for the last paperwork clearance three years ago, are based primarily on OGE's experience with administration of the qualified trust program.

i. Trust Certificates

A. *Certificate of Independence:* Total filers (executive branch): 10; Private citizen filers (100%): 10; OGE-processed certificates (private citizens): 10; OGE burden hours (20 minutes/certificate): 3.

B. *Certificate of Compliance:* Total filers (executive branch): 35; Private citizen filers (100%): 35; OGE-processed certificates (private citizens): 35; OGE burden hours (20 minutes/certificate): 12; and

ii. Model Qualified Trust Documents

A. *Blind Trust Communications:* Total Users (executive branch): 35; Private citizen users (100%): 35; OGE-processed documents (private citizens): 210 (based on an average of six communications per user, per year); OGE burden hours (20 minutes/communication): 70.

B. *Model Qualified Blind Trust:* Total Users (executive branch): 10; Private citizen users (100%): 10; OGE-processed models (private citizens): 10; OGE burden hours (100 hours/model): 1,000.

C. *Model Qualified Diversified Trust:* Total users (executive branch): 15; Private citizen users (100%): 15; OGE-processed models (private citizens): 15; OGE burden hours (100 hours/model): 1,500.

D.–H. *Each of the five remaining model qualified trust documents:* Total users (executive branch): 2; Private citizen users (100%): 2; OGE-processed models (private citizens): 2, multiplied by 5 (five different models) = 10; OGE burden hours (100 hours/model): 200, multiplied by 5 (five different models) = 1,000.

I.–J. *Each of the two model confidentiality agreements:* Total users (executive branch): 2; Private citizens users (100%): 2; OGE-processed agreements (private citizens): 2, multiplied by 2 (two different models) = 4; OGE burden hours (50 hours/agreement): 100, multiplied by 2 (two different models) = 200.

Based on these estimates, the total number of forms expected annually at OGE remains unchanged at 294 with a cumulative total of 3,785 burden hours.

In this second round notice, public comment is again invited on all aspects of OGE's qualified trust model certificates and model trust documents as proposed for renewal with minor revision, including specifically views on: the accuracy of OGE's public burden estimate; the potential for enhancement of quality, utility, and clarity of the information to be collected; and the minimization of burden (including the possibility of use of information technology). The Office of Government Ethics, in consultation with OMB, will consider all comments received, which will become a matter of public record.

Approved: January 10, 2002.

Amy L. Comstock,

Director, Office of Government Ethics.

[FR Doc. 02–1144 Filed 1–15–02; 8:45 am]

BILLING CODE 6345–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–13–02]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7090. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

Evaluation of Effectiveness of NIOSH Publications—NEW—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). Through the development, organization, and dissemination of information, NIOSH promotes awareness about occupational hazards and their control, and improves the quality of American working life. Although NIOSH uses a variety of media and delivery mechanisms to communicate with its constituents, one of the primary vehicles is through the distribution of NIOSH-numbered publications. The extent to which these publications successfully meet the information needs of their intended audience is not currently known. In a period of diminishing resources and increasing accountability, it is important that NIOSH be able to demonstrate that communications about its research and service programs are both effective and efficient in influencing workplace change. This requires a social marketing evaluation of NIOSH products to measure the degree of customer satisfaction and their adoption of recommended actions.

The present project proposes to do this by conducting a mail survey of a primary segment of NIOSH's customer base, the community of occupational safety and health professionals. In collaboration with the American Association of Occupational Health Nurses (13,000 members), the American Industrial Hygiene Association (12,400 members), the American College of Occupational and Environmental Medicine (6,500 members), and the American Society of Safety Engineers (33,000 members), NIOSH will survey a sample of their memberships to ascertain, among other things: (1) Their perceptions and attitudes toward NIOSH as a general information resource; (2) their perceptions and attitudes about specific types of NIOSH publications (*e.g.*, criteria documents, technical reports, alerts); (3) the frequency and nature of referral to NIOSH in affecting occupational safety and health practices and policies; (4) the extent to which they have implemented NIOSH recommendations; and (5) their recommendations for improving NIOSH products and delivery systems. The results of this survey will provide an empirical assessment of the impact of NIOSH publications on occupational safety and health practice and policy in the United States as well as provide direction for shaping future NIOSH communication efforts. The annual burden for this data collection is 400 hours.

Respondents	No. of responses/ respondents	Average burden per response
1,200	1	20/60

Dated: January 8, 2002.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 02–1053 Filed 1–15–02; 8:45 am]

BILLING CODE 4163–18–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 (SOR), called the ''Evaluations of The Medicaid Reform Demonstrations (EMRD),'' HHS/CMS/OSP No. 09–70–0068. The primary purpose of this SOR is to collect and provide data necessary to evaluate a series of Medicaid Reform Demonstrations that rely on waivers of section 1115 of the Social Security Act. This system will allow measurement of the effects of the demonstration on beneficiaries eligibility, access to care, utilization, health care costs, satisfaction with care, quality of care and health status. The information retrieved from this SOR will be used: (1) To support program administration, reporting, and regulatory, reimbursement, and policy functions performed within the CMS or by a contractor or consultant; (2) to enable another Federal or State Agency to contribute to the accuracy of the CMS's proper payment of Medicaid, State Children's Health Insurance Program and Medicare benefits; (3) to enable CMS to administer a Federal health benefits program or to enable CMS 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; (4) to support constituent requests made by a Congressional representative; (5) to support litigation involving the Agency; (6) to support program administration, reporting, research, evaluation, and related issues; (7) and to disclose individual-specific information for the purpose of combating fraud and abuse in health benefits programs administered by CMS. 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 January 4, 2002. 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: Sydney Galloway, Office of Strategic Planning, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. The telephone number is 410–786–6645.

SUPPLEMENTARY INFORMATION:

I. Description of the New System of Records

A. Statutory and Regulatory Basis for System of Records

CMS proposes to initiate a new SORs collecting data under the authority of section 1875(a) (42 U.S.C. 1395ll) and section 1115 (42 U.S.C. 1315) of the Social Security Act. The EMRD SOR will provide data necessary to evaluate CMS's Evaluations of the Medicaid Reform Demonstrations. As part of this effort, individually identifiable data will be used to analyze the effects of the demonstration on beneficiary eligibility, access to care, utilization, health care costs, satisfaction with care, quality of care, and health status. The information retrieved from this SOR will be used: (1) To support program administration, reporting, and regulatory, reimbursement, and policy functions performed within the Centers for Medicare & Medicaid Services (CMS) or by a contractor or consultant; (2) to enable another Federal or State agency to contribute to the accuracy of the CMS's proper payment of Medicaid, State Children's Health Insurance Program and Medicare benefits; (3) to enable CMS to administer a Federal health benefits program or to enable CMS 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; (4) to support constituent requests made by a Congressional representative; (5) to support litigation involving the Agency; (6) to support program administration, reporting, research, evaluation, and related issues; (7) and to disclose individual-specific information for the purpose of combating fraud and abuse in health benefits programs administered by CMS.

B. Background

As of September 1, 1999, 21 section 1115 waivers for demonstrations in the following States have been approved and implemented: Alabama (Mobile County only), Arizona, Arkansas, California (Los Angeles County only), Delaware, District of Columbia, Florida, Hawaii, Kentucky, Maryland, Massachusetts, Minnesota, New Jersey, New York, Ohio, Oklahoma, Oregon, Rhode Island, Tennessee, Vermont and Wisconsin.

CMS has awarded a number of contracts to independent evaluators to assess the demonstrations thus far. These evaluations include:

Evaluation of the State Health Reform Demonstrations (Contract Number 500–94–0047)—Awarded to prime contractor Mathematica Policy Research, Inc. and subcontractors.

Examines the impact of five State Medicaid reform demonstrations (Hawaii, Maryland, Oklahoma, Rhode Island, and Tennessee).

Evaluation of the Medicaid Health Reform Demonstrations (Contract Number 500–95–0040) Awarded to Urban Institute and its subcontractors.

Examines five health reform demonstrations (California (Los Angeles County only), Kentucky, Minnesota, New York, and Vermont).

Evaluation of the Oregon Medicaid Reform Demonstration (Contract Number 500–94–0056)—Awarded to Health Economics Research, Inc. and subcontractors.

Examines the impacts of the Oregon Medicaid Reform Demonstration.

Evaluation of Delaware's Diamond State Health Plan (500–92–0033 Delivery Order Nos. 1 and 4)—Awarded to Research Triangle Institute and subcontractors.

Examines the impacts of the Delaware demonstration, with particular emphasis on children, including children with special health care needs.

Evaluation of Mass Health Quality Improvement Plan and Insurance Reimbursement Program (Contract Number 500–95–0058/T.O. #9)—Awarded to Health Economics Research, Inc. and subcontractors.

The evaluation will consist of two parts: (1) A case study of the quality improvement process in Medicaid MCOs and PCCs; (2) A case study of the implementation of the Insurance Reimbursement Program for low-income families.

Evaluation of the District of Columbia's Demonstration Project, ''Managed Care System for Disabled and

Special Needs Children'' (Contract Number 500–96–0003)—Awarded to Abt Associates, Inc. and subcontractors.

The goal of this project is to document and analyze the experiences of the District of Columbia's managed care system for children and adolescents under the age of 22 who are eligible for Medicaid and who are considered disabled according to Supplemental Security Income (SSI) Program guidelines.

Focused Evaluation of Ohio Section 1115 State Health Reform Demonstration: Behavioral Health (Contract Number 500–97–0022)—Awarded to Heath Economics Research, Inc. and subcontractors.

This evaluation will consist of the following two components: (1) A focused evaluation of the behavioral health component of OhioCare, Ohio's section 1115 State health reform demonstration; and (2) A case study of the implementation of OhioCare.

Additional contracts will be awarded to evaluate other demonstrations as they are approved.

1. Each evaluation conducts analyses to answer the following broad questions for participants, individuals, employers or other relevant parties; or nonparticipant comparison populations from the pre-demonstration period, during the demonstration, and post-demonstration period.

2. How were the demonstrations implemented, and what processes were put in place to administer them. Are these processes effective?

3. What are the impacts of the demonstrations on eligibility and access to care?

4. What are the demonstrations' impacts on quality, including health status impacts, the process of care delivered, and satisfaction with care received?

5. What are the impacts of the demonstrations on the utilization of services?

6. What are the impacts of the demonstrations on cost, from Federal, State, provider, employer, and beneficiary perspectives?

As part of these efforts, the contractors will use individually identifiable data from state administrative data bases (including, but not, limited to, Medicaid eligibility, claims and encounter data), CMS data bases, data from other Federal and State agencies (including, but not limited to, the Social Security Administration), and other relevant data bases, surveys and vital records to analyze the effects of the demonstration on beneficiary eligibility, access to care, health care costs, satisfaction with care, and health status. CMS and the contractor will collect only that information necessary to perform the system's function.

II. Collection and Maintenance of Data in the System

A. Scope of the Data Collected

The SOR is expected to include data on the number and type of services used by demonstration participants and comparison group members and their experiences in accessing health care before, during, and after the demonstration period. Sources of information contained in this records system are expected to include: State Medicaid Management Information Systems, managed care organizations (i.e., encounter data), fee-for-service providers, surveys of demonstration participants or providers and comparison group members, medical records, Social Security Administration data bases, vital statistics, and other relevant data systems.

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 EMRD 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 EMRD information and identifiers. Non-identifiable data includes individual records with EMRD information and masked identifiers or EMRD information with identifiers stripped out of the file.

We will only disclose the minimum personal data necessary to achieve the purpose of the EMRD. 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.,* to evaluate the effects of the demonstration on beneficiaries eligibility, access to care, utilization, health care costs, satisfaction with care; quality of care, and health status.

1. 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 EMRD 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 the Agency of a state or local government, or established by state law, for purposes of ensuring that no payments are made with respect to any item or service furnished by an individual or entity during the period when such individual or entity is excluded from participation in Medicaid, SCHIP, Medicare or other Federal and State health care programs. Data will be released to the State only on those individuals who are either individuals or entities excluded from participation in Medicaid, SCHIP, Medicare, or other Federal and State health care programs, or employers of excluded individuals or entities, or are legal residents of the State, irrespective of the location of a provider or supplier furnishing items or services.

Program evaluation relies, in large part, on program integrity and the integrity of collected data, the routine use proposed in this paragraph is a necessary requirement for this database, and is therefore, compatible with the purpose for which the information is being collected.

3. To another Federal or state agency:

a. To contribute to the accuracy of CMS's proper payment of Medicaid, SCHIP, or 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 fulfill reporting requirements, research, evaluation, or other policy or epidemiological considerations.

CMS, and other Federal or state and local agencies, all contribute data to the databases included in this SOR, and (both separately and jointly) have an interest in performing program evaluation, conducting research and maintaining program integrity. Therefore, the routine uses described herein are compatible with the purpose for which the data are being collected.

4. To an individual or other private or public entity for research, evaluation or epidemiological projects related to the prevention of disease or disability, the restoration or maintenance of health, or for projects designed to increase the efficiency and economy of care provision.

The EMRD data will provide an opportunity for comprehensive research, evaluation and epidemiological projects regarding EMRD patients. CMS anticipates that many researchers will have legitimate requests to use these data in projects that could ultimately improve the care provided to Medicaid, SCHIP and Medicare beneficiaries 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 CMS or State contractors, to administer some aspect of the health benefits programs, or to a CMS grantee or program which is or could be affected by fraud and abuse, for the purpose of preventing, deterring, discovering, detecting, investigating, examining, prosecuting, suing with respect to, defending against, correcting, remedying, or otherwise combating such fraud and abuse in such programs.

CMS contemplates 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 CMS functions relating to purposes for this SORs.

CMS occasionally contracts out certain of its functions when this 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 (like ensuring 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 those stated in II.B above), 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 to return or destroy all information.

Program evaluation relies, in large part, on program integrity and the integrity of collected data, the routine use proposed in this paragraph is a necessary requirement for this database, and is therefore, compatible with the purpose for which the information is being collected.

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 government agency, for the purpose of preventing, deterring, discovering, detecting, investigating, examining, prosecuting, suing with respect to, defending against, correcting, remedying, or otherwise combating such fraud and abuse in health benefits program funded in whole or in part by Federal funds.

Other State or local agencies in their administration of a Federal health program may require EMRD information for the purpose of preventing, deterring, discovering, detecting, investigating, examining, prosecuting, suing with respect to, defending against, correcting, remedying, or otherwise combating such fraud and abuse in such programs. 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.

Program evaluation relies, in large part, on program integrity and the integrity of collected data, the routine use proposed in this paragraph is a necessary requirement for this database, and is therefore, compatible with the

purpose for which the information is being collected.

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 EMRD 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.'' CMS 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 CMS 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.

A. 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.

A. 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.

II. 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 EMRD data. EMRD information on patients is 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 EMRD 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: January 4, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

09–70–0068

SYSTEM NAME:

''Evaluations of the Medicaid Reform Demonstrations,'' (EMRD).

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:

Individuals eligible for Medicaid under the demonstrations (eligibility requirements vary by State) and individuals selected as comparison group members for the evaluations.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system will contain information concerning individual identifiers, demographics, employment, health care coverage, diagnostic and health status information, utilization and cost of health care services, and responses to survey or, other types of data collection methods.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 1875(a) (42 U.S.C. 1395ll) and section 1115 (42 U.S.C. 1315) of the Social Security Act.

PURPOSE(S) OF THE SYSTEM:

The primary purpose of this system of records (SOR) is to collect and provide data necessary to evaluate a series of Medicaid Reform Demonstrations that rely on waivers of section 1115 of the Social Security Act. This system will allow measurement of the effects of the demonstration on beneficiaries eligibility, access to care, utilization, health care costs, satisfaction with care, quality of care and health status. The information retrieved from this SOR will be used: (1) To support program administration, reporting, and regulatory, reimbursement, and policy functions performed within the Health Care Financing Administration (CMS) or by a contractor or consultant; (2) to enable another Federal or State agency to contribute to the accuracy of the CMS's proper payment of Medicaid, State Children's Health Insurance Program and Medicare benefits; (3) to enable CMS to administer a Federal health benefits program or to enable CMS 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; (4) to support constituent requests made by a Congressional representative; (5) to support litigation involving the agency; (6) to support program administration, reporting, research, evaluation, and related issues; (7) and to disclose individual-specific information for the purpose of combating fraud and abuse in health benefits programs administered by CMS.

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 EMRD 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 the Agency of a state or local government, or established by state law, for purposes of ensuring that no payments are made with respect to any item or service furnished by an individual or entity during the period when such individual or entity is excluded from participation in Medicaid, SCHIP, Medicare or other Federal and state health care programs. Data will be released to the State only on those individuals who are either individuals or entities excluded from participation in Medicaid, SCHIP, Medicare, or other Federal and state health care programs, or employers of excluded individuals or entities, or are legal residents of the State, irrespective of the location of a provider or supplier furnishing items or services.

3. To another Federal or state agency:

a. To contribute to the accuracy of CMS's proper payment of Medicaid, SCHIP, or 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 fulfill reporting requirements, research, evaluation, or other policy or epidemiological considerations.

4. To an individual or other private or public entity for research, evaluation or epidemiological projects related to the prevention of disease or disability, the restoration or maintenance of health, or for projects designed to increase the efficiency and economy of care provision.

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 CMS or state contractors, to administer some aspect of the health benefits programs, or to a CMS grantee or program which is or could be affected by fraud and abuse, for the purpose of preventing, deterring, discovering, detecting, investigating, examining, prosecuting, suing with respect to, defending against, correcting, remedying, or otherwise combating such fraud and abuse in such programs.

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 government agency, for the purpose of preventing, deterring, discovering, detecting, investigating, examining, prosecuting, suing with respect to, defending against, correcting, remedying, or otherwise combating such fraud and abuse in health benefits program funded in whole or in part by Federal funds.

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

STORAGE:

All records are stored on paper or electronic media.

RETRIEVABILITY:

Beneficiary's name, Medicaid identification number, Health Insurance Claim Number, Social Security Number or other identifying variables retrieve the records.

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 and the repository of the National Archive and Records Administration (NARA) will retain identifiable EMRD data permanently, or as an indefinite retention.

SYSTEM MANAGER AND ADDRESS:

CMS, Director, Office of Strategic Planning, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

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 part 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 part 5b.7.)

RECORD SOURCE CATEGORIES:

Sources of information contained in this records system are expected to include: State Medicaid Management Information Systems, managed care organizations (i.e., encounter data), fee-for-service providers, surveys of demonstration participants or providers and comparison group members, medical records, Social Security Administration data bases, vital statistics and other relevant data systems.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

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BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Prescription Drug User Fee Rates for Fiscal Year 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2002. The Prescription Drug User Fee Act of 1992 (PDUFA), as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA), authorizes FDA to collect user fees for certain applications for approval of drug and biological products, on establishments where the products are made, and on such products. Fees for applications for FY 2002 were set by PDUFA, as amended, subject to adjustment for inflation. Total application fee revenues fluctuate with the number of fee-paying applications FDA receives. Fees for establishments and products are calculated so that total revenues from each category will approximate FDA's estimate of the revenues to be derived from applications.

FOR FURTHER INFORMATION CONTACT: Frank Claunts, Office of Management and Systems (HFA–300), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4427.

SUPPLEMENTARY INFORMATION:

I. Background

PDUFA (Public Law 102–571), as amended by FDAMA (Public Law 105–