

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. 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

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 new system in the "Supplementary Information" section below. Although the Privacy Act requires only that CMS provide an opportunity for interested persons to comment on the proposed routine uses, CMS invites comments on all portions of this notice. See **EFFECTIVE DATES** section for comment period.

**EFFECTIVE DATE:** CMS filed 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 comments 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 e-mail at [Rosemarie.Hakim@cms.hhs.gov](mailto:Rosemarie.Hakim@cms.hhs.gov).

**SUPPLEMENTARY INFORMATION:** CMS has determined that there is sufficient evidence to conclude that an FDG PET for the detection of pre-treatment metastases in one of six cancers: Newly diagnosed cervical cancer subsequent to conventional imaging that is negative for extra-pelvic metastasis is reasonable and necessary as an adjunct test. However for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, Testicular and other Cancers, CMS determined that the evidence is sufficient to conclude that an FDG PET is reasonable and necessary only when the provider is participating in and patients are enrolled in one of the following types of prospective clinical studies: a clinical trial of FDG PET that meets the Food and Drug Administration category B investigational device exemption or an

FDG PET clinical study that is designed to prospectively collect information at the time of the scan to assist in patient management. All other previous positive national coverage determination for FDG PET will remain in effect. All other previous non-coverage determination for FDG PET based on evidence of lack of benefit will remain in effect.

To qualify for payment, providers must prescribe FDG PET only for patients with a set of clinical criteria specific to each cancer type and stage. In addition, CMS is requiring stakeholders including specialty societies, industry, independent scanning facilities, health plans and hospital associations to create systematic clinical data bases or registries in order to be reimbursed for PET scans done for all other cancer indications not previously specified in an NCD, including: Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers.

CMS will consider prospective data collection systems to be qualified if they provide assurance that the specific hypotheses are addressed and they collect appropriate data elements. The data collection shall include baseline patient characteristics: Indications for the PET scan; PET scan type and characteristics; FDG PET results; results of all other imaging studies; facility and provider characteristics; cancer type, grade, and stage; long term patient outcomes; disease management changes; and anti-cancer treatment received. The clinical data collection must ensure that specific hypotheses are identified prospectively; hospitals and providers are qualified to provide FDG PET and interpret the results; and participating hospitals and providers collect prospective data at the time of payment on all enrolled patients undergoing FDG PETs for cancer therapeutic or diagnostic indications. Data elements will be transmitted to CMS for evaluation of the short and long term benefits of the FDG PET for its beneficiaries and inform future clinical decision making. CMS shall be assured that all applicable patient confidentiality, privacy, and other Federal laws are complied with, including the Standards for Privacy of Individually Identifiable Health Information.

## 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

The data collection shall include baseline patient characteristics: Indications for the PET scan; PET scan type and characteristics; FDG PET results; results of all other imaging studies; facility and provider characteristics; cancer type, grade, and stage; long term patient outcomes; disease management changes; and anti-cancer treatment received. The collected information will also contain, but is not limited to, 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 PET 6 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 PET 6. 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 information on

Medicare beneficiaries receiving FDG PET scans for indications for which 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.

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. Contribute to the accuracy of CMS's proper payment of Medicare benefits,

b. Enable such agency to administer a Federal health benefits program, or as necessary to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds, and/or

c. Assist Federal/state Medicaid programs within the state.

Other Federal or state agencies in their administration of a Federal health program may require PET 6 information in order to collect information on Medicare beneficiaries receiving FDG PET scans for sufficient evidence to reach a firm conclusion that the scan 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 PET 6 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 this 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 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 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 PET 6 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 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. 09-70-0549

##### SYSTEM NAME:

"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."

##### 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:

Providers participating in and patients enrolled in one of the following types of prospective clinical studies: A clinical trial of FDG PET that meets the Food and Drug Administration category B investigational device exemption or an FDG PET clinical study that is designed to prospectively collect information at the time of the scan to assist in patient management.

#### CATEGORIES OF RECORDS IN THE SYSTEM:

The data collection should include baseline patient characteristics: Indications for the PET scan; PET scan type and characteristics; FDG PET results; results of all other imaging studies; facility and provider characteristics; cancer type, grade, and stage; long term patient outcomes; disease management changes; and anti-cancer treatment received. The collected information will also contain, but is not limited to, 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, 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.

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

The purpose of this system is to collect and maintain information on Medicare beneficiaries receiving FDG PET scans for indications 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 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 OF 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 and who need to have access to the records in order to perform the activity.

2. To another Federal or state agency to:

a. Contribute to the accuracy of CMS's proper payment of Medicare benefits,

b. Enable such agency to administer a Federal health benefits program, or as necessary to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds, and/or

c. Assist Federal/state Medicaid programs within the state.

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 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 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 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).

**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 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).

**RECORDS SOURCE CATEGORY:**

The data on patients receiving the FDG PET will be collected from providers. In addition, CMS is requiring stakeholders including specialty societies, industry, independent scanning facilities, health plans and hospital associations to create systematic clinical data bases or registries in order to be reimbursed for PET scans done for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, Testicular and other Cancers.

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

None.

[FR Doc. E5-6810 Filed 12-2-05; 8:45 am]

BILLING CODE 4120-03-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2005N-0445]

**Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Acne Ingredient**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of eligibility; request for data and information.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a call-for-data for safety and effectiveness information on the following conditions as part of FDA's ongoing review of over-the-counter (OTC) drug products: Triclosan, 0.2 to 0.5 percent and 0.3 to 1.0 percent, as a topical acne active ingredient in leave-on and rinse-off dosage forms, respectively. FDA has reviewed a time and extent application (TEA) for these conditions and determined that they are eligible for consideration in its OTC drug monograph system. FDA will evaluate the submitted data and information to determine whether these conditions can be generally recognized as safe and effective (GRAS/E) for their proposed OTC use.

**DATES:** Submit data, information, and general comments by March 6, 2006.

**ADDRESSES:** You may submit comments, identified by Docket No. 2005N-0445, by any of the following methods:

*Electronic Submissions*

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

*Written Submissions*

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

*Instructions:* All submissions received must include the agency name and docket number. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments, see the "Request for Comments, Data, and Information" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Michael L. Koenig, Center for Drug Evaluation and Research (mail stop 5411), Food and Drug Administration, 10903 New Hampshire Ave., bldg. 22, Silver Spring, MD 20993, 301-796-2090.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of January 23, 2002 (67 FR 3060), FDA published a final rule establishing criteria and procedures for additional conditions to become eligible for consideration in the OTC drug monograph system. These criteria and procedures, codified in § 330.14 (21 CFR 330.14), permit OTC drugs initially marketed in the United States after the OTC drug review began in 1972 and OTC drugs without any marketing experience in the United States to become eligible for FDA's OTC drug monograph system. The term "condition" means an active ingredient or botanical drug substance (or a combination of active ingredients or botanical drug substances), dosage form, dosage strength, or route of administration, marketed for a specific OTC use (§ 330.14(a)). The criteria and procedures also permit conditions that are regulated as cosmetics or dietary supplements in foreign countries but that would be regulated as OTC drugs in the United States to become eligible for the OTC drug monograph system.

Sponsors must provide specific data and information in a TEA to demonstrate that the condition has been marketed for a material time and to a material extent to become eligible for consideration in the OTC drug monograph system. When the condition is found eligible, FDA publishes a notice of eligibility and request for safety and effectiveness data for the proposed OTC use. The TEA that FDA reviewed (Ref. 1) and FDA's evaluation of the TEA (Ref. 2) have been placed on public display in the Division of Dockets Management (see **ADDRESSES**) under the docket number found in brackets in the heading of this document. Information deemed confidential under 18 U.S.C. 1905, 5 U.S.C. 552(b), or 21 U.S.C. 331(j)