II. Criteria for Applicants

We are seeking eligible organizations which are a subsection (d) hospital, as defined in section 1886(d)(1)(B) of the Social Security Act (the Act), with high readmission rates that partner with community-based organizations (CBOs) or CBOs that provide care transition services. CBOs are defined as community-based organizations that provide care transition services across the continuum of care through arrangements with subsection (d) hospitals and whose governing bodies include sufficient representation of multiple health care stakeholders, including consumers.

This program creates a source of funding for care transition services that effectively manage transitions from acute to community-based settings and report specified process and outcome measures on their results. CBOs will be paid on a per eligible discharge basis for eligible Medicare beneficiaries at high risk for readmission, including those with multiple chronic conditions, depression, or cognitive impairments.

In selecting CBOs to participate in the program, preference will be given to eligible entities that are Administration on Aging (AoA) grantees that provide concurrent care transition interventions with multiple hospitals and practitioners or entities that provide services to medically-underserved populations, small communities, and rural areas. The program will run for 5 years beginning April 11, 2011; however, participants will be awarded 2-year agreements that may be extended on an annual basis for the remaining 3 years based on performance.

Applicants must identify root causes of readmissions and define their target population and strategies for identifying high risk patients. Applicants must also specify care transition interventions including strategies for improving provider communications in care transitions and improving patient activation. Lastly, applicants will be required to provide a budget including a per eligible discharge rate for care transition services, provide an implementation plan with milestones, and demonstrate prior experience with effectively managing care transition services and reducing readmissions.

A competitive process will be used to select eligible organizations. We will accept proposals on a rolling basis. The program will continue through 2015.

For specific details regarding the CCTP and the application process, please refer to the solicitation on the CMS Web site at *http://www.cms.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?itemID=CMS1239313.*

III. Application Information

Please refer to file code [CMS–5055–N2] on the application. Proposals (an unbound original and 3 copies plus an electronic copy on CD–ROM) must be typed for clarity and should not exceed 30 double-spaced pages, exclusive of cover letter, the executive summary, resumes, forms, and supporting documentation. Because of staffing and resource limitations, we cannot accept proposals by facsimile (FAX) transmission. Applicants may, but are not required to, submit a total of 10 copies to assure that each reviewer receive a proposal in the manner intended by the applicant (for example, collated, tabulated color copies). Hard copies and electronic copies must be identical.

IV. Eligible Organizations

As discussed above, subsection (d) hospitals with high readmission rates that partner with CBOs or CBOs that provide care transition services are eligible to participate in the CCTP. We anticipate that a wide variety of interested parties may be eligible to form a CBO in order to apply in collaboration with other organizations to perform the responsibilities specified. CBOs may be characterized as physician practices, particularly primary care practices, a corporate entity that has a separate quality improvement organization (QIO) contract with CMS under Part B of title XI of the Act, in situations that will not result in or create the appearance of a conflict of interest between the QIO's review tasks under title XI and the corporate entity's role as a CBO, an Aging and Disability Resource Center, Area Agency on Aging, or other appropriate organization that meets the statutory definition at section 3026(b)(1)(B) of the Act.

Authority: Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.

Dated: December 27, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–9126 Filed 4–12–11; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

AGENCY: Center for Consumer Information and Insurance Oversight (CCIIO), Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice of a new Privacy Act system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, the Centers for Medicare and Medicaid Services (CMS), Center for Consumer Information and Insurance Oversight (CCIIO) is establishing a new system of records (SOR) titled the "Health Insurance Assistance Database (HIAD)," System No. 09–70–0586. This SOR is established under the authority of Sections 2719, 2723, and 2761 of the Public Health Service Act (PHS Act) (Public Law (Pub. L.) 97–35) and § 1321(c) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148). Section 1321(c) of the Affordable Care Act authorizes HHS (1) to ensure that States with Exchanges are substantially enforcing the Federal standards to be set for the Exchanges and (2) to set up Exchanges in States that elect not to do so or are not substantially enforcing related provisions. Sections 2723 and 2761 of the PHS Act authorize HHS to enforce provisions that apply to non-Federal governmental plans and to enforce PHS Act provisions that apply to other health insurance coverage in States that HHS has determined are not substantially enforcing those provisions. The HIAD database will be maintained by the Office of Consumer Support Health Insurance Assistance Team (the Team) to assist the Office of Oversight with its compliance activities. HIAD is the primary tool through which the Team will track information for the purposes of oversight.

The primary purpose of this system is to collect and maintain information on consumer inquiries and complaints regarding insurance issuers that will permit CCIIO to exercise its direct enforcement authority over non-Federal governmental health plans, investigate any inquiries or complaints from enrollees of those plans, to determine which States may not be substantially enforcing the Affordable Care Act and PHS Act provisions and to determine whether complaints that indicate

possible noncompliance with Federal law are resolved by the plans. In addition, information maintained will enable CCIIO to develop aggregate reports that will inform CMS and HHS about compliance issues. Information in this system will also be disclosed to: (1) Support regulatory and programmatic activities such as investigations and reporting activities performed by an Agency contractor, consultants, CMS grantees, student volunteers, interns and other workers who do not have the status of Federal employees; (2) assist another Federal and/or State agency, agency of a State government, or an agency established by State law; (3) support litigation involving the Agency; (4) combat fraud, waste, and abuse in certain health benefits programs, and (5) assist in a response to a suspected or confirmed breach of the security or confidentiality of information. We have provided background information about this new system in the **SUPPLEMENTARY INFORMATION** section below. Although the Privacy Act requires only that CMS provide an opportunity for interested persons to comment on the proposed routine uses, CMS invites comments on all portions of this notice. See "Effective Dates" section for information about the comment period.

DATES: *Effective Dates:* CMS filed a new system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Homeland Security & Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on *April 11, 2011.* To ensure that all parties have adequate time in which to comment, the new 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 Information Security and Privacy Management, Enterprise Architecture and Strategy Group, Office of Information Services, CMS, Room N1–24–08, 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: Mr. Paul Tibbits, Team Leader, Health Insurance Assistance Team, Office of Consumer Support, Center for Consumer Information and Insurance Oversight, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244. His telephone number is 301–492–4229 or via e-mail at *paul.tibbits@hhs.gov.*

SUPPLEMENTARY INFORMATION: CCIIO has direct enforcement authority over non-Federal governmental health plans, and any inquiries or complaints from enrollees of those plans will be logged into this database for the purpose of following up to determine whether complaints that indicate possible noncompliance with Federal law are resolved by the plans. In addition, consumer inquiries and complaints regarding insurance issuers will be logged into the database in order to help CCIIO determine which States may not be substantially enforcing Affordable Care Act and PHS Act provisions, and, in the event Federal enforcement is necessary, in order to follow up to determine whether complaints that indicate possible noncompliance with Federal law are resolved by the issuers.

Section 1321(c) of the Affordable Care Act authorizes HHS (1) to ensure that States with Exchanges are substantially enforcing the Federal standards to be set for the Exchanges and (2) to set up Exchanges in States that elect not to do so or are not substantially enforcing related provisions. Sections 2723 and 2761 of the PHS Act authorize HHS to enforce PHS Act provisions that apply to non-Federal governmental plans and to enforce PHS Act provisions that apply to other health insurance coverage in States that HHS has determined are not substantially enforcing those provisions.

The database will be maintained by the Team to help CCIIO Office of Oversight with its compliance activities under the Affordable Care Act and PHS Act. Consumer inquiries and complaints addressed by the Team will help CCIIO conduct direct enforcement over non-Federal governmental health plans; the database will also help CCIIO determine which States are not substantially enforcing PHS Act provisions under HHS's Federal fallback authority in sections 2723 and 2761 of the PHS Act.

In the course of its work, the Team will: (1) Receive consumer inquiries; (2) respond to consumer inquiries in order to obtain the necessary information to determine the best course of action; (3) refer consumers to appropriate entities; and (4) when appropriate, gather information about consumers in order to assist CCIIO oversight capacity.

When responding to consumer contacts, the Team will pursue one of the following courses of action: (1) If it is determined that the consumer is covered by a non-Federal governmental plan, the Team will obtain enough information to determine whether the case merits referral to the Office of Oversight; (2) if it is determined that jurisdiction over a consumer's case lies with another entity, the Team will refer consumers to that entity, such as a State insurance department, the U.S. Department of Labor, or a State Consumer Assistance Program; or (3) if it is determined that the consumer seeks to file an appeal in a State or territory without an external appeals process in place, the Team will refer the consumer to the appropriate entity carrying out the Federal external appeals process.

As mentioned, the system will be used to create reports regarding the types of consumer inquiries and Affordable Care Act and PHS Act compliance issues that are brought to the attention of CCIIO by consumers. These reports will assist the Office of Oversight in identifying areas where compliance concerns may arise, and will be stripped of any information in identifiable form (IIF) and personal health information when written and prepared.

I. Description of the Proposed System of Records

A. Statutory and Regulatory Basis for System

Authority for the collection, maintenance, and disclosures from this system is provided under provisions of §§ 2719, 2723, and 2761 of the Public Health Service Act (PHS Act) (Pub. L. 97–35) and § 1321(c) of the Patient Protection and Affordable Care Act (AFFORABLE CARE ACT) (Pub. L. 111—148).

B. Collection and Maintenance of Data in the System

The Health Insurance Assistance Database (HIAD) contains information on individuals who contact CCIIO's Health Insurance Assistance Team, complainants or other individuals with health insurance issues. The HIAD contains the name, address, State of residence and zip code; contact information such as telephone numbers, e-mail address, demographic information such as age, gender, ethnicity, family status, employment status, income level and veteran's status; and health insurance identification number, health insurance status, background, recent history and available options.

II. Agency Policies, Procedures, and Restrictions on Routine Uses

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 information collected in the HIAD that can be associated with an individual as provided for under "Section III. Proposed Routine Use Disclosures of Data in the System." Identifiable data may be disclosed under a routine use.

CMS has the following policies and procedures concerning disclosures of information that will be maintained in the system. In general, disclosure of information from the system will be approved only for the minimum information 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, maintain, and process information on consumer inquiries and complaints regarding insurance issuers that will permit CCIIO to exercise its direct enforcement authority over non-Federal governmental health plans, if CMS;

2. Determines that:

a. the purpose of the disclosure can only be accomplished if the record is provided in an 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 provider that additional exposure of the record might bring; and

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

3. Requires the information recipient to:

a. establish administrative, technical, and physical safeguards to prevent unauthorized use of disclosure of the record;

b. remove or destroy at the earliest time all individually identifiable information; and

c. agree to not use or disclose the information for any purpose other than the stated purpose under which the information was disclosed.

4. Determines that the data are valid and reliable.

III. Proposed Routine Use Disclosures of Data in the System

A. Entities Who May Receive Disclosure Under Routine Use

These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974, under which CMS may release information from the HIAD without the consent of the individual to whom such information pertains. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure is legally permissible, including but not limited to ensuring that the purpose of the disclosure is compatible with the purpose for which the information was collected. We propose to establish the following routine use disclosures of information maintained in the system:

1. To support Agency contractors, consultants, CMS grantees, student volunteers, interns and other workers who do not have the status of Federal employees, and who have been engaged by the Agency to assist in accomplishment of a CMS function relating to the purposes for this SOR and who need to have access to the records in order to assist CMS.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual or similar agreement with a third party to assist in accomplishing a CMS function relating to purposes for this SOR.

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, CMS grantees, student volunteers, interns and other workers who do not have the status of Federal employees 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, consultant, CMS grantees, student volunteers, interns and other workers who do not have the status of Federal employees from using or disclosing the information for any purpose other than that described in the contract and requires the contractor, consultant, CMS grantees, student volunteers, interns and other workers who do not have the status of Federal employees to return or destroy all information at the completion of the contract.

2. To assist another Federal or State agency, agency of a State government, or an agency established by State law pursuant to agreements with CMS to:

a. Increase consumer assistance and accessibility to health care coverage by identifying insurer noncompliance with Federal, State and other applicable law, and

b. Assist Federally funded health insurance programs in administering functions tasked to them pursuant to the Affordable Care Act and other relevant Federal and State laws which may require CCIIO Program information related to this system.

c. Assist other Federal/State agencies that have the authority to perform collection of debts owed to the Federal government.

State Departments of Insurance can achieve greater regulation and oversight of the health insurance industry and strengthen enforcement in areas where problems arise by identifying trends and patterns in consumer inquiries and complaints.

The Internal Revenue Service (IRS), Department of the Treasury, can use CCIIO information for the purpose of resolving difficulties with obtaining premium tax credits under 36B of the Internal Revenue Code (IRC) of 1986 and to understand the consumer needs leading to the State health insurance Exchanges starting in 2014.

Federal, State, and local law enforcement agencies and private security contractors, may require CCIIO information to protect CCIIO employees and customers, provide security for CCIIO facilities or to assist investigations or prosecutions with respect to activities that affect such safety and security or activities that disrupts the operation of CCIIO operations and facilities.

3. To support 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, HHS 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 HHS is involved in litigation, or occasionally when another party is involved in litigation and HHS's policies or operations could be affected

by the outcome of the litigation, HHS would be able to disclose information to the DOJ, court, or adjudicatory body involved.

4. To assist a CMS contractor (including, but not limited to Medicare Administrative Contractors, 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 contract or grant with a third party to assist in accomplishing CMS functions relating to the purpose of combating fraud, waste or abuse.

CMS occasionally contracts out certain of its functions when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor or grantee whatever information is necessary for the contractor or grantee to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor or grantee from using or disclosing the information for any purpose other than that described in the contract and requiring the contractor or grantee to return or destroy all information.

5. To assist 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 CCIIO Program information for the purpose of combating fraud, waste or abuse in such Federally-funded programs.

6. To assist appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and unnecessary for the assistance.

Other Federal agencies and contractors may require CCIIO Program information for the purpose of assisting in a respond to a suspected or confirmed breach of the security or confidentiality of information.

IV. Safeguards

CMS has safeguards in place for authorized users and monitors such users to ensure against unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations 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; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

V. Effects of the New System on the Rights of Individuals

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. We will only disclose the minimum personal data necessary to achieve the purpose of the data collection and the routine uses contained in this notice. Disclosure of information from the system will be approved only to the extent necessary to accomplish the purpose of the disclosure. CMS has assigned a higher level of security clearance for the information maintained in this system in an effort to provide added security and protection of data in this system.

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. 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 the disclosure of information relating to individuals.

Dated: March 18, 2011.

Steve Larsen,

Director, Center for Consumer Information and Insurance Oversight, Centers for Medicare & Medicaid Services.

SYSTEM NUMBER:

09–70–0586.

SYSTEM NAME:

"Health Insurance Assistance Database" (HIAD), HHS/CMS/CCIIO.

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive.

SYSTEM LOCATION:

CMS Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244–1850 and at various contractor sites.

Center for Consumer Information and Insurance Oversight, Centers for Medicare and Medicaid Services, U.S. Department of Health & Human Services, Triple-I Core Site, 12100 Sunrise Valley Drive, Reston, Virginia 20191.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Information in this system is maintained on individuals who contact the CCIIO Health Insurance Assistance Team, complainants or other individuals with health insurance issues.

CATEGORIES OF RECORDS IN THE SYSTEM:

The HIAD contains the name, address, State of residence and zip code; contact information such as telephone numbers, e-mail address, demographic information such as age, gender, ethnicity, family status, employment status, income level and veteran's

status; and health insurance identification number, health insurance status, background, recent history and available options.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for the collection, maintenance, and disclosures from this system is provided under provisions of §§ 2719, 2723, and 2761 of the Public Health Service Act (PHS Act) (Public Law (Pub. L.) 97–35) and § 1321(c) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148).

PURPOSE(S) OF THE SYSTEM:

The primary purposes of this system is to collect and maintain information on consumer inquiries and complaints regarding insurance issuers that will permit CCIIO to exercise its direct enforcement authority over non-Federal governmental health plans, investigate any inquiries or complaints from enrollees of those plans, to determine which States may not be substantially enforcing the Affordable Care Act and PHS Act provisions and to determine whether complaints that indicate possible noncompliance with Federal law are resolved by the plans. In addition, information maintained will enable CCIIO to develop aggregate reports that will inform CMS and HHS about compliance issues. Information in this system will also be disclosed to: (1) Support regulatory and programmatic activities such as investigations and reporting activities performed by an Agency contractor, consultants, CMS grantees, student volunteers, interns and other workers who do not have the status of Federal employees; (2) assist another Federal and/or State agency, agency of a State government, or an agency established by State law; (3) support litigation involving the Agency; (4) combat fraud, waste, and abuse in certain health benefits programs, and (5) assist in a response to a suspected or confirmed breach of the security or confidentiality of information.

I. PROPOSED ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OR USERS AND THE PURPOSES OF SUCH USES:

B. Entities Who May Receive Disclosure Under Routine Use

These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974, under which CMS may release information from the HIAD without the consent of the individual to whom such information pertains. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure is legally permissible, including but not limited to ensuring that the purpose of the disclosure is compatible with the purpose for which the information was collected. We propose to establish the following routine use disclosures of information maintained in the system:

3. To support Agency contractors, consultants, CMS grantees, student, volunteers, interns and other workers who do not have the status of Federal employees, who have been engaged by the Agency to assist in accomplishment of a CMS function relating to the purposes for this SOR and who need to have access to the records in order to assist CMS.

4. To assist another Federal or State agency, agency of a State government, or an agency established by State law pursuant to agreements with CMS to:

a. Increase consumer assistance and accessibility to health care coverage by identifying insurer noncompliance with Federal, State and other applicable law, and

b. Assist Federally funded health insurance programs in administering functions tasked to them pursuant to the Affordable Care Act and other relevant Federal and State laws which may require CCIIO Program information related to this system.

c. Assist other Federal/State agencies that have the authority to perform collection of debts owed to the Federal government.

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

e. The Agency or any component thereof, or

f. Any employee of the Agency in his or her official capacity, or

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

h. 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 assist a CMS contractor (including, but not limited to Medicare Administrative Contractors, 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.

7. To assist 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.

8. To assist appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and unnecessary for the assistance.

II. SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations 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; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

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

STORAGE:

Records are maintained electronically in the CCIIO developed database for collection, tracking and storage of casework information and for reporting purposes. Any manually maintained records will be kept in locked cabinets or otherwise secured areas.

RETRIEVABILITY:

The records are retrieved electronically by a variety of fields, including but not limited to name, State, zip code, and health insurance identification number issued to the individual.

RETENTION AND DISPOSAL:

Records are maintained with identifiers for all transactions after they are entered into the system for a period of 10 years. Records are housed in both active and archival files. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from the Department of Justice.

SYSTEM MANAGER(S) AND ADDRESS:

Team Lead, Health Insurance Assistance Team, Office of Consumer Support, Center for Consumer Information and Insurance Oversight, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244.

NOTIFICATION PROCEDURE:

For purpose of notification, the subject individual should write to the system manager who will require the system name and the retrieval selection criteria (*e.g.,* name, health insurance claim number, SSN, *etc.*).

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2)).

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORD SOURCE CATEGORIES:

The identifying information contained in these records is provided voluntarily by the individual consumers, confidential informants, or by reports received from other sources . Additional case-relevant information may also be provided by the individual's employer or insurer to assist in achieving resolution of the specific case.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 2011–9105 Filed 4–14–11; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0264]

Agency Information Collection Activities; Proposed Collection; Comment Request; Request for Designation as Country Not Subject to the Restrictions Applicable to Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of existing FDA regulations regarding countries seeking to be designated as not subject to certain bovine spongiform encephalopathy (BSE)-related restrictions applicable to FDA-regulated human food and cosmetics.

DATES: Submit either electronic or written comments on the collection of information by June 14, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.