and (3) escape respirators for protection against CBRN.

Status: This meeting is hosted by NIOSH and will be open to the public, limited only by the space available. The meeting room will accommodate approximately 150 people. Interested parties should make hotel reservations directly with the Sheraton Station Square Hotel (412–261–2000 or 800–325–3535) before the cut-off date of December 8, 2005. A special group rate of $91 per night for meeting guests has been negotiated for this meeting. The NIOSH/NPPTL Public Meeting must be referenced to receive this rate. Interested parties should confirm their attendance to this meeting by completing a registration form and forwarding it by e-mail (*npptlevents@cdc.gov*) or fax (304–225–2003) to the NPPTL Event Management Office. A registration form may be obtained from the NIOSH Homepage (*http://www.cdc.gov/niosh*) by selecting conferences and then the event.

An opportunity to make presentations regarding the discussions of concepts for standards and testing processes for PAPR standards and for Closed Circuit, SCBA standards suitable for respiratory protection against CBRN agents and PAPRs for industrial applications of NIOSH-approved CBRN respirators will be given. Requests to make such presentations at the public meeting should be made by e-mail to the NPPTL Event Management Office (*npptlevents@cdc.gov*). All requests to present should include the name, address, telephone number, relevant business affiliations of the presenter, a brief summary of the presentation, and the approximate time requested for the presentation. Oral presentations should be limited to 15 minutes. After reviewing the requests for presentation, NPPTL Event Management will notify each presenter of the approximate time that their presentation is scheduled to begin. If a participant is not present when their presentation is scheduled to begin, the remaining participants will be heard in order. At the conclusion of the meeting, an attempt will be made to allow presentations by any scheduled participants who missed their assigned times. Attendees who wish to speak but did not submit a request for the opportunity to make a presentation may be given this opportunity at the conclusion of the meeting, at the discretion of the presiding officer.

Comments on the topics presented in this notice and at the meeting should be mailed to: NIOSH Docket Office, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, Telephone 513–533–8303, Fax 513–533–8285. Comments may also be submitted by e-mail to *niocindocket@cdc.gov*. E-mail attachments should be formatted in Microsoft Word. Comments regarding the Industrial PAPR should reference Docket Number NIOSH–008 in the subject heading. Comments regarding CBRN PAPR should reference Docket Number NIOSH–010 in the subject heading. Comments regarding the CBRN Closed Circuit, SCBA should reference Docket Number NIOSH–039.

Due to administrative issues that had to be resolved, the **Federal Register** notice is being published on short notice.

FOR FURTHER INFORMATION CONTACT: NPPTL Event Management, 3604 Collins Ferry Road, Suite 100, Morgantown, West Virginia 26505–2353, Telephone 304–599–5941 x138, Fax 304–225–2003, E-mail *npptlevents@cdc.gov*.

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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 30, 2005.

Diane Allen,

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

[FR Doc. 05–23653 Filed 12–1–05; 10:03 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers For Medicare & Medicaid Services

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

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

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

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system of records title, ''Implantable Cardioverter-Defibrillator (ICD) System, System No. 09–70–0548.'' National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act (the Act) § 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be ''reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,'' § 1862(a)(1)(A). CMS has determined that the evidence is adequate to conclude that an implantable cardioverter-defibrillator (ICD) is reasonable and necessary in several patient groups where certain criteria for these patients have been met. The reasonable and necessary determination requires that patients meet the ICD implantation criteria set forth in the decision memorandum and are consistent with the trials discussed. Collection of these data elements allows that determination to be made.

The purpose of this system is to provide reimbursement for ICDs and assist in the collection of data on patients receiving an ICD for primary prevention to a data collection process to assure patient safety and protection and to determine that the ICD is reasonable and necessary. Information retrieved from this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant; (2) assist another Federal or state agency with information to enable such agency to administer a Federal health benefits program, or to enable such agency to fulfill a requirement of Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds; (3) 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; (4) support constituent requests made to a congressional representative; (5) support litigation involving the agency; and (6) combat fraud and abuse in certain health benefits programs. We have provided background information about the modified 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.

EFFECTIVE DATE: CMS filed a new SOR 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 November 28, 2005 . We will not disclose any information under a routine use until 30 days after publication. We may defer implementation of this SOR or one or more of the routine use statements listed below if we receive comments that persuade us to defer implementation.

ADDRESSES: The public should address comment to the CMS Privacy Officer, Mail Stop N2–04–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.–3 p.m., eastern daylight time.

FOR FURTHER INFORMATION CONTACT: Rosemarie Hakim, Epidemiologist, Office of Clinical Standards and Quality, CMS, Mail Stop C1–09–06, 7500 Security Boulevard, Baltimore, Maryland 21244–1849, Telephone Number (410) 786–3934, *Rosemarie.Hakim@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION: We desire to ensure that defibrillator implantation only occurs in those patients who are most likely to benefit and that the procedures are done only by competent providers in facilities with a history of good outcomes and a quality assessment/improvement program to identify providers with poor outcomes and other areas for improvement. As mentioned above, we are concerned that the available evidence does not allow providers to target these devices to patients who will clearly derive benefit. In order to provide maximum protection to our beneficiaries, CMS will require that reimbursement for ICDs for primary prevention of sudden cardiac death occur only if the beneficiary receiving the defibrillator implantation is enrolled in either a FDA approved category B IDE clinical trial, a trial under the CMS Clinical Trial Policy or a qualifying data collection system including approved clinical trials and registries.

The submission of data on patients receiving an ICD for primary prevention to a data collection process is needed to assure patient safety and protection and to determine that the ICD is reasonable and necessary. These patient protections and safeguards require that data be made available in some form to providers and practitioners to inform their decisions, monitor performance quality, benchmark and identify best practices. The reasonable and necessary determination requires that patients meet the ICD implantation criteria set forth in this decision memorandum and are consistent with the trials discussed. Collection of these data elements allows that determination to be made. We will also ensure that any future data collection system are consistent with the Standards for Privacy of Individually Identifiable Health Information and that all issues related to patient confidentiality, privacy, and compliance with other Federal laws will be resolved prior to the collection of any data.

There will be an initial ICD registry so that data collection can begin with the posting of this decision. A data submission mechanism will be used that is already in use by Medicare participating hospitals to submit quality data. Initial hypotheses to be addressed by the registry will include the following:

1. The clinical characteristics of the registry patients receiving ICDs are similar to those of patients involved in the primary prevention randomized clinical trials.
2. The indications for ICD implantation in registry patients are similar to those in the primary prevention randomized clinical trials.
3. The in-hospital procedure related complications for registry patients is similar to those in the primary prevention randomized clinical trials.
4. Certified providers competent in ICD implantation are implanting ICD devices in registry patients.
5. Registry patients who receive an ICD represent patients for which current clinical guidelines and the evidence base recommend implantation.
6. The clinical characteristics and indications for ICD implantation in registry patients do not differ significantly among facilities.
7. The clinical characteristics and indications for ICD implantation in registry patients do not differ significantly among providers.
8. The in-hospital procedure related complications for ICD implantation in registry patients does not differ significantly among facilities.
9. The in-hospital procedure related complications for ICD implantation in registry patients does not differ significantly among providers.
10. The in-hospital procedure related complications for ICD implantation in registry patients does not differ significantly among device manufacturer, types, and/or programming.

Data elements necessary to address these hypotheses are the minimum necessary to determine that the ICD is reasonable and necessary. CMS reserves the right to modify these hypotheses and elements as other evidence becomes available. Initially, an ICD registry will be maintained using a data submission mechanism that is already in use by Medicare participating hospitals to submit quality data. Data collection will be completed using the ICDA (ICD Abstraction Tool) and transmitted via Quality Network Exchange (QNET) to the Iowa Foundation for Medical Care (IFMC) who will collect and maintain registry data. CMS will post additional information on data submission on its coverage website, through the MedLearn system, and through the QNET education program.

This registry is only an initial data collection process. A follow-on registry that will replace the QNET registry and address additional hypotheses is currently being explored with specialty societies, industry, health plans and hospital associations. Industry has committed to developing a system to more closely evaluate the benefit in patients with LVEF 30–35%, NYHA Class IV in CRT–D, or NIDCM of 3–9 months duration. Specialty societies have indicated interest in more clearly defining appropriate facility and provider standards. CMS will continue to encourage the public discussion of the appropriate replacement registry. We will also ensure that any future data collection system is consistent with the Standards for Privacy of Individually Identifiable Health Information and that all issues related to patient confidentiality, privacy, and compliance with other Federal laws will be resolved prior to the collection of any data.

Finally, technology exists to easily capture the type of data collected in our initial registry and to prevent repeated entry of identical data into the several trials or registries in which hospitals participate. CMS is interested in public input into how the Agency might assist the healthcare community in creating a single data entry system.

I. Description of the Proposed System of Records

A. Statutory and Regulatory Basis for SOR

The statutory authority for linking coverage decisions to the collection of additional data is derived from Sec. 1862(a)(1)(A) of the Act, which states that Medicare may not provide payment for items and services unless they are ''reasonable and necessary'' for the treatment of illness or injury. In some cases, CMS will determine that an item or service is only reasonable and necessary when specific data collections accompany the provisions of the

service. In these cases, the collection of data is required to ensure that the care provided to individual patients will improve health outcomes.

B. Collection and Maintenance of Data in the System

CMS has determined that the evidence is adequate to conclude that an implantable cardioverter-defibrillator (ICD) is reasonable and necessary for the following:

- Patients with ischemic dilated cardio-myopathy, documented prior myocardial infarction (MI), New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular ejection fraction (LVEF) ≤ 35%;
- Patients with nonischemic dilated cardiomyopathy > 9 months, NYHA Class II and III heart failure, and measured LVEF ≤ 35%;
- Patients who meet all current CMS coverage requirements for a cardiac resynchronization therapy device and have NYHA Class IV heart failure.

The collected information will contain name, address, telephone number, Health Insurance Claim Number (HICN), geographic location, race/ethnicity, gender, and date of birth, as well as, background information relating to Medicare or Medicaid issues.

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

A. 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 ICD 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 ICD. 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 that the data is being collected, e.g., to provide reimbursement for ICDs and assist in the collection of data on patients receiving an ICD for primary prevention to a data collection process to assure patient safety and protection and to determine that the ICD is reasonable and necessary.

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 or consultants who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual or similar agreement with a third party to assist in accomplishing 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 or consultant whatever information is necessary for the contractor or consultant to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor or consultant 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 another Federal or state agency to:

a. To provide reimbursement for ICDs and assist in the collection of data on patients receiving an ICD for primary prevention to a data collection process to assure patient safety and protection and to determine that the ICD is reasonable and necessary,

b. Contribute to the accuracy of CMS's proper payment of Medicare benefits, and/or

c. 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.

Other Federal or state agencies in their administration of a Federal health program may require ICD information in order to provide reimbursement for ICDs and assist in the collection of data on patients receiving an ICD for primary prevention to a data collection process to assure patient safety and protection and to determine that the ICD is reasonable and necessary.

3. 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 ICD data will provide for research or in support of evaluation projects, 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 policy that governs the care.

4. To a member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

Beneficiaries sometimes request the help of a member of Congress in resolving an 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.

5. 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.

6. 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 or abuse in such program.

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

CMS occasionally contracts out certain of its functions and makes grants 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 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 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 or abuse in such programs. Other agencies may require ICD information for the purpose of combating fraud and abuse in such Federally funded programs.

B. *Additional Provisions Affecting Routine Use Disclosures.* This system contains Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 Code of Federal Regulations (CFR) Parts 160 and 164, 65 Fed. Reg. 82462 (12–28–00), Subparts A and E.) Disclosures of PHI 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.''

In addition, our policy will be to prohibit release even if not directly identifiable information, 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 who are familiar with the enrollees 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 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 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, HHS, and CMS policies and standards include but are not limited to: all pertinent National Institute of Standards and Technology publications; HHS Information Systems Program Handbook and the CMS Information Security Handbook.

V. Effects of the Proposed System of Records on Individual Rights

CMS proposes to establish this system in accordance with the principles and requirements of the Privacy Act and will collect, use, and disseminate information only as prescribed therein. Data in this system will be subject to the authorized releases in accordance with the routine uses identified in this system of records.

CMS will take precautionary measures (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 information relating to individuals.

Lori Davis,

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

SYSTEM NO. 09–70–0548

SYSTEM NAME:

''Implantable Cardioverter-Defibrillator (ICD) System;'' HHS/CMS/OCSQ.

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive Data.

SYSTEM LOCATION:

Centers for Medicare & Medicaid Services (CMS) Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244–1850 and at various co-locations of CMS contractors.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

CMS has determined that the evidence is adequate to conclude that an implantable cardioverter-defibrillator (ICD) is reasonable and necessary for the following:

- Patients with ischemic dilated cardio-myopathy, documented prior myocardial infarction (MI), New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular ejection fraction (LVEF) ≤ 35%;
- Patients with nonischemic dilated cardiomyopathy > 9 months, NYHA Class II and III heart failure, and measured LVEF ≤ 35%;
- Patients who meet all current CMS coverage requirements for a cardiac resynchronization therapy device and have NYHA Class IV heart failure.

CATEGORIES OF RECORDS IN THE SYSTEM:

The data collection should include baseline patient characteristics. The collected information will contain name, address, telephone number, Health Insurance Claim Number (HICN), geographic location, race/ethnicity, gender, and date of birth, as well as, background information relating to Medicare or Medicaid issues.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The statutory authority for linking coverage decisions to the collection of additional data is derived from Sec. 1862 (a) (1) (A) of the Social Security Act (the Act), which states that Medicare may not provide payment for items and services unless they are ''reasonable and necessary'' for the treatment of illness or injury. In some cases, CMS will determine that an item or service is only reasonable and necessary when specific data collections accompany the provision of the service. In these cases, the collection of data is required to ensure that the care provided to individual patients will improve health outcomes.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to provide reimbursement for ICDs and assist in the collection of data on patients receiving an ICD for primary prevention to a data collection process to assure patient safety and protection and to determine that the ICD is reasonable and necessary. Information retrieved from this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant; (2) assist another Federal or state agency with information to enable such agency to administer a Federal health benefits program, or to enable such agency to fulfill a requirement of Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds; (3) 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; (4) support constituent requests made to a congressional representative; (5) support litigation involving the agency; and (6) combat fraud 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 or consultants who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity.

2. To another Federal or state agency to:

a. Provide reimbursement for ICDs and assist in the collection of data on patients receiving an ICD for primary prevention to a data collection process to assure patient safety and protection and to determine that the ICD is reasonable and necessary,

b. Contribute to the accuracy of CMS's proper payment of Medicare benefits, and/or

c. 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.

3. 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.

4. 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.

5. 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.

6. 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 or abuse in such program.

7. 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 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 or abuse in such programs.

B. Additional Provisions Affecting Routine Use Disclosures. This system contains Protected Health Information (PHI) as defined by the Department of Health and Human Services (HHS) regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 Code of Federal Regulations (CFR) Parts 160 and 164, 65 Fed. Reg. 82462 (12–28–00), Subparts A and E.) Disclosures of PHI 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.''

In addition, our policy will be to prohibit release even of not directly identifiable information, 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 who are familiar with the enrollees 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 electronically.

RETRIEVABILITY:

The data are retrieved by an individual identifier *i.e.*, name of beneficiary or provider.

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 implements 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 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, HHS, and CMS policies and standards include but are not limited to: all pertinent National Institute of Standards and Technology publications; HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

CMS will retain information for a total period of 10 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, Office of Clinical Standards and Quality, CMS, Room S2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

For the purpose of access, the subject individual should write to the system manager who will require the system name, address, age, gender, and for verification purposes, the subject individual's name (woman's maiden name, if applicable).

RECORD ACCESS PROCEDURE:

For the purpose of access, use the same procedures outlines 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).

CONTESTING RECORDS PROCEDURES:

The subject individual should contact the system manager named above and reasonable identify the records 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:

Records maintained in this system are derived from Carrier and Fiscal Intermediary Systems of Records, Common Working File System of Records, clinics, institutions, hospitals and group practices performing the procedures, and outside registries and professional interest groups.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. E5–6808 Filed 12–2–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

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

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

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new SOR titled, ''Fluoro-Deoxy Glucose (FDG) Positron Emission Tomography (PET) for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, Testicular and Other Cancers (PET 6), HHS/CMS/OCSQ, System No. 09–70–0549.'' National Coverage Determinations (NCD) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under Title XVIII of the Social Security Act (the Act) § 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained in Part A or Part B, and must not be otherwise excluded from coverage.

In our review of the other cancer indications, we found sufficient evidence to determine that PET scans are no longer experimental. However, the evidence was insufficient to reach a conclusion that FDG PET is reasonable and necessary in all instances. A sufficient inference of benefit, however, can be drawn to support limited coverage if certain safeguards for patients are provided. This inference is based on both the physiological basis for FDG PET usefulness in cancer, as well as, evidence of a positive benefit of FDG PET for patients with several other cancers for which there is evidence of sufficient quality to warrant coverage.

The purpose of this system is to collect and maintain information on Medicare beneficiaries receiving FDG PET scans for indications for when there is not sufficient evidence to reach a firm conclusion that the scan is reasonable and necessary unless they are enrolled in an approved study. Information retrieved from this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant; (2) assist another Federal or state agency with information to enable such agency to administer a Federal health benefits program, or to enable such agency to fulfill a requirement of Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds; (3) 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; (4) support constituent requests made to a Congressional