

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.

The primary purpose of the system of records is to maintain information on Medicare ESRD beneficiaries, non-Medicare ESRD patients, Medicare approved ESRD hospitals and dialysis facilities, and Department of Veterans Affairs (DVA) patients. The ESRD/PMMIS is used by CMS and the renal community to perform their duties and responsibilities in monitoring the Medicare status, transplant activities, dialysis activities, and Medicare utilization (inpatient and physician/supplier bills) of ESRD patients and their Medicare providers, as well as in calculating the Medicare covered periods of ESRD. Information retrieved from this system of records 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) support an ESRD Network Organizations; (4) assist Quality Improvement Organizations (QIO) to implement quality improvement programs; (5) facilitate research on the quality and effectiveness of care provided and payment related projects; (6) permit the release of priority personal information to complete a transfer out event and/or a transfer-in event; (7) support litigation involving the agency; and, (8) combat fraud, waste, and abuse in certain health benefits programs. We have provided background information about the 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 modified or altered system 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 April 12, 2007. To ensure that all parties have adequate time in which to comment, the modified system, including routine uses, will become effective 30 days from the publication of the notice, or 40 days from the date it was submitted to OMB and 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:** Dennis Stricker, Director, Information Support Group, Office of Clinical Standards and Quality, CMS, Room S3-02-01, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. The telephone number is (410) 786-3116. The e-mail address is [dennis.stricker@cms.hhs.gov](mailto:dennis.stricker@cms.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **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 Sections 226A, 1875, and 1881 of the Social Security Act (the Act) (Title 42 United States Code (U.S.C.), sections 426-1, 1395ll, and 1395rr).

###### *B. Collection and Maintenance of Data in the System*

This system will collect and maintain individually identifiable and other data collected on individuals with ESRD who receive Medicare benefits or who are treated by DVA health care facilities. The system contains information on both the beneficiary and the provider of services.

The collected information will include, but is not limited to beneficiary/patient medical records, claims data, and payment data collected from several non-reimbursement data collection instruments and Medicare bills. The provider of services' name, address, Medicare identification number, types of services provided, certification and/or termination date, and ESRD network number.

##### **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 PMMIS 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 PMMIS.

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 maintain information on Medicare ESRD beneficiaries, non-Medicare ESRD patients, Medicare approved ESRD hospitals and dialysis facilities, and Department of Veterans Affairs (DVA) patients.

2. Determines that:

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

- b. The purpose for which the disclosure is to be made is of sufficient importance to warrant the effect and/or risk on the privacy of the individual that additional exposure of the record might bring; and

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

3. Requires the information recipient to:

- a. Establish administrative, technical, and physical safeguards to prevent 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 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, 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, consultant or grantee to return or destroy all information at the completion of the contract.

2. To 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. Determine compliance with the Federal conditions that an ESRD facility must meet in order to participate in Medicare.

Other Federal or State agencies in their administration of a federal health program may require PMMIS 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 PMMIS information for the purposes of determining, evaluating and/or assessing cost, effectiveness, and/or the quality of health care services provided in the state.

In addition, disclosure under this routine use shall be used by state agencies pursuant to agreements with the HHS for determining Medicare

eligibility, for quality control studies, for determining eligibility of recipients of assistance under titles IV, XVIII, and XIX of the Act, and for the administration of the Medicare program. Data will be released to the state only on those individuals who are patients under the services of a program within the state or who are residents of that state.

We also contemplate disclosing information under this routine use in situations in which state auditing agencies require PMMIS information for auditing eligibility considerations. CMS may enter into an agreement with state auditing agencies to assist in accomplishing functions relating to purposes for this system of records.

3. To ESRD Network Organizations in connection with review of claims, or in connection with studies or quality improvements projects or other review activities, and in performing affirmative outreach activities to individuals for the purpose of establishing and maintaining their entitlement to Medicare benefits or health insurance plans.

ESRD Network Organizations will work to implement quality improvement programs, provide consultation to CMS, its contractors, and its state agencies, in connection with studies or quality improvements projects or in performing affirmative outreach activities to individuals.

4. To Quality Improvement Organizations in connection with review of claims, or in connection with studies or quality improvements projects or other review activities, conducted pursuant to Part B of Title XI of the Social Security Act and in performing affirmative outreach activities to individuals for the purpose of establishing and maintaining their entitlement to Medicare benefits or health insurance plans.

QIOs will work to implement quality improvement programs, provide consultation to CMS, its contractors, and its state agencies, in connection with studies or quality improvements projects or other review activities.

The QIOs will assist the state agencies in related monitoring and enforcement efforts; assist CMS and intermediaries in program integrity assessment; and prepare summary information for release to CMS.

5. To 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 PMMIS 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.

6. To assist with a transfer out event from a losing ESRD facility and/or a transfer-in event to a gaining ESRD facility to:

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

b. 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; and

c. Assist ESRD programs which may require PMMIS information for purposes related to this system.

Information will be released to these facilities upon specific request, and only for those facilities if they meet the following requirements:

a. Provide an attestation or other qualifying information that they are providing assistance to qualified ESRD beneficiaries/patients;

b. Submit a report of the transfer-in or transfer-out event with the following required priority information: Name, address, HICN or SSN, date of birth;

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

d. complete a written statement attesting to the information recipient's understanding of and willingness to abide by these provisions.

Both the gaining and losing facilities may require priority information submitted as a transfer-in or transfer-out report to implement quality transfer of beneficiaries from one facility to another; provide consultation to CMS, its contractors, and its state agencies, in connection with transfer of patients.

7. To the Department of Justice (DOJ), court or adjudicatory body when:

a. The agency or any component thereof, or

b. Any employee of the agency in his or her official capacity, or

c. Any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee, or

d. The United States Government, is a party to litigation or has an interest in such litigation, and, by careful review, CMS determines that the records are both relevant and necessary to the litigation and 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.

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

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

Other agencies may require PMMIS 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 Fed. Reg. 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 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 Modified 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: April 12, 2007.

**Charlene Frizzera,**

*Acting Chief Operating Officer, Centers for Medicare & Medicaid Services.*

#### **System No. 09-70-0520.**

##### **SYSTEM NAME:**

"ESRD Program Management and Medical Information (PMMIS)," HHS/CMS/OCSQ.

##### **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 with ESRD who receive Medicare benefits or who are treated by DVA health care facilities. The system contains information on both the beneficiary and the provider of services.

##### **CATEGORIES OF RECORDS IN THE SYSTEM:**

The collected information will include, but is not limited to

beneficiary/patient medical records, claims data, and payment data collected from several non-reimbursement data collection instruments and Medicare bills. The provider of services' name, address, Medicare identification number, types of services provided, certification and or termination date, and ESRD network number.

#### **AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

The statutory authority for this system is given under the provisions of Sections 226A, 1875, and 1881 of the Social Security Act (the Act) (Title 42 United States Code (U.S.C.), sections 426-1, 1395ll, and 1395rr).

#### **PURPOSE(S) OF THE SYSTEM:**

The primary purpose of the system of records is to maintain information on Medicare ESRD beneficiaries, non-Medicare ESRD patients; Medicare approved ESRD hospitals and dialysis facilities, and Department of Veterans Affairs (DVA) patients. The ESRD/PMMIS is used by CMS and the renal community to perform their duties and responsibilities in monitoring the Medicare status, transplant activities, dialysis activities, and Medicare utilization (inpatient and physician/supplier bills) of ESRD patients and their Medicare providers, as well as in calculating the Medicare covered periods of ESRD. Information retrieved from this system of records 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) support an ESRD Network Organizations; (4) assist Quality Improvement Organizations (QIO) to implement quality improvement programs; (5) facilitate research on the quality and effectiveness of care provided and payment related projects; (6) permit the release of priority personal information to complete a transfer out event and/or a transfer-in event; (7) support litigation involving the agency; and, (8) 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 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 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. Determine compliance with the Federal conditions that an ESRD facility must meet in order to participate in Medicare.

3. To ESRD Network Organizations in connection with review of claims, or in connection with studies or quality improvements projects or other review activities, and in performing affirmative outreach activities to individuals for the purpose of establishing and maintaining their entitlement to Medicare benefits or health insurance plans.

4. To Quality Improvement Organizations in connection with review of claims, or in connection with studies or quality improvements projects or other review activities, conducted pursuant to Part B of Title XI of the Social Security Act and in performing affirmative outreach activities to individuals for the purpose of establishing and maintaining their entitlement to Medicare benefits or health insurance plans.

5. To 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.

6. To assist with a transfer out event from a losing ESRD facility and/or a transfer-in event to a gaining ESRD facility to:

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

b. 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; and

c. Assist ESRD programs which may require PMMIS information for purposes related to this system.

Information will be released to these facilities upon specific request, and only for those facilities if they meet the following requirements:

d. Provide an attestation or other qualifying information that they are providing assistance to qualified ESRD beneficiaries/patients;

e. Submit a report of the transfer-in or transfer-out event with the following required priority information: Name, address, HICN or SSN, date of birth;

f. Safeguard the confidentiality of the data and prevent unauthorized access; and

g. Complete a written statement attesting to the information recipient's understanding of and willingness to abide by these provisions.

7. To the Department of Justice (DOJ), court or adjudicatory body when:

a. The agency or any component thereof, or

b. Any employee of the agency in his or her official capacity, or

c. Any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee, or

d. The United States Government, is a party to litigation or has an interest in such litigation, and, by careful review, CMS determines that the records are both relevant and necessary to the litigation and 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.

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

9. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud, waste, or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect,

investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste, 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., 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:**

Records will be retained until an approved disposition authority is obtained from the National Archives and Records Administration. 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, Information Support Group, Office of Clinical Standards and Quality, CMS, Room S3-02-01, 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 contained in these records are obtained from Medicare ESRD medical evidence reports, kidney transplant reports, ESRD beneficiary reimbursement method selection forms, ESRD death notification forms, Medicare bills, CMS Medicare Master files, ESRD facility surveys, ESRD facility certification notices, and the Medicare/Medicaid Automated Certification System (MMACS).

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**Appendix A**

1. ESRD Network of New England, Incorporated, Post Office Box 9484, New Haven, Connecticut 06534.
2. ESRD Network of New York, Incorporated, 1249 Fifth Avenue, A-419, New York, New York 10029.
3. Trans-Atlantic Renal Council, Cranbury Plaza, 2525 Route 130—Building C, Cranbury, New Jersey 08512-9595.
4. ESRD Network Organization Number 4, 200 Lothrop Street, Pittsburgh, Pennsylvania 15213-2582.
5. Mid-Atlantic Renal Coalition, 1527 Huguenot Road, Midlothian, Virginia 23113.
6. Southeastern Kidney Council, Incorporated, 1000 Saint Albans Drive, Suite 270, Raleigh, North Carolina 27609.
7. ESRD Network of Florida, Incorporated, One Davis Boulevard, Suite 304, Tampa, Florida 33606.
8. Network 8, Incorporated, Post Office Box 55868, Jackson, Mississippi 39296-5868.
- 9 & 10. The Renal Network, Incorporated, 911 East 86th Street, Suite 202, Indianapolis, Indiana 46240.
11. Renal Network of the Upper Midwest, 970 Raymond Avenue #205, Saint Paul, Minnesota 55114.
12. ESRD Network Number 12, 7509 NW T Tiffany Spring Parkway, Suite 105, Kansas City, Missouri 64153.
13. ESRD Network Organization Number 13, 6600 North Meridan Avenue, Suite 155, Oklahoma City, Oklahoma 73116-1411.
14. ESRD Network of Texas, Incorporated, 14114 Dallas Parkway, Suite 660, Dallas, Texas 75240-4349.
15. Intermountain ESRD Network, Incorporated, 1301 Pennsylvania Street, Suite 220, Denver, Colorado 80203-5012.
16. Northwest Renal Network, 4702 42nd Avenue, Seattle, Washington 98116.
17. TransPacific Renal Network, 25 Mitchell Boulevard, Suite 7, San Rafael, California 94903.
18. Southern California Renal Disease Council, 6255 Sunset Boulevard, Suite 2211, Los Angeles, California 90082.

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