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 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 FR 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 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.

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. 05–18488 Filed 9–19–05; 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 create a new SOR titled, ''Carotid Artery Stenting (CAS) System, System No. 09–70–0556.'' 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) section 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.'' section 1862(a) (1) (A). CMS has determined that the evidence is adequate to conclude that CAS with embolic protection is reasonable and necessary to symptomatic patients who are at high risk for carotid endarterectomy (CEA), have significant comorbidities, or have anatomic risk factors. The reasonable and necessary determination requires that patients meet the criteria 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 collect and maintain data on patients to review determinations of ''reasonable and necessary'' with respect to CAS in patients who are at high risk for CEA. 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 September 13, 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. She can be reached by telephone at (410) 786–3934, or via email at *rhakim@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION: Each year about 700,000 people in the United States experience a new or recurrent stroke. About 500,000 of these are first attacks and 200,000 are recurrent attacks. The term stroke refers to a ''group of cerebrovascular disorders in which part of the brain is transiently or permanently affected by ischemia or hemorrhage, or in which one or more blood vessels of the brain are primarily affected by a pathologic process, or both.'' There are three main categories of strokes: Cerebral infarction (greater than 80%), intracerebral hemorrhage, and subarachnoid hemorrhage. Of the cerebral infarctions, ''20% to 30% are due to atherothrombosis or thromboembolism from the extracranial or intracranial vessels.''

Risk factors for stroke include advanced age, male gender, hypertension, history of stroke or transient ischemic attack, atrial fibrillation, valvular heart disease, diabetes mellitus, carotid artery stenosis, hypercoagulable conditions, and cigarette smoking. Hypertension is ''the single most important risk factor for both ischemic and hemorrhage stroke.'' Awareness of stroke warning signs is important since ''the inability of patients and bystanders to recognize stroke symptoms and to quickly access the emergency medical system are the largest barriers to effective acute stroke therapy.''

Prevention of stroke remains important and includes among others, treatment of hypertension and diabetes mellitus; smoking cessation; limiting alcohol intake; control of diet and obesity; antiplatelet drugs or anticoagulants for atrial fibrillation and appropriate acute myocardial infarctions; antiplatelet drugs for symptomatic carotid or vertebrobasilar atherosclerosis; and CEA for specifically defined populations of patients with symptomatic carotid artery stenosis. CEA is a surgical procedure used to prevent stroke in which the surgeon removes fatty deposits or ulcerated and stenotic plaques from the carotid arteries, the two main arteries in the neck supplying blood to the brain. Although carotid artery stenosis is an important risk factor, it was estimated that ''approximately 20% and 45% of strokes in the territory of symptomatic and asymptomatic carotid arteries with 70% to 99% stenosis, respectively, are unrelated to carotid stenosis.'' In these patients, optimal medical therapy would be most important since CEA does not reduce lacunar and cardio embolic strokes. CAS is performed with a catheter, usually inserted through the femoral artery, and threaded up to the carotid artery beyond the area of narrowing. A distal embolic protection device or filter is usually placed first to catch emboli or debris that may dislodge during the procedure. A self-expandable or balloon-expandable, metal mesh stent is then placed to widen the stenosis and the protection device is removed.

On June 18, 2004, CMS began an NCD process for CAS with distal embolic protection for patients at high risk for CEA. Previously, Medicare covered percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stent placement in accordance with the Food and Drug Administration (FDA) approved protocols governing Category B Investigational Device Exemption clinical trials and in FDA required post approval studies. Effective July 1, 2001, PTA of the carotid artery, when provided solely for the purpose of carotid artery dilation concurrent with carotid stent placement, is considered to be a reasonable and necessary service only when provided in the context of such a clinical trial, and therefore is considered a covered service for the purposes of these trials. Effective October 12, 2004, Medicare covered PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies.

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 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.

B. Collection and Maintenance of Data in the System

Information will be collected on individuals where CMS has determined that the evidence is adequate to conclude that certain identified diagnoses are reasonable and necessary in several patient groups where certain criteria for these patients have been met and the criteria are consistent with the trials reviewed. 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 CAS 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 CAS. CMS has the following policies and procedures concerning disclosures of information that will be maintained in the system. Disclosure of information from the system will be approved only to the extent necessary to accomplish the purpose of the disclosure and only after CMS:

1. Determines that the use or disclosure is consistent with the reason that the data is being collected, *e.g.*, to collect and maintain data on patients to review determinations of ''reasonable and necessary'' with respect to CAS in patients who are at high risk for CEA.

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 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. Assist in the review determinations of ''reasonable and necessary'' with respect to CAS in patients who are at high risk for CEA.

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 CAS information in order to assist in the review determinations of ''reasonable and necessary'' with respect to CAS in patients who are at high risk for CEA.

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 CAS 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 CAS 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 parts 160 and 164, 65 FR 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).

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. 09–70–0556

SYSTEM NAME:

''Carotid Artery Stenting (CAS) System,'' HHS/CMS/OCSQ.

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive Data.

SYSTEM LOCATION:

Centers for Medicare and 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:

Individuals where CMS has determined that the evidence is adequate to conclude that certain identified diagnoses are reasonable and necessary in several patient groups where certain criteria for these patients have been met and the criteria are consistent with the trials reviewed.

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 section 1862(a)(1)(A) of the Social Security 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 collect and maintain data on patients to review determinations of ''reasonable and necessary'' with respect to CAS in patients who are at high risk for carotid endarterectomy. 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:

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.'' We are proposing to establish the following routine use disclosures of information maintained in the system. Information will be disclosed to:

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 and who need to have access to the records in order to perform the activity.

2. To another Federal or state agency to:

a. Assist in the review determinations of ''reasonable and necessary'' with respect to carotid artery stenting in patients who are at high risk for carotid endarterectomy.

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, 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 defines by 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 FR 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 complaint population is so small that individuals who are familiar with the complainants could, because of the small size, use this information to deduce the identity of the complainant).

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.

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.

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 reasonably 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. 05–18489 Filed 9–19–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission of OMB Review; Comment Request

Title: Compassion Capital Fund Evaluation.

OMB No.: New Collection.

Description: This proposed information collection activity is for two rounds of surveys to be completed by faith-based and community organizations participating in two studies within the Compassion Capital Fund (CCF) evaluation project. The first survey will be conducted as a baseline survey and the second will be a follow-up survey conducted several months later.

The CCF evaluation is an important opportunity to examine the effectiveness of the Compassion Capital Fund in meeting its objective of improving the capacity of faith-based and community organizations. The evaluation includes three distinct studies: a random assignment impact study, an outcome study, and a retrospective study. This notice pertains to the impact and outcome studies. The impact study will involve up to 1,000 faith-based and community organizations that seek services from CCF-funded intermediary organizations. Information will be collected from these faith-based and community-based organizations to assess change and improvement in various areas of capacity. The study design includes the random assignment of faith-based and community organizations to either a treatment group that receives capacity-building services from a CCF intermediary grantee or to a control group that does not. The impact of the services provided by intermediaries, primarily through sub-awards and/or technical assistance (TA), will be determined by comparing the changes in organizational and service capacity of the recipient organizations with those of the control group.

The outcome study will examine changes and improvements in a representative sample of about 750 faith-based and community organizations served by all CCF intermediaries operating in FY2005 and FY2006, except those already part of the impact study. The survey instruments will be used to track changes in the faith-based and community organizations' organizational capacity between baseline and follow-up.

Respondents: The respondents for both studies will be faith-based and community organizations that seek sub-awards or TA from CCF intermediary grantees. The baseline survey will be primarily self-administered and is expected to be completed as part of the intermediary's sub-award application or TA request process. The follow-up survey also will be primarily self-administered and contain questions similar to those in the baseline survey as well as additional questions related to services received from the intermediary or other organizations. It is expected that the follow-up survey will be administered approximately 12 months after the baseline survey. As needed to increase response rates, the survey will be administered by telephone to organizations that do not initially return a completed survey.