

Dated: June 4, 2004.

Alvin Hall,

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

[FR Doc. 04-13133 Filed 6-9-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health; Public Meeting

The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following public meeting and request for information:

Name: Public Meeting to Seek Input on Gaps in Chronic Lymphocytic Leukemia Radiogenicity Research.

Time and Date: 9 a.m.–12 noon, July 21, 2004.

Place: Best Western Skyline Inn, 10 I Street, SW., Washington, DC 20024.

Status: Forum will include scientists and representatives from various government agencies, industry, labor, and other stakeholders, and is open to the public, limited only by the space available. The meeting room accommodates up to 100 people. Due to limited space, notification of intent to attend the meeting should be made with Patty Gudlewski, no later than Friday, July 16, 2004. Ms. Gudlewski can be reached by telephone at 513-841-4419, or by e-mail at pkg1@cdc.gov. Access to the meeting will be accommodated on a first-come basis.

Purpose: To discuss possible scientific research strategies to evaluate any relationship between exposure to ionizing radiation and chronic lymphocytic leukemia (CLL). Current scientific opinion, based largely on epidemiological data, holds that the incidence of CLL is not related to exposure to ionizing radiation. The U.S. Congress directed NIOSH to conduct epidemiological research and other activities to establish the scientific link between radiation exposure and the occurrence of CLL.

The public is invited to attend and will have an opportunity to provide limited comments. Written comments may be submitted to the address listed below by August 16, 2004, so that they may be considered by NIOSH in planning its research priorities.

Summary: CLL is the most common adult leukemia in the Western world, but its etiology is largely unknown. Exposures to some herbicides have been implicated in epidemiologic studies. Yet other studies to date largely have shown no evidence of an association between external ionizing radiation and CLL; however, a number of uncertainties remain and additional studies may be informative. Recent laboratory

studies have identified sub-types of CLL and at least one familial form of B-cell CLL has been identified. In addition, new technologies including interphase fluorescence *in situ* hybridization, expression microarrays and flow cytometric analysis provide diagnostic and prognostic indicators of disease. This meeting will assist in identifying gaps in existing research needed to address the radiogenicity of CLL.

Addresses: Comments should be submitted to David F. Utterback, 4676 Columbia Parkway, M/S R-44, Cincinnati, Ohio 45226, or by e-mail to dutterback@cdc.gov. Any attachments should be formatted in Microsoft Word.

All information received in response to this notice will be available for public examination and copying.

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 the Agency for Toxic Substances and Disease Registry.

Dated: June 4, 2004.

Alvin Hall,

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

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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).

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 SOR, titled "MMA Section 641 Prescription Drug Benefit Demonstration" (MMA641) System NO. 09-70-0545, HHS/CMS/ORDI. The primary purposes of the system of records are to maintain information on individual Medicare beneficiaries who voluntarily enroll in a demonstration project for coverage of certain prescription drugs and biologicals. This demonstration project is mandated in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 under section 641. The system of records will enable CMS to: Enroll and communicate with eligible Medicare beneficiaries who volunteer to participate in the demonstration project, communicate with clinicians and other

providers and suppliers who submit claims payable under the demonstration project, review submitted claims and pay those conforming to applicable payment criteria and federal law, and develop, maintain, and analyze research information showing the potential impact of providing certain prescription drugs and biologicals.

Information retrieved from this system of records will also be disclosed to support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant; support constituent requests made to a Congressional representative; support litigation involving the agency; support activities reasonably necessary to fulfill the provisions of the demonstration project and ensure appropriate use of Medicare trust fund and program funds; and third parties where the contact is expected to have information relating to the individual's capacity to manage his or her own affairs.

We have provided background information about the proposed system in the "Supplementary Information" section, below. 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 June 4, 2004. In any event, we will not disclose any information under a routine use until forty (40) calendar 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 Privacy Compliance Data Development (DPCDD), 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: James Coan, Division of Health Promotion and Disease Prevention Demonstrations (DHPDPD), Office of Research, Development, and Information, CMS, MS-S3-02-01, 7500 Security Boulevard, Baltimore,

Maryland 21244–1850. The telephone number is (410) 786–9168.

SUPPLEMENTARY INFORMATION:

I. Description of the New System of Records

A. Statutory and Regulatory Basis for System of Records

The authority for this system of records is Section 641 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173).

B. Background

Section 641 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) provides for a demonstration that would pay for drugs and biologicals that are prescribed as replacements for drugs currently covered under Medicare Part B. The legislation specifies that no more than 50,000 beneficiaries be covered under the demonstration and that funding is limited to \$500 million.

The demonstration will apply to the 50 United States and the District of Columbia and will provide this coverage for the period up to December 31, 2005, or until legislated limitations have been reached. Provisions under the demonstration include enhanced low-income benefits for those unable to afford deductibles and cost sharing. Interested beneficiaries will be screened for eligibility and asked for basic information about diagnosis, treatment, and income. Once they are determined to be eligible, they will be assigned to a national pharmacy benefits manager where their individual prescription plan will be established.

Prescription drug and biological coverage will follow the conditions outlined in MMA for the new Part D prescription drug plan, including all deductibles, cost sharing percentages, and out-of-pocket expense limitations.

II. Collection and Maintenance of Data in the System

A. Scope of the Data Collected

MMA641 includes standard data for identification such as Name, Medicare Health Insurance Claim (HIC) Number, sex, race, date of birth, zip code, state and county for Medicare beneficiaries who are voluntarily participating in the Section 641 Demonstration. All of the included data is necessary to employ proper research methods and to verify eligibility criteria. It also includes claims information related to prescription drug claims, supplemental prescription drug coverage plans, income attestation, physician

certification, answers to eligibility questions, answers to enrollment questionnaires and other information needed to confirm the beneficiaries eligibility for enrollment and ongoing participation in the demonstration, as well as other survey and research information needed to pay claims, administer the demonstration project, and develop research reports on the study's findings. Information collected is critical to implementing the demonstration as mandated in the legislation. Specifically, the demonstration must follow the new Part D Prescription Drug Benefit rules for participation, low-income subsidies, use of supplemental drug coverage plans, and enrollment. Furthermore, because this is a research demonstration project and a Report to Congress is required, evaluation of the effects of the demonstration must include scientifically relevant data and controls for comparative analysis.

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 MMA641 information that can be associated with an individual as provided for under "Section III. Entities Who May Receive Disclosures Under Routine Use." Both identifiable and non-identifiable data may be disclosed under a routine use. Identifiable data includes individual records with MMA641 information and identifiers. Non-identifiable data includes individual records with MMA641 information and masked identifiers or MMA641 information with identifiers stripped out of the file.

CMS will only disclose the minimum personal data necessary to achieve the purpose of the MMA641. 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 are being collected; *e.g.*, to maintain information on individual Medicare beneficiaries who voluntarily enroll in a demonstration project for coverage of certain prescription drugs and biologicals.
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 individually, 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. Entities That 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 MMA641 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. CMS proposes to establish the following routine use disclosures of information maintained in the system:

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

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 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 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.

Individuals 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.

3. 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.

4. To an individual or organization engaged in, or assisting in: the appropriate submission of claims payments payable under the demonstration project; the screening, enrollment, communications, and research efforts related to beneficiary participation in the demonstration project (including summary analyses demonstrating the impact of the demonstration project); the inter-relationship of the demonstration claims processing system with other Medicare

systems of records to beneficiary information and claims payment; and, other activities reasonably necessary to fulfill the provisions of the demonstration project and ensure appropriate use of Medicare trust fund and program funds.

5. To third party contacts in situations where the party to be contacted has, or is expected to have information relating to the individual's capacity to manage his or her affairs or to his or her eligibility for, or an entitlement to, benefits under the Medicare program and,

a. The individual is unable to provide the information being sought (an individual is considered to be unable to provide certain types of information when any of the following conditions exists: the individual is confined to a mental institution, a court of competent jurisdiction has appointed a guardian to manage the affairs of that individual, a court of competent jurisdiction has declared the individual to be mentally incompetent, or the individual's attending physician has certified that the individual is not sufficiently mentally competent to manage his or her own affairs or to provide the information being sought, the individual cannot read or write, cannot afford the cost of obtaining the information, a language barrier exist, or the custodian of the information will not, as a matter of policy, provide it to the individual), or

b. The data are needed to establish the validity of evidence or to verify the accuracy of information presented by the individual, and it concerns one or more of the following: the individual's entitlement to benefits under the Medicare program, the amount of reimbursement, and in cases in which the evidence is being reviewed as a result of suspected fraud and abuse, program integrity, quality appraisal, or evaluation and measurement of activities.

Third party contacts require MMA641 information in order to provide support for the individual's entitlement to benefits under the Medicare program; to establish the validity of evidence or to verify the accuracy of information presented by the individual, and assist in the monitoring of Medicare claims information of beneficiaries, including proper reimbursement of services provided.

B. Additional Provisions Affecting Routine Use Disclosures

In addition, CMS 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 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 individual).

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 **Federal Register** 82462 as amended by 66 **Federal Register** 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

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, DHHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include 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, DHHS, and CMS policies and standards include but are not limited to: all pertinent NIST publications; the DHHS Automated Information Systems Security Handbook and the CMS Information Security Handbook.

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 MMA641 data. MMA641 information is submitted to CMS through standard systems. CMS will use a variety of onsite and offsite edits and audits to increase the accuracy of MMA641 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 are 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: June 4, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

SYSTEM NO. 09-70-0545

SYSTEM NAME:

"MMA Section 641 Prescription Drug Benefit Demonstration" (MMA641) System No. 09-70-0545, HHS/CMS/ORDI.

SECURITY CLASSIFICATION:

Level 3, Privacy Act Sensitive.

SYSTEM LOCATION:

Records are stored at the Office of Information System and the Office of Operations Management, CMS, 7500 Security Boulevard, Baltimore, Maryland 21244 and Trailblazer Health Enterprises, LLC, 1954 Greenspring Drive, Timonium, MD 21093.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system will contain claims and demographic information on Medicare beneficiaries who are voluntarily participating in the MMA641.

CATEGORIES OF RECORDS IN THE SYSTEM:

The MMA641 will contain information on Medicare beneficiaries who are voluntarily participating in the project including, standard data for identification such as Name, Medicare Health Insurance Claim (HIC) Number, sex, race, date of birth, zip code, state and county for Medicare beneficiaries who are voluntarily participating in the Section 641 Demonstration. It also includes claims information related to prescription drug claims, supplemental prescription drug coverage plans, income attestation, physician certification, answers to eligibility questions, answers to enrollment questionnaires and other information needed to confirm the beneficiaries eligibility for enrollment and ongoing participation in the demonstration, as well as other survey and research information needed to pay claims, administer the demonstration project, and develop research reports on the study's findings.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for this system of records comes from the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), (Pub. L. 108-173) Title XVIII of the Social Security Act, Section 1860D, Subtitle D-Additional Demonstrations, Studies, and Other Provisions, Sec 641(a).

PURPOSE (S) OF THE SYSTEM:

The primary purposes of the system of records are to maintain information on individual Medicare beneficiaries who voluntarily enroll in a demonstration project for coverage of certain prescription drugs and biologicals. This demonstration project is mandated in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 under section 641. The system of records will enable CMS to: Enroll and communicate with eligible Medicare beneficiaries who volunteer to participate in the demonstration project, communicate with clinicians and other providers and suppliers who submit claims payable under the demonstration project, review submitted claims and pay those conforming to applicable payment criteria and federal law, and develop, maintain, and analyze research information showing the potential impact of providing certain prescription drugs and biologicals.

Information retrieved from this system of records will also be disclosed to support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant; support constituent requests made to a Congressional representative;

support litigation involving the agency; and to support activities reasonably necessary to fulfill the provisions of the demonstration project and ensure appropriate use of Medicare trust fund and program funds; and third parties where the contact is expected to have information relating to the individual's capacity to manage his or her own affairs.

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 MMA641 System 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, CMS 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 population is so small that individuals who are familiar with the enrollees could, because of the small size, use this information to deduce personal identity).

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

2. 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.

3. 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.

4. To an individual or organization engaged in, or assisting in: The appropriate submission of claims payments payable under the demonstration project; the screening, enrollment, maintenance, communications, and research efforts related to beneficiary participation in the demonstration project (including summary analyses demonstrating the impact of the demonstration project); the inter-relationship of the demonstration claims processing system with other Medicare systems of records to beneficiary information and claims payment; and, other activities reasonably necessary to fulfill the provisions of the demonstration project and ensure appropriate use of Medicare trust fund and program funds.

5. To third party contacts in situations where the party to be contacted has, or is expected to have information relating to the individual's capacity to manage his or her affairs or to his or her eligibility for, or an entitlement to, benefits under the Medicare program and,

a. The individual is unable to provide the information being sought (an individual is considered to be unable to provide certain types of information when any of the following conditions exists: The individual is confined to a mental institution, a court of competent jurisdiction has appointed a guardian to manage the affairs of that individual, a court of competent jurisdiction has declared the individual to be mentally incompetent, or the individual's attending physician has certified that the individual is not sufficiently mentally competent to manage his or her own affairs or to provide the information being sought, the individual cannot read or write, cannot afford the cost of obtaining the information, a language barrier exist, or the custodian of the information will not, as a matter of policy, provide it to the individual), or

b. The data are needed to establish the validity of evidence or to verify the accuracy of information presented by the individual, and it concerns one or more of the following: The individual's entitlement to benefits under the Medicare program, the amount of reimbursement, and in cases in which the evidence is being reviewed as a result of suspected fraud and abuse, program integrity, quality appraisal, or evaluation and measurement of activities.

Third party contacts require MMA641 information in order to provide support for the individual's entitlement to benefits under the Medicare program; to establish the validity of evidence or to

verify the accuracy of information presented by the individual, and assist in the monitoring of Medicare claims information of beneficiaries, including proper reimbursement of services provided.

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

STORAGE:

All records are stored on magnetic media. Some input data may arrive as paper enrollment applications as in the case of income attestations and physician certifications before transcription to magnetic media.

RETRIEVABILITY:

The Medicare records are retrieved by health insurance claim (HIC) number of the beneficiary.

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, DHHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include 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, DHHS, and CMS policies and standards include but are not limited to: all pertinent NIST publications; the DHHS Automated Information Systems Security Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

CMS will retain identifiable MMA641 data for a total period not to exceed 25 years. Data residing with the designated enrollment and claims payment contractor shall be returned to CMS at the end of the contract period, with all data then being the responsibility of CMS for adequate storage and security.

SYSTEM MANAGER AND ADDRESS:

Director, Office of Research, Development, and Information, CMS, Room C3-20-11, 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, the subject individual's name (woman's maiden name, if applicable), social security number (SSN) (furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay), phone no., if known, address, date of correspondence and control number.

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:

1. Eligibility data on Medicare beneficiaries volunteering to participate in the MMA Prescription Drug Benefit Demonstration will come from input from beneficiaries who report to CMS officials or contractors, pursuant to information collection activities approved at the Office of Management and Budget and through an Institutional Review Board as required by law. Eligibility will be and crosschecked with information contained in the Common Working File (CWF). Enrollment application information and questionnaires for participants will also come directly from beneficiaries' voluntary reporting.

2. Income attestation information will come from beneficiaries who voluntarily report this information in an approved format and pursuant to information collection activities approved at the Office of Management and Budget and through an Institutional Review Board as required by law.

3. Physician certification information will come through voluntary submission of physicians or other health care providers who have the legal authority to provide such information.

4. Claims data will come through submissions provided by a pharmacy benefits manager who will be providing coverage for specified drugs and biologicals as discussed in the MMA legislation (section 641) in accordance with the provisions of the demonstration and the conditions of participation in the Medicare program.

5. Eligibility information as well as financial or quality reporting related to program integrity or other matters may also interact with existing CMS registries such as those relating to Medicare claims, provider registries, beneficiary enrollment databases, and national claims histories.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 04-13240 Filed 6-9-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Agency Recordkeeping/Reporting Requirement Under Emergency Review By the Office of Management and Budget (OMB)

Title: Custodial Sponsorship Agreement.

OMB No.: New Request.

Description: Following the passage of the 2002 Homeland Security Act (Pub. L. 107-296), the Administration for Children and Families (ACF), Office of Refugee Resettlement, is charged with the placement and care of unaccompanied alien children in Federal custody, and implementing a policy for releasing these children, when appropriate, to eligible sponsors.

In order for the Office of Refugee Resettlement to authorize the release of these children, the potential sponsors must agree to certain conditions pursuant to section 462 of the Homeland Security Act and the *Flores v. Reno* Settlement Agreement (C.D. Cal. 1997). In this Notice, ACF announces that it proposes to employ the usage of a collection of information to indicate the agreement of a sponsor to the terms of a custodial release of an unaccompanied alien child. The Office of Refugee Resettlement considers the eligibility of a sponsor based on their ability and agreement to provide for the physical, mental and financial well-being of an unaccompanied minor and ensure the appearance before immigration courts. Eligible sponsors may be parents close relatives, friends, or entities concerned with the child's welfare. This document will also require the child being considered for release to understand the conditions of the custodial release.

Respondents

Potential sponsors of unaccompanied alien children and unaccompanied alien children in Federal custody.

ANNUAL BURDEN ESTIMATE

Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
5000	1	.1	500

Estimated Total Annual Burden Hours: 500.

Additional Information: ACF is requesting that OMB grant a 90-day approval for this information collection under procedures for emergency processing by June 17, 2004. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Robert Sargis at (202) 690-7275. In addition, a request may be made by sending an e-mail request to: grjohnson@acf.hhs.gov.

Comments and questions about the information collection described above should be directed to the following address by June 17, 2004: Office of Information and Regulatory Affairs,

Attn. OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503.

Dated: June 30, 2004.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 04-13077 Filed 6-9-04; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Request for State Data Needed to Determine the Amount of a Tribal Family Assistance Grant.

OMB No.: 0970-0173.

Description: 42 U.S.C. 612 (section 412 of the Social Security Act) gives Federally recognized Indian Tribes the opportunity to apply to operate a Tribal Temporary Assistance for Needy Families (TANF) program. The Act specifies that the Secretary shall use state submitted data to determine the amount of the grant to the Tribe. This form (letter) is used to request those data from the states.

Respondents: States that have Indian Tribes applying to operate a TANF program.