

Control and Prevention (CDC), National Center for Environmental Health/ Agency for Toxic Substances and Disease Registry (NCEH/ATSDR): Teleconference.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), CDC, NCEH/ATSDR announces the following subcommittee meeting:

Name: Program Peer Review Subcommittee (PPRS).

Time and Date: 10:30 a.m.–12:30 p.m. Eastern Daylight Savings Time, October 16, 2006.

Place: The teleconference will originate at NCEH/ATSDR in Atlanta, Georgia. To participate, dial (877) 315-6535 and enter conference code 383520.

Purpose: Under the charge of the BSC, NCEH/ATSDR, the PPRS will provide the BSC, NCEH/ATSDR with advice and recommendations on NCEH/ATSDR program peer review. They will serve the function of organizing, facilitating, and providing a long-term perspective to the conduct of NCEH/ATSDR program peer review.

Matters to be Discussed: A review of the previous meeting; an update on the planning of the Site Specific Activities Peer Review; a discussion of Terrorism Preparedness and Emergency Response Peer Review in February 2007, to include: revisions to the review process, revisions to the questionnaires, areas of expertise required for the review, and nominations for PPRS panel member, chairperson, and peer reviewers; and review the revised schedule for Program Peer Reviews.

Agenda items are subject to change as priorities dictate.

Supplementary Information: This meeting is scheduled to begin at 10:30 a.m. Eastern Daylight Savings Time. To participate, please dial (877) 315-6535 and enter conference code 383520. Public comment period is scheduled for 11:10–11:20 a.m.

For Further Information Contact: Sandra Malcom, Committee Management Specialist, Office of Science, NCEH/ATSDR, MS E-28, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404)498-0622.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and NCEH/ATSDR.

Dated: September 25, 2006.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E6-16189 Filed 9-29-06; 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 a New System of Records

AGENCY: Department of Health and Human Services (HHS), Center for Medicare & Medicaid Services (CMS).

ACTION: Notice of a 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 titled, "Rural Hospice Demonstration (RHD), System No. 09-70-0563." The program is mandated by § 409 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) (Public Law (Pub. L.) 108-173), which was enacted into law on December 8, 2003, and amended Title XVIII of the Social Security Act (the Act). Section 409 authorizes the Secretary of HHS (the Secretary) to conduct a demonstration project for the delivery of hospice care to Medicare beneficiaries in rural areas. Under the demonstration, Medicare beneficiaries who are unable to receive hospice care at home for lack of an appropriate caregiver are provided such care in a facility of 20 or fewer beds that offers, within its walls, the full range of services provided by hospice programs.

In order for a hospice organization or agency to participate in this demonstration, it must be Medicare certified and meet all of the Medicare Conditions of Participation as described in subparts C (General Provisions), D (Core Services), and E (Other Services) of 42 CFR 418, except it shall not be required to offer services outside the facility or meet the 20 percent inpatient cap requirements of section 1861(dd)(2) (A) (iii) of the Act.

The purpose of this system is to collect and maintain a person-level view of identifiable data of Medicare beneficiaries who participate in the rural hospice demonstrations. Information retrieved from this system may be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor, consultant, or grantee; (2) assist another Federal or State agency with information to contribute to the accuracy of CMS's proper payment of Medicare benefits, enable such agency to administer a Federal health benefits program, or to enable such agency to fulfill a requirement of Federal statute or

regulation that implements a health benefits program funded in whole or in part with Federal funds; (3) support an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects; (4) support litigation involving the agency; and (5) combat fraud, waste, and abuse in certain Federally-funded health benefits programs. We have provided background information about this system in the "Supplementary Information" section below. Although the Privacy Act requires only that CMS provide an opportunity for interested persons to comment on the proposed routine uses, CMS invites comments on all portions of this notice. See "Effective Dates" section for comment period.

DATES: *Effective Date:* CMS filed a SOR report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Homeland Security & Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on September 26, 2006. To ensure that all parties have adequate time in which to comment, the new system will become effective 30 days from the publication of the notice, or 40 days from the date it was submitted to OMB and the Congress, whichever is later. We may defer implementation of this system 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 comment to the CMS Privacy Officer, Division of Privacy Compliance, Enterprise Architecture and Strategy Group, Office of Information Services, Mail-stop 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.

FOR FURTHER INFORMATION CONTACT: Cindy Massuda, Project Officer, Division of Deliver System Demonstration, Office of Research Development & Information, Mail Stop C4-18-03, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1849. She can be reached by telephone at 410-786-0652 or e-mail Cindy.Massuda@cms.hhs.gov.

SUPPLEMENTARY INFORMATION: The demonstration will be offered to up to three hospice programs and will not exceed a period of 5 years. The demonstration will test whether provisions of hospice services provided by a demonstration hospice program to Medicare beneficiaries who lack an appropriate caregiver and who reside in rural areas results in wider access, improved hospice services, benefits to the community, and a sustainable pattern of care. Hospice provides palliative care to individuals who have a terminal illness with a prognosis of 6 months or less. The care is provided typically in the individual's home or place of residence with family members present.

Individuals who lack family or someone to serve as the primary caregiver need proportionately more support from hospice staff. Due to long distances and difficult terrain, it can be particularly difficult to provide the Medicare hospice benefit efficiently in rural areas. There may be situations where the hospice benefit could be provided to beneficiaries who would not otherwise be able to receive these services if the location of hospice care is altered.

This demonstration will allow a hospice with up to 20 beds to provide all levels of hospice services within its walls to individuals who reside in rural areas and lack an appropriate caregiver, while not having to provide services outside of the hospice facility or comply with the 20-percent cap on inpatient care days.

While the demonstration provider will not have to meet the limit on inpatient care days or provide care outside of the facility, it will not alter the level of care requirements for general inpatient care. In order to provide general inpatient care to hospice patients, a hospice participating in the demonstration must assure that the need for general inpatient care is met according to Medicare guidelines. The demonstration will test whether hospice services provided by a facility that does not meet the limit on inpatient care days or provide services outside of the facility for hospice individuals residing in rural areas who lack an appropriate caregiver results in wider access, improved hospice services, benefits to the rural community, and a sustainable pattern of care.

The demonstration is designed for a demonstration hospice to provide the full range of services within its facility to Medicare beneficiaries who reside in rural areas and lack an appropriate caregiver. If a demonstration hospice

provides care to any patient who either lives outside a rural area or has an appropriate caregiver, then the hospice must comply with all of Medicare hospice requirements at § 1861(dd) of the SSA for these patients since they are not considered part of the demonstration.

I. Description of the Proposed System of Records

A. Statutory and Regulatory Basis for SOR

The statutory authority for this system is given under the provisions of § 409 of the Medicare Prescription Drug Improvement, and Modernization Act of 2003 and § 1861(dd) of the Social Security Act. This program is codified at Title 42 United States Code 1395x (dd).

B. Collection and Maintenance of Data in the System

This system will collect and maintain individually identifiable and other data collected on Medicare beneficiaries and their providers who provide service to such beneficiaries who participate in this demonstration. Data will be collected from Medicare administrative and claims records, patient medical charts, physician records, and via survey instruments administered to beneficiaries and providers. The collected information will include, but is not limited to Medicare claims and eligibility data, name, address, telephone number, health insurance claims number, race/ethnicity, gender, date of birth, provider name, unique provider identification number, medical record number, as well as clinical, demographic, health/well-being, family and/or caregiver contact information, and background information relating to Medicare issues.

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

A. 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 RHD information that can be associated with an individual as provided for under "Section III. Proposed Routine Use Disclosures of Data in the System." Both identifiable and non-identifiable data may be disclosed under a routine use. We will only collect the minimum personal data necessary to achieve the purpose of RHD.

CMS has the following policies and procedures concerning disclosures of information that will be maintained in the system. Disclosure of information from the system will be approved only to the extent necessary to accomplish the purpose of the disclosure and only after CMS:

1. Determines that the use or disclosure is consistent with the reason that the data is being collected; e.g., to collect and maintain a person-level view of identifiable data of Medicare beneficiaries who participate in the rural hospice demonstrations.

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 unauthorized use of disclosure of the record;

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

c. 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. The Privacy Act allows 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 compatible use of data is known as a "routine use." The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. We are proposing to establish the following routine use disclosures of information maintained in the system:

1. To support agency contractors, consultants or grantees, who have been engaged by the agency to assist in the performance of a service related to this collection 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 CMS function relating to purposes for this system.

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, consultant or grantee whatever information is necessary for the contractor or consultant to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor, consultant or grantee from using or disclosing the information for any purpose other than that described in the contract and requires the contractor, consultant or grantee to return or destroy all information at the completion of the contract.

2. To assist another Federal or State agency to:

a. Contribute to the accuracy of CMS's proper payment of Medicare benefits;

b. 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; and/or

c. Assist Federal/State Medicaid programs within the State.

Other Federal or State agencies, in their administration of a Federal health program, may require RHD information in order to support evaluations and monitoring of Medicare claims information of beneficiaries, including proper reimbursement for services provided.

3. To assist an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects.

The RHD data will provide for research or support of evaluation projects and a broader, longitudinal, national perspective of the status of Medicare beneficiaries. CMS anticipates that many researchers will have legitimate requests to use these data in projects that could ultimately improve the care provided to Medicare beneficiaries and the policies that govern their care.

4. To support 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 that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

Whenever CMS is involved in litigation, and occasionally when another party is involved in litigation and CMS 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.

5. To assist 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, waste, and abuse in such program.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual, grantee, cooperative agreement or consultant relationship with a third party to assist in accomplishing CMS functions relating to the purpose of combating fraud, waste, and abuse. CMS occasionally contracts out certain of its functions or makes grants or cooperative agreements when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor, grantee, consultant or other legal agent whatever information is necessary for the agent to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the agent from using or disclosing the information for any purpose other than that described in the contract and requiring the agent to return or destroy all information.

6. To assist 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, waste, and 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, waste, and abuse in such programs.

Other agencies may require RHD information for the purpose of combating fraud, waste, and abuse in such Federally-funded programs.

B. Additional Provisions Affecting Routine Use Disclosures

To the extent this system contains Protected Health Information (PHI) as defined by HHS regulation "Standards for Privacy of Individually Identifiable Health Information" (45 CFR parts 160 and 164, subparts A and E) 65 FR 82462 (12-28-00). Disclosures of such PHI that are otherwise 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." (See 45 CFR 164.512(a) (1)).

In addition, our policy will be to prohibit release even of data not directly identifiable, except pursuant to one of the routine uses or if required by law, if we determine 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 because of the small size, use of this information could allow for the deduction of the identity of the beneficiary).

IV. Safeguards

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

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and

Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A-130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

V. Effects of the Proposed System of Records 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 take precautionary measures 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 are maintained in this 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 information relating to individuals.

Dated: September 19, 2006.

John R. Dyer,

Chief Operating Officer, Centers for Medicare & Medicaid Services.

SYSTEM NO. 09-70-0563

SYSTEM NAME:

"Rural Hospice Demonstration (RHD)," HHS/CMS/ORDI.

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive Data.

SYSTEM LOCATION:

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

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system will collect and maintain individually identifiable and other data collected on Medicare beneficiaries and their providers who provide service to such beneficiaries who participate in this demonstration.

CATEGORIES OF RECORDS IN THE SYSTEM:

Data will be collected from Medicare administrative and claims records, patient medical charts, physician records, and via survey instruments administered to beneficiaries and providers. The collected information will include, but is not limited to Medicare claims and eligibility data, name, address, telephone number, health insurance claims number, race/ethnicity, gender, date of birth, provider name, unique provider identification number, medical record number, as well as clinical, demographic, health/well-being, family and/or caregiver contact information, and background information relating to Medicare issues.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The statutory authority for this system is given under the provisions of § 409 of the Medicare Prescription Drug Improvement, and Modernization Act of 2003 and § 1861(dd) of the Social Security Act. This program is codified at Title 42 United States Code 1395x (dd).

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to collect and maintain a person-level view of identifiable data of Medicare beneficiaries who participate in the rural hospice demonstrations. Information retrieved from this system may be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor, consultant, or grantee; (2) assist another Federal or State agency with information to contribute to the accuracy of CMS's proper payment of Medicare benefits, enable such agency to administer a Federal health benefits program, or to enable such agency to fulfill a requirement of Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds; (3) support an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects; (4) support litigation involving the agency; and (5) combat fraud, waste, and abuse in certain Federally-funded health benefits programs.

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

A. The Privacy Act allows 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 compatible use of data is known as a "routine use." The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. We are proposing to establish the following routine use disclosures of information maintained in the system:

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

2. To assist another Federal or State agency to:

a. Contribute to the accuracy of CMS's proper payment of Medicare benefits;

b. 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; and/or

c. Assist Federal/State Medicaid programs within the State.

3. To support an individual or organization for a research project or in support of an evaluation project related to the prevention of disease, disability, or quality care projects, the restoration or maintenance of health, and payment related projects.

4. To support 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 that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

5. To assist 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, waste, and abuse in such program.

6. To assist 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, waste, and 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, waste, and abuse in such programs.

B. Additional Provisions Affecting Routine Use Disclosures.

To the extent this system contains Protected Health Information (PHI) as defined by HHS regulation "Standards for Privacy of Individually Identifiable Health Information" (45 CFR parts 160 and 164, subparts A and E) 65 FR 82462 (12-28-00). Disclosures of such PHI that are otherwise 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." (See 45 CFR 164.512(a)(1)).

In addition, our policy will be to prohibit release even of data not directly identifiable, except pursuant to one of the routine uses or if required by law, if we determine 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 because of the small size, use of this information could allow for the deduction of the identity of the beneficiary).

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

STORAGE:

All records are stored on electronic media.

RETRIEVABILITY:

The collected data are retrieved by an individual identifier; e.g., beneficiary name or HICN, and unique provider identification number.

SAFEGUARDS:

CMS has safeguards in place 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 information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A-130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

CMS will retain information for a total period not to exceed 25 years. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from DOJ.

SYSTEM MANAGER AND ADDRESS:

Director, Division of Deliver Systems Demonstration, Office of Research Development and Information, Mail Stop C4-18-03, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1849.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, provider's tax identification number, national provider number, and for verification purposes, or the subject individual's name (woman's maiden

name, if applicable), HICN, and/or 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).

RECORDS SOURCE CATEGORIES:

Information maintained in this system will be collected from physicians volunteering to participate in the RHD. Additional data will be collected from Medicare claims payment records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. E6-16107 Filed 9-29-06; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0211]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Proposed Collection; Comment Request; Guidance for Industry on Submitting and Reviewing Complete Responses to Clinical Holds

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by November 1, 2006.