but not necessarily limited to fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such program.

8. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such programs.

9. To a national accrediting organization that has been approved for deeming authority for Medicare requirements for inpatient rehabilitation services (i.e., the Joint Commission for the Accreditation of Healthcare Organizations, the American Osteopathic Association and the Commission on Accreditation of Rehabilitation Facilities). Data will be released to these organizations only for those facilities that participate in Medicare by virtue of their accreditation status.

10. To insurance companies, third party administrators (TPA), employers, self-insurers, managed care organizations, other supplemental insurers, non-coordinating insurers, multiple employer trusts, group health plans (i.e., health maintenance organizations (HMO) or a competitive medical plan (CMP)) with a Medicare contract, or a Medicare-approved health care prepayment plan (HCPP), directly or through a contractor, and other groups providing protection for their enrollees. Information to be disclosed shall be limited to Medicare entitlement data. In order to receive the information, they must agree to:

a. Certify that the individual about whom the information is being provided is one of its insured or employees, or is insured and/or employed by another entity for whom they serve as a third party administrator;

b. Utilize the information solely for the purpose of processing the individual's insurance claims; and

c. Safeguard the confidentiality of the data and prevent unauthorized access

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

STORAGE:

All records are stored on magnetic media.

RETRIEVABILITY:

The Medicare records are retrieved by health insurance claim (HIC) number, social security number.

SAFEGUARDS:

CMS 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, CMS has physical safeguards in place to reduce the exposure of computer equipment and thus achieve an optimum level of protection and security for the CMS 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; CMS Information Systems Security, Standards Guidelines Handbook and OMB Circular No. A–130 (revised) Appendix III.

RETENTION AND DISPOSAL:

CMS will retain identifiable IRF–PAI data for a total period of 15 years.

SYSTEM MANAGER AND ADDRESSES:

Health Care Financing Administration, Center for Medicaid and State Operations, Director, Survey and Certification Group, 7500 Security Boulevard, S2–12–25, Baltimore, Maryland 2124–1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, health insurance claim number, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), address, age, and sex, 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:

Inpatient Rehabilitation Facilities—Patient Assessment Instrument.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 01–28219 Filed 11–8–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0335]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Food Labeling: Nutrition Labeling of Dietary Supplements on a ''Per Day'' Basis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by December 10, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Labeling: Nutrition Labeling of Dietary Supplements on a ''Per Day'' Basis

Section 403(q)(5)(F) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(F)) provides that dietary supplements must bear nutrition labeling in a manner that is appropriate for the product and that is specified in regulations issued by FDA. FDA issued regulations establishing the requirements for dietary supplements in nutrition labeling in 21 CFR 101.36 in the September 23, 1997, final rule (62 FR 49826). FDA published a proposed rule in the **Federal Register** of January 12, 1999 (64 FR 1765), to amend its nutrition labeling regulations for dietary supplements. This amendment would provide that the quantitative amount and the percentage of the daily value of a dietary ingredient may be voluntarily presented on a ''per day'' basis in addition to the required ''per serving'' basis. The proposed rule stated that this voluntary information may be provided if a dietary supplement label recommends that the dietary supplement be consumed more than once per day. These proposed provisions are in response to a citizen petition submitted by a manufacturer and marketer of dietary supplements. This proposed action would provide suppliers of dietary supplements flexibility to present additional label information voluntarily to consumers.

In the **Federal Register** of August 14, 2001 (66 FR 42663), the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Operating & Maintenance Costs	Total Hours
101.36(d)	85	10	850	0.25	$83,000	213

[1] There are no capital costs associated with this collection of information.

These estimates are based on agency communications with industry and FDA's knowledge of, and experience with, food labeling. FDA estimated in the September 23, 1997, final rule (62 FR 49826 at 49846) that there was a maximum of 850 suppliers of dietary supplements and that, on average, each supplier had 40 products whose labels required revision. FDA estimates that only 10 percent, or 85 of the dietary supplement suppliers, would revise the labels of their products to incorporate nutrition levels for the daily use of their products. FDA also estimates that daily use levels for nutrition information would generally be placed on at most 25 percent, or at most 10 of a firm's estimated 40 products, although this number would vary by firm based on the types of products that it produces. FDA also believes that the burden associated with the proposed disclosure of nutrition information on a daily use basis for dietary supplements would be a one-time burden for the small number of firms that would decide voluntarily to add this additional information to the labels for their products. FDA estimates that at least 90 percent of firms would coordinate the addition of daily use nutrition information with other changes in their labels, in which case the voluntary cost of transmitting the information to consumers in labeling would be subsumed almost entirely in the cost of these other voluntary or required labeling changes. The incremental cost for these 76 firms would be approximately $50 per label for 760 labels, or $38,000 total. For the remaining 9 firms that would not coordinate changes with other labeling changes, FDA estimates that the cost would be approximately $500 per label (64 FR 1765 at 1769) for 90 labels, or $45,000 total. The estimated total operating costs in table 1 of this