ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Students	24,500	1	45/60
State and School Education Officials	537	1	30/60

Dated: November 8, 2005.

Betsey Dunaway,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 05–22714 Filed 11–15–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of a new system of records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we propose to create a new system of records titled, ''Medicare True Out-of-Pocket (TrOOP) Expenditures System,'' HHS/CMS/OIS, System No. 09–70–0557. The TrOOP facilitation process is mandated by the Medicare Prescription Drug Benefit Program enacted into law December 8, 2003 under provisions of Section 101 of Title 1 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). MMA amends Title XVIII, Section 1860D of the Social Security Act (the Act). Section 1860D–2 of the Act requires the tracking of beneficiaries' TrOOP expenditures. TrOOP costs are treated as ''incurred'' only if they were paid by the individual (or by another person, such as a family member, on behalf of the individual), paid on behalf of a low-income subsidy-eligible individual under the § 1860D–14 provisions, or paid under a State Pharmaceutical Assistance Program (SPAP) as defined in § 1860D–23. Section 1860D–2(b)(4)(D)(i) of the MMA authorizes CMS to establish procedures for determining whether costs for Part D enrollees are being reimbursed by excluded payers and alerting Part D plans about the existence of such payers.

The purpose of this system is to collect and maintain a master file to establish a ''TrOOP'' facilitation process, maintain information on individuals and entities that make payments on covered drugs under the Medicare Part D Program, and coordinate TrOOP relevant data from State Pharmaceutical Programs (SPAPs) and other health insurers. Information retrieved from this system may be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor, grantee, consultant or other legal agent; (2) support Medicare Prescription Drug Plans (PDP) and Medicare Advantage Prescription Drug Plans (MAPD) directly or through a CMS contractor for the administration of Title XVIII of the Act; (3) 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; (4) assist Quality Improvement Organization (QIO) in connection with review of claims; (5) assist insurance companies and other groups providing protection against medical expenses of their enrollees; (6) assist an individual or organization engaged in the performance activities of the demonstration or in 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; (7) support constituent requests made to a congressional representative; (8) support litigation involving the agency; and (9) 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 DATE** 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 11/07/2005. In any event, we will not disclose any information under a routine use until 40 days after publication. We may defer implementation of this system 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, Room N2–04–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location by appointment during regular business hours, Monday through Friday from 9 a.m.–3 p.m., eastern time.

FOR FURTHER INFORMATION CONTACT: Henry Chao, Manager, Immediate Office of the Director, Office of Information Services, CMS, Room N3–19–23, 7500 Security Boulevard, Baltimore, Maryland 21244–1849, telephone number (410) 786–7811, e-mail *Henry.Chao@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: In order to calculate TrOOP, Medicare Part D plans will have to determine if other entities have made payments on covered drugs, and whether such payments fall under the legal definition of incurred costs. If the payments by alternate payers, such as retiree prescription drug coverage, do not count toward the TrOOP threshold, then Part D plans must reduce the out-of-pocket amounts accumulated in their claims processing systems. Alternatively, if the payments by alternate payers, such as SPAPs, do count toward the TrOOP threshold, then the Part D plan will maintain the level of beneficiary out-of-pocket spending in their systems.

All Part D Plans will have to correctly calculate the TrOOP amount in order to properly adjudicate beneficiary claims, as well as to communicate to beneficiaries where they are in their benefits. Beneficiaries will expect that pharmacies will have all the information they need to determine their eligibility and to bill the appropriate payers and that plans will

have accurate real-time TrOOP calculations on demand.

The process, along with coordination of benefits (COB) is logistically complex because there may be multiple payers (e.g., SPAPs or employer or union retiree plans, etc.). True COB, in which the order of payment among multiple payers with responsibility for paying prescription drug claims on behalf of an individual is established and programmed into the systems of the alternate payers, does not take place in pharmacy benefit management today. In the absence of significant change, this would mean that Part D plans would have to separately set up procedures to coordinate benefits with every other payer with responsibility for drug coverage for one of their Part D enrollees.

Importantly, this process will enable Part D Plans to track and calculate a beneficiary's TrOOP expenditures in as near to real time as possible, so that when a beneficiary calls, they can retrieve accurate TrOOP information. In addition, the TrOOP level will be available on-line to correctly process the beneficiary's next claim. This will mean that beneficiaries will know when they have reached certain coverage limits or when they can expect even greater financial relief in the case of catastrophic coverage, and will have their claims processed correctly without the need for bringing in receipts or submitting other documentation from other coverage.

I. Description of the Proposed System of Records

A. Statutory and Regulatory Basis for SOR

The statutory authority for this system is given under Part D of Title XVIII of the Social Security Act, as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

B. Collection and Maintenance of Data in the System

This system will maintain individually identifiable information on individuals and entities that make payments on covered drugs under the Medicare Part D Program. The collected information will contain name, address, health insurance claim number (HICN), gender type, and date of birth.

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 TrOOP 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 TrOOP.

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 a master file to establish a ''TrOOP'' facilitation process, maintain information on individuals and entities that make payments on covered drugs under the Medicare Part D Program, and coordinate TrOOP relevant data from SPAPs and other health insurers.

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. Entities Who May Receive Disclosures 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 TrOOP facilitator 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 or modify the following routine use disclosures of information maintained in the system:

1. To Agency contractors or consultants who have been contracted 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 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 Medicare Prescription Drug Plans (PDP) and Medicare Advantage Prescription Drug Plans (MAPD) directly or through a CMS contractor for the administration of Title XVIII of the Act.

PDPs and MAPDs require TrOOP information in order to establish the validity of evidence or to verify the accuracy of information presented by the individual, as it concerns the individual's entitlement to Part D benefits under the Medicare Prescription Drug Benefit Program.

3. To another Federal or state agency, agency of a state government, an agency

established by state law, or its fiscal agent pursuant to agreements with CMS 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 TrOOP information in order to support evaluations and monitoring of Medicare claims information of beneficiaries, including proper reimbursement for services provided.

The Internal Revenue Service may require TrOOP data for the application of tax penalties against employers and employee organizations that contribute to Employer Group Health Plan or Large Group Health Plans that are not in compliance with 42 U.S.C. 1395y(b).

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

Disclosure under this routine use shall be used by state Medicaid agencies pursuant to agreements with the HHS for determining Medicaid and Medicare eligibility, for quality control studies, for determining eligibility of recipients of assistance under Titles IV, XVIII, and XIX of the Act, and for the administration of the Medicaid program. Data will be released to the state only on those individuals who are patients under the services of a Medicaid program within the state or who are residents of that state.

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

4. To Quality Improvement Organization (QIO) in connection with review of claims, or in connection with studies or other review activities conducted pursuant to Part D of Title XVIII of the Act and in performing affirmative outreach activities to individuals for the purpose of establishing and maintaining their entitlement to Medicare Prescription Drug Program benefits or other drug plan benefits.

QIOs will work to implement quality improvement programs, provide consultation to CMS, its contractors, and to state agencies. QIOs will assist the state agencies in related monitoring and enforcement efforts, assist CMS and intermediaries in program integrity assessment, and prepare summary information for release to CMS.

5. To insurance companies, underwriters, third party administrators (TPA), employers, self-insurers, group health plans, health maintenance organizations (HMO), health and welfare benefit funds, managed care organizations, other supplemental insurers, non-coordinating insurers, multiple employer trusts, other groups providing protection against medical expenses of their enrollees without the beneficiary's authorization, and any entity having knowledge of the occurrence of any event affecting: (a) An individual's right to any such benefit or payment, or (b) the initial right to any such benefit or payment, for the purpose of coordination of benefits with the Medicare program and implementation of the Medicare Secondary Payer (MSP) provision at 42 U.S.C. 1395y(b). Information to be disclosed shall be limited to Medicare utilization data necessary to perform that specific function. In order to receive the information, they must agree to:

a. Certify that the individual about whom the information is being provided is one of its insured or employees, or is insured and/or employed by another entity for whom they serve as a TPA;

b. Utilize the information solely for the purpose of processing the individual's insurance claims; and

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

Other insurers may require TrOOP information in order to support evaluations and monitoring of Medicare claims information of beneficiaries, including proper reimbursement for services provided.

6. To an individual or organization for research, evaluation, or epidemiological projects related to the prevention of disease or disability, and the restoration or maintenance of health, or payment related projects.

TrOOP data will provide for research, evaluations and epidemiological 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.

7. To a Member of Congress or 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 often 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.

8. 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, or occasionally when another party is involved in litigation and CMS's 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.

9. To a CMS contractor (including, but not 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 contract 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 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.

10. 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 TrOOP information for the purpose of combating fraud and abuse in such Federally-funded programs.

B. Additional Circumstances Affecting Routine Use Disclosures

This system contains Protected Health Information as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, subparts A and E, 65 FR 82462 (12–28–00). Disclosures of Protected Health Information 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 data not directly identifiable, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals 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; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

V. Effect of the Proposed System 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. We will only disclose the minimum personal data necessary to achieve the purpose of TrOOP. 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: October 27, 2005.

Charlene Frizzera,

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

SYSTEM NO. 09–70–0557

SYSTEM NAME:

''True Out-of-Pocket (TrOOP) Expenditures System,'' HHS/CMS/OIS.

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive Data.

SYSTEM LOCATION:

CMS Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244–1850 and at various co-locations of CMS contractors.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system will maintain individually identifiable information on individuals and entities that make payments on covered drugs under the Medicare Part D Program.

CATEGORIES OF RECORDS IN THE SYSTEM:

The collected information will contain name, address, telephone number, health insurance claim number (HICN), gender type, and date of birth.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The statutory authority for this system is given under Part D of Title XVIII of the Social Security Act, as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to collect and maintain a master file to establish a ''TrOOP'' facilitation process, maintain information on individuals and entities that make payments on covered drugs under the Medicare Part D Program, and coordinate TrOOP relevant data from State Pharmaceutical Programs (SPAPs) and other health insurers. Information retrieved from this system may be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor, grantee, consultant or other legal agent; (2) support Medicare Prescription Drug Plans (PDP) and Medicare Advantage Prescription Drug Plans (MAPD) directly or through a CMS contractor for the administration of Title XVIII of the Act; (3) 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; (4) assist Quality Improvement Organization (QIO) in connection with review of claims; (5) assist insurance companies and other groups providing protection against medical expenses of their enrollees; (6) assist an individual or organization engaged in the performance activities of the demonstration or in 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; (7) support constituent requests made to a congressional representative; (8) support litigation involving the agency; and (9) 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:

C. Entities Who May Receive Disclosures 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 TrOOP facilitator 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 or modify the following routine use disclosures of information maintained in the system:

To Agency contractors or consultants who have been contracted 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.

1. To Medicare Prescription Drug Plans (PDP) and Medicare Advantage Prescription Drug Plans (MAPD) directly or through the Enterprise Business Services, a CMS intermediary for the administration of Title XVIII of the Act.

2. To another Federal or state agency, agency of a state government, an agency established by state law, or its fiscal agent pursuant to agreements with CMS to:

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

e. 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

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

3. To Quality Improvement Organization (QIO) in connection with review of claims, or in connection with studies or other review activities conducted pursuant to Part D of Title XVIII of the Act and in performing affirmative outreach activities to individuals for the purpose of establishing and maintaining their entitlement to Medicare Prescription Drug Program benefits or other drug plan benefits.

4. To insurance companies, underwriters, third party administrators (TPA), employers, self-insurers, group health plans, health maintenance organizations (HMO), health and welfare benefit funds, managed care organizations, other supplemental insurers, non-coordinating insurers, multiple employer trusts, other groups providing protection against medical expenses of their enrollees without the beneficiary's authorization, and any entity having knowledge of the occurrence of any event affecting: (a) An individual's right to any such benefit or payment, or (b) the initial right to any such benefit or payment, for the purpose of coordination of benefits with the Medicare program and implementation of the Medicare Secondary Payer (MSP) provision at 42 U.S.C. 1395y (b). Information to be disclosed shall be limited to Medicare utilization data necessary to perform that specific function. In order to receive the information, they must agree to:

b. Certify that the individual about whom the information is being provided is one of its insured or employees, or is insured and/or employed by another entity for whom they serve as a TPA;

c. Utilize the information solely for the purpose of processing the individual's insurance claims; and

d. Safeguard the confidentiality of the data and prevent unauthorized access.

5. To an individual or organization for research, evaluation, or epidemiological projects related to the prevention of disease or disability, and the restoration or maintenance of health, or payment related projects.

6. To a Member of Congress or 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.

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

d. The Agency or any component thereof, or

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

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

g. The United States Government, is a party to litigation or has an interest in such litigation, and, by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

8. To a CMS contractor (including, but not 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.

9. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any state or local governmental agency), that administers, or that has the authority to investigate potential fraud 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.

D. Additional Circumstances Affecting Routine Use Disclosures

This system contains Protected Health Information as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, subparts A and E, 65 FR 82462 (12–28–00). Disclosures of Protected Health Information 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 data not directly identifiable, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals 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. Some input may be generated in hardcopy, such as eligibility, enrollment, or other health insurance information before transcription to electronic media.

RETRIEVABILITY:

The collected data are retrieved by an individual identifier; e.g., beneficiary name or HIC number.

SAFEGUARDS:

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

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations 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.

RETENTION AND DISPOSAL:

CMS will retain information for a total period not to exceed 25 years. Data residing with the TrOOP facilitation contractor site agent shall be returned to CMS at the end of the contract period, with all data then being the responsibility of CMS for adequate storage and security.

SYSTEM MANAGER AND ADDRESS:

Henry Chao, Manager, Immediate Office of the Director, Office of Information Services, CMS, Room N3–19–23, 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 type, 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 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, parts 160, 162, and 164.)

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).

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 05–22657 Filed 11–15–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0425]

Agency Information Collection Activities; Proposed Collection; Comment Request; General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions

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 reporting requirements contained in existing FDA regulations regarding the general administrative procedures for a person to take the following actions: Petition the Commissioner of Food and Drugs (the Commissioner) to issue, amend, or revoke a rule; file a petition for an administrative reconsideration or an administrative stay of action; and request an advisory opinion from the Commissioner.

DATES: Submit written or electronic comments on the collection of information by January 17, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. 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: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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