

Nebraska

Arsenic in Soil in East Omaha,
Nebraska; March 20, 2007.

New Jersey

Celotex Corporation; January 10, 2007.

North Carolina

APAC Carolina Inc. and Associated
Asphalt Inc., Jake Alexander
Boulevard; February 14, 2007.
Weyerhaeuser Pulp and Paper Mill—
Exposure Investigation Report; March
22, 2007.

Pennsylvania

Ivy Industrial Park Site—Public Health
Evaluation of Residential Indoor Air
and Well Water Sample Results;
March 5, 2007.

Remacor Site; January 10, 2007.

Tennessee

Mr. Zip Convenience Store; March 14,
2007.

Texas

Former Delroc Oil Refinery/Woodwind
Lakes Subdivision; February 23, 2007.

Utah

Vermiculite Intermountain and
Intermountain Products, Inc.—
Epidemiological Investigation of
Human Exposure to a Contaminated
Vermiculite Ore Processing Site in
Utah; March 1, 2007.

Washington

Home Heating Oil Release, Technical
Review of the Site Hazard
Assessment; March 29, 2007.

Wisconsin

Amery-Dresser Trail; January 23, 2007.
Dated: May 2, 2007.

Kenneth Rose,

*Acting Director, Office of Policy, Planning,
and Evaluation, National Center for
Environmental Health/Agency for Toxic
Substances and Disease Registry.*

[FR Doc. E7-8758 Filed 5-7-07; 8:45 am]

BILLING CODE 4163-70-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of a Modified or Altered System of Records

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

ACTION: Notice of a Modified or Altered
System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, CMS is proposing to modify or alter existing system of records titled “Complaints Against Health Insurance Issuers and Health Plans (CAHII),” System No. 09-70-9005, established at 66 FR 9858, (February 12, 2001). We propose to assign a new CMS identification number to this system to simplify the obsolete and confusing numbering system originally designed to identify the Bureau, Office, or Center that maintained information in the Health Care Financing Administration systems of records. The new assigned identifying number for this system should read: System No. 09-70-0516.

We propose to modify existing routine use number 1 that permits disclosure to agency contractors and consultants to include disclosure to CMS grantees who perform a task for the agency. CMS grantees, charged with completing projects or activities that require CMS data to carry out that activity, are classified separate from CMS contractors and/or consultants. The modified routine use will remain as routine use number 1. We will delete routine use number 2 authorizing disclosure to support constituent requests made to a congressional representative. If an authorization for the disclosure has been obtained from the data subject, then no routine use is needed. The Privacy Act allows for disclosures with the “prior written consent” of the data subject.

We propose to add 2 new routine uses authorizing disclosure to support a CMS contractor, consultant, or a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to combat fraud, waste, and abuse in certain health care programs. The new routine use will be published as routine use number 6. We will add a second new routine use to support another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States, when disclosure is deemed reasonably necessary by CMS to combat fraud, waste, and abuse in certain health care programs. This new routine use will be published as routine use number 7. We will broaden the scope of this system by including the section titled “Additional Circumstances Affecting Routine Use Disclosures,” that addresses “Protected Health Information (PHI)” and “small cell size.” The requirement for compliance with HHS regulation “Standards for Privacy of Individually Identifiable Health Information” apply when ever the system collects or maintain PHI. This system may contain

PHI. In addition, our policy to prohibit release if there is a possibility that an individual can be identified through “small cell size” will apply to the data disclosed from this system.

We are modifying the language in the remaining routine uses to provide a proper explanation as to the need for the routine use and to provide clarity to CMS’s intention to disclose individual-specific information contained in this system. The routine uses will then be prioritized and reordered according to their usage. We will also take the opportunity to update any sections of the system that were affected by the recent reorganization or because of the impact of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) provisions and to update language in the administrative sections to correspond with language used in other CMS SORs.

The primary purpose of this system is to collect and maintain information initiated by consumers complaints/reports to CMS that their health insurance issuers and/or non-Federal governmental health plans are in violation of one or more of the following statutes: §§ 2722 and 2761 of the Public Health Service (PHS) Act; the Mental Health Parity Act of 1996 (MHPA); the Newborns’ and Mothers’ Health Protection Act of 1996 (NMHPA); and, the Women’s Health and Cancer Rights Act of 1998 (WHCRA). Information maintained in this system will also 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, agency of a state government, an agency established by state law, or its fiscal agent; (3) assist 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; (4) inform a health insurance issuer and/or health plan who has been named in a complaint/inquiry and is believed to be potentially in violation of relevant portions of the PHS; (5) support litigation involving the Agency; and (6) combat fraud, waste, and abuse in certain health benefits programs. We have provided background information about this new 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 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 Homeland Security and Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on April 12, 2007. To ensure that all parties have adequate time in which to comment, the new SOR, including routine uses, will become effective 40 days from the publication of the notice, or from the date it was submitted to OMB and the Congress, whichever is later, unless CMS receives comments that require alterations to this notice.

ADDRESSES: The public should address comments to: CMS Privacy Officer, Division of Privacy Compliance, Enterprise Architecture and Strategy Group, Office of Information Services, 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: Dave Mlawsky, Health Insurance Specialist, Division of Employer Operations, Employer Policy and Operations Group, Center for Beneficiary Choices, CMS, 7500 Security Boulevard, Mail Stop S3-16-26, Baltimore, Maryland 21244-1850. The telephone number is 410-786-6851 or e-mail david.mlawsky@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Description of the Modified or Altered System of Records

A. Statutory and Regulatory Basis for SOR

Authority for maintenance of this system is given under §§ 2722 and 2761 of the Public Health Service (PHS) Act; the Mental Health Parity Act of 1996 (MHPA); the Newborns' and Mothers' Health Protection Act of 1996 (NMHPA); and the Women's Health and Cancer Rights Act of 1998 (WHCRA) with respect to non-Federal governmental plans.

B. Collection and Maintenance of Data in the System

This system will collect and maintain individually identifiable and other data collected on individuals/consumers who make complaints/inquiries to CMS that their health insurance issuers and/or non-Federal governmental health plans are in violation of the PHS.

The system contains information such as consumer's name, address, phone number, the name and address of their health plan or health insurance issuer, their plan ID number or social security number, the nature of their complaint/inquiry against their health plan or issuer, and any medical and other additional information that is necessary for CAHII to help resolve the consumer's complaint.

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 CAHII 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 CAHII. CMS has the following policies and procedures concerning disclosures of information that will be maintained in the system. Disclosure of information from the SOR 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 data is being collected; e.g., to collect and maintain information initiated by consumers complaints/reports to CMS that their health insurance issuers and/or non-Federal governmental health plans are in violation of the PHS;

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

- a. 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

- b. 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. Modified 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 that have been contracted by the Agency to assist in accomplishment of a CMS function relating to the purposes for this system and who need access to the records in order to assist CMS. 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 a 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, consultant, or grantee 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 or consultant to return or destroy all information at the completion of the contract.

2. To assist another Federal or state agency, agency of a state government, an agency established by state law, or its fiscal agent 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. Refer a complaint or inquiry with respect to Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Mental Health Parity Act of 1996 (MHPA), the Newborns' and Mothers' Health Protection Act of 1996 (NMHPA), and the Women's Health and Cancer Rights Act of 1998 (WHCRA).

CAHII shares enforcement responsibilities with the U.S. Department of Labor, the U.S. Department of Treasury and State regulatory bodies with respect to Title I of HIPAA, MHPA, NMHPA and WHCRA. CAHII's enforcement responsibilities are discussed in the "Description of the New System of Records" section above. The Department of Labor enforces Title I of HIPAA, MHPA, NMHPA and WHCRA with respect to private group health plans. The Department of Treasury may levy excise taxes against private group health plans that do not comply with these Acts, except for WHCRA. In States that are substantially enforcing Title I of PHS, MHPA, NMHPA and WHCRA, the appropriate State agency enforces these provisions with respect to health insurance issuers.

Occasionally, CAHII will receive an inquiry or complaint related to one of these four Acts in situations where it is within Labor's or Treasury's or a State's, and not CAHII's, jurisdiction to resolve. In such cases, CAHII must disclose information from the system of records to the appropriate agency so they can perform their enforcement function.

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

In addition, other state agencies in their administration of a Federal health program may require CAHII information for the purposes of determining, evaluating and/or assessing cost, effectiveness, and /or the quality of health care services provided in the state.

3. To assist 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 parties contacts require CAHII 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.

4. To inform a health insurance issuer and/or health plan, who has been named in a complaint and is believed to be potentially in violation of relevant portions of the PHS Act.

When individuals file complaints or inquiries asking CAHII to clarify or enforce their rights under Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Mental Health Parity Act of 1996 (MHPA), the Newborns' and Mothers' Health Protection Act of 1996 (NMHPA), and the Women's Health and Cancer Rights Act of 1998 (WHCRA), CAHII often must disclose information maintained in this system of records to the individual's health insurance issuer or health plan in order for CAHII to satisfy its statutory charge to enforce these Federal Acts with respect to non-Federal governmental health plans in all States and health insurance issuers in some States.

5. To assist 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, 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.

6. To support a CMS contractor 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 or abuse in such programs.

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

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

7. To support 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, or abuse in a 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 or abuse in such programs.

Other agencies may require CAHII information for the purpose of combating fraud, waste or 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 individuals could, because of the small size, use this information to deduce the identity of the beneficiary).

IV. Safeguards

CMS has safeguards in place for authorized users and monitors such users to ensure against 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 Modified or Altered System of Records on Individual Rights

CMS proposes to modify 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 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 information relating to individuals.

Dated: April 12, 2007.

Charlene Frizzera,

Acting Chief Operating Officer Centers for Medicare & Medicaid Services.

System No. 09-70-0516.

SYSTEM NAME:

• Complaints Against Health Insurance Issuers and Health Plans (CAHII)," HHS/CMS/CBC.

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 other contractor locations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system will collect and maintain individually identifiable and other data collected on individuals/consumers who make complaints/inquiries to CMS

that their health insurance issuers and/or non-Federal governmental health plans are in violation of the PHS ACT.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system contains information such as consumer's name, address, phone number, the name and address of their health plan or health insurance issuer, their plan ID number or social security number, the nature of their complaint/inquiry against their health plan or issuer, and any medical and other additional information that is necessary for CAHII to help resolve the consumer's complaint.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for maintenance of this system is given under §§ 2722 and 2761 of the Public Health Service (PHS) Act; the Mental Health Parity Act of 1996 (MHPA); the Newborns' and Mothers' Health Protection Act of 1996 (NMHPA); and the Women's Health and Cancer Rights Act of 1998 (WHCRA) with respect to non-Federal governmental plans.

PURPOSE(S) OF THE SYSTEM:

The primary purpose of this system is to collect and maintain information initiated by consumers complaints/reports to CMS that their health insurance issuers and/or non-Federal governmental health plans are in violation of one or more of the following statutes: §§ 2722 and 2761 of the Public Health Service (PHS) Act; the Mental Health Parity Act of 1996 (MHPA); the Newborns' and Mothers' Health Protection Act of 1996 (NMHPA); and , the Women's Health and Cancer Rights Act of 1998 (WHCRA). Information maintained in this system will also 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, agency of a state government, an agency established by state law, or its fiscal agent; (3) assist 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; (4) inform a health insurance issuer and/or health plan who has been named in a complaint/inquiry and is believed to be potentially in violation of relevant portions of the PHS ACT; (5) support litigation involving the Agency; and (6) combat fraud, waste, and abuse in certain 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 that have been contracted by the Agency to assist in accomplishment of a CMS function relating to the purposes for this system and who need access to the records in order to assist CMS.

2. To assist another Federal or state agency, agency of a state government, an agency established by state law, or its fiscal agent to:

a. Contribute to the accuracy of CMS's 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. Refer a complaint or with respect to Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Mental Health Parity Act of 1996 (MHPA), the Newborns' and Mothers' Health Protection Act of 1996 (NMHPA), and the Women's Health and Cancer Rights Act of 1998 (WHCRA).

3. To assist 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 exists, 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.

4. To inform a health insurance issuer and/or health plan, who has been named in a complaint and is believed to be potentially in violation of relevant portions of the PHS Act.

5. To assist 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.

6. To support a CMS contractor that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such programs.

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

remedy, or otherwise combat fraud or abuse in such programs.

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 individuals could, because of the small size, use this information to deduce 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., consumer's name or health insurance claims number, if, applicable.

SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against 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 6 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 Policy, Employer Policy and Operations Group, Center for Beneficiary Choices, CMS, 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, employee identification number, tax identification number, national provider number, and for verification purposes, 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:

The data collected and maintained in this system are retrieved from individuals/consumers who file complaints/reports to CMS that their health insurance issuers and/or non-Federal governmental health plans are in violation of the PHS ACT.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of a Modified System of Records

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

ACTION: Notice of a Modified System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to modify or alter a system titled, "End Stage Renal Disease (ESRD) Program Management and Medical Information System (PMMIS), System No. 09-70-0520," and last modified at 67 Fed. Reg. 41244 (June 17, 2002). This system contains records on individuals with ESRD who are entitled to receive Medicare benefits or who are treated by Department of Veteran Affairs (DVA) health care facilities. We propose to modify existing routine use number 1 that permits disclosure to agency contractors and consultants to include disclosure to CMS grantees who perform a task for the agency. The modified routine use will remain as routine use number 1. For further clarity, we propose to separate existing routine use number 3 that permit disclosures to ESRD Network Organizations and to Quality Improvement Organizations into separate routine uses. The activities performed by the 2 different type organizations are not so closely related that they should be combined in one routine use. The modified routine use will be republished as routine use number 3 for ESRD Network Organizations and routine use number 4 for Quality Improvement Organizations. We will delete routine use number 5 authorizing disclosure to support constituent requests made to a congressional representative. If an authorization for the disclosure has been obtained from the data subject,

then no routine use is needed. The Privacy Act allows for disclosures with the "prior written consent" of the data subject.

We propose to broaden the scope of the disclosure provisions of this system by adding a routine use to permit the release of priority personal information to complete a transfer out event from a losing ESRD facility and/or a transfer-in event to a gaining ESRD facility to: (1) Contribute to the accuracy of CMS' proper payment of Medicare benefits; and (2) enable such facilities to ensure the proper transfer of health records, and/or as necessary to enable such a facility 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; (3) assist ESRD programs which may require PMMIS information for purposes related to this system. Information will be released to these organizations upon specific request, and only for those organizations if they meet the following requirements: (1) Provide an attestation or other qualifying information that they are providing assistance to qualified ESRD beneficiaries; (2) submit a report of the transfer-in or transfer-out event; (3) safeguard the confidentiality of the data and prevent unauthorized access; and (4) complete a written statement attesting to the information recipient's understanding of and willingness to abide by these provisions. The PMMIS data will provide the ESRD facility with information regarding its enrollees' enrollment status, transplant activities, dialysis activities, and Medicare utilization; facilitate the facility's required utilization reviews and medication management program activities; and assist in quality of care issues as they relate to the beneficiary. The added routine use will be numbered as routine use number 6.

We are modifying the language in the remaining routine uses to provide a proper explanation as to the need for the routine use and to provide clarity to CMS's intention to disclose individual-specific information contained in this system. The routine uses will then be prioritized and reordered according to their usage. We will also take the opportunity to update any sections of the system that were affected by the recent reorganization or because of the impact of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) provisions and to update language in the administrative sections to correspond with language used in other CMS SORs.