

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, 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 on magnetic media.

RETRIEVABILITY:

Information collected will be retrieved by the name or other identifying information of the participating provider, and may also be retrievable by HICN at the individual beneficiary record level.

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 identifiable information maintained in the PGPD system of records for a period of 6 years. Data residing with the designated claims payment contractor shall be returned to CMS at the end of the project, with all data then being the responsibility of CMS for adequate storage and security. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from the DOJ.

SYSTEM MANAGER AND ADDRESS:

Director, Medicare Demonstration Programs Group, CMS, 7500 Security Boulevard, Mail stop C4-17-27, Baltimore, Maryland, 21244-1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, and for verification purposes, the subject individual's name, provider identification number, and the patient's Medicare number.

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:

Information maintained in this system will be collected from physicians voluntarily participating through claims data requesting payment for services. The PGPD information will also be collected from the reporting of ambulatory care data by participating physician groups.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 05-19904 Filed 10-5-05; 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 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.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, CMS is proposing to establish a new system of records (SOR) titled "Medicare Drug Data Processing System (DDPS)," System No. 09-70-0553. On December 8, 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law (Pub. L.) 108-173). MMA amends the Social Security Act (the Act) by adding the Medicare Part D Program under Title XVIII and mandate that CMS establish a voluntary Medicare prescription drug benefit program effective January 1, 2006. Under the new Medicare Part D benefit, the Act allows Medicare payment to plans that contract with CMS to provide qualified Part D prescription drug coverage as described in 42 Code of Federal Regulations (CFR) § 423.401. As a condition of payment, all Part D plans must submit data and information necessary for CMS to carry out payment provisions (§ 1860D-15(c)(1)(C) and (d)(2) of the Act, and 42 CFR 423.322).

The primary purpose of this system is to collect, maintain, and process information on all Medicare covered and non-covered drug events, including non-Medicare drug events, for Medicare beneficiaries participating in the Part D voluntary prescription drug coverage under the Medicare program. The system will process drug event transactions and other drug events as necessary for CMS to help determine appropriate payment of covered drugs. The DDPS will consist of the transaction validation processing, storing and maintaining the drug event data in a large-scale database, and staging the data into data marts to support beneficiary and plan analysis of incurred payment. Information in 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 Quality Improvement Organizations; (3) assist Part D prescription drug plans; (4) support an individual or organization for a research, evaluation or epidemiological project; (5) support constituent requests made to a congressional representative; (6) support litigation involving the agency; and (7) 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 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 Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on September 28, 2005. To ensure that all parties have adequate time in which to comment, the new system will become effective 30 days from the publication of the notice, or from the date it was submitted to OMB and the Congress, whichever is later, unless CMS receives comments that require alterations to this notice.

ADDRESSES: The public should address comments to the CMS Privacy Officer, Division of Privacy Compliance Data Development, CMS, 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 daylight time.

FOR FURTHER INFORMATION CONTACT:

Harvey Hull, Health Insurance Specialist Division of Program Analysis and Performance, Medicare Drug Benefit Group, Centers for Beneficiary Choices, CMS, Room C1-25-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. The telephone number is 410-786-4036 or contact harvey.hull@cms.hhs.gov.

SUPPLEMENTARY INFORMATION: In December 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act, amending the Act by adding Part D under Title XVIII. Under the new Medicare benefit, the Act allows

Medicare payment to plans that contract with CMS to provide qualified Part D prescription drug coverage as described in 42 CFR 423.401. For simplicity, we use the term "plans" to refer to these entities that provide Part D prescription drug benefits and that must submit claims data to CMS for payment calculations. The Act provides four summary mechanisms for paying plans: 1. Direct subsidies; 2. premium and cost-sharing subsidies for qualifying low-income individuals (low-income subsidy); 3. federal reinsurance subsidies; and 4. risk-sharing.

As a condition of payment, all Part D plans must submit data and information necessary for CMS to carry out payment provisions (§ 1860D-15(c)(1)(C) and (d)(2) of the Act, and 42 CFR § 423.322). This document describes how CMS will implement the statutory payment mechanisms by collecting a limited subset of data elements on 100 percent of prescription drug "claims" or events. Much of the data, especially dollar fields, will be used primarily for payment. However, some of the other data elements such as pharmacy and prescriber identifiers will be used for validation of the claims as well as for other legislated functions such as quality monitoring, program integrity, and oversight. In addition, we note that this paper only covers data collected on claims and does not cover data CMS may collect from plans through other mechanisms, for example monitoring plan formularies and beneficiary appeals.

Every time a beneficiary fills a prescription covered under Part D, plans must submit a summary record called the prescription drug event (PDE) record to CMS. The PDE record contains prescription drug cost and payment data that will enable CMS to make payment to plans and otherwise administer the Part D benefit. Specifically, the PDE record will include covered drug costs above and below the out-of-pocket threshold; distinguish enhanced alternative costs from the costs of drugs provided under the standard benefit; and will record payments made by Part D plan sponsors, other payers, and by or on behalf of beneficiaries. Plans must also identify costs that contribute towards a beneficiary's true-out-of-pocket or TrOOP limit, separated into three categories: low-income cost-sharing subsidy amounts paid by the plan at the point of sale (POS), beneficiary payments, and all TrOOP-eligible payments made by qualified entities on behalf of a beneficiary. Much of the data, especially dollar fields, will be used primarily for payment. However, some of the other data

elements such as pharmacy and prescriber identifiers will be used for validation of the claims as well as for other legislated functions such as quality monitoring, program integrity, and oversight.

I. Description of the Proposed System of Records

A. Statutory and Regulatory Basis for System

Authority for maintenance of this system is given under provisions of the Medicare Prescription Drug, Improvement, and Modernization Act, amending the Social Security Act (the Act) by adding Part D under Title XVIII (§ 1860D-15(c)(1)(C) and (d)(2)), as described in 42 Code of Federal Regulation (CFR) 423.401.

B. Collection and Maintenance of Data in the System

The system contains summary prescription drug claim information on all Medicare covered and non-covered drug events, including non-Medicare drug events, for Medicare beneficiaries of the Medicare program. This system contains summary prescription drug claim data, health insurance claim number, card holder identification number, date of service, gender, and optionally, the date of birth. The system contains provider characteristics, prescriber identification number, assigned provider number (facility, referring/servicing physician), and national drug code, total charges, Medicare payment amount, and beneficiary's liability.

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

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 DDPS 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 disclose the minimum personal data necessary to achieve the purpose of DDPS. 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 assist in a variety of health care initiatives with other entities related to the evaluation and study of the operation and effectiveness of the Medicare program.

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 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 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 DDPS 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 system 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 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 Quality Improvement Organization (QIO) in connection with review of claims, or in connection with studies or other review activities conducted pursuant to Part B of Title XI of the Act and in performing affirmative outreach activities to individuals for the purpose of establishing and maintaining their entitlement to Medicare benefits or health insurance plans.

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.

3. To Part D Prescription Drug Plans and their Prescription Drug Event submitters, providing protection against medical expenses of their enrollees without the beneficiary's authorization, and 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 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 Third Party Administrator;

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 DDPS information in order to support evaluations and monitoring of Medicare claims information of beneficiaries, including proper reimbursement for services provided.

4. To an individual or organization for a research, evaluation, or epidemiological project related to the prevention of disease or disability, the restoration or maintenance of health, or payment-related projects.

DDPS data will provide for research, evaluation, 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.

5. 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.

6. 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.

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.

7. 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.

8. 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 DDPS 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, 65 FR 82462 (Dec. 28, 00), as amended by 66 FR 12434 (Feb. 26, 01)). 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 non-identifiable information, except pursuant to one of the routine uses, if 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 Modified 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 DDPS. 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: September 28, 2005.

John R. Dyer,

Chief Operating Officer, Centers for Medicare & Medicaid Services.

System No. 09-70-0553

SYSTEM NAME:

Medicare Drug Data Processing System (DDPS), HHS/CMS/CBC.

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.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system contains summary prescription drug claim information on all Medicare covered and non-covered drug events, including non-Medicare drug events, for Medicare beneficiaries of the Medicare program.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains summary prescription drug claim data, health insurance claim number (HICN), card holder identification number, date of service, gender, and optionally, the date of birth. The system contains provider characteristics, prescriber identification number, assigned provider number (facility, referring/servicing physician), and national drug code, total charges, Medicare payment amount, and beneficiary's liability.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for maintenance of this system is given under provisions of the Medicare Prescription Drug, Improvement, and Modernization Act, amending the Social Security Act (the

Act) by adding Part D under Title XVIII (§ 1860D–15(c)(1)(C) and (d)(2), as described in 42 Code of Federal Regulation (CFR) § 423.401.

PURPOSE(S) OF THE SYSTEM:

The primary purpose of this system is to collect, maintain, and process information on all Medicare covered and non-covered drug events, including non-Medicare drug events, for Medicare beneficiaries participating in the Part D voluntary prescription drug coverage under the Medicare program. The system will process drug event transactions and other drug events as necessary for CMS to help determine appropriate payment of covered drugs. The DDPS will consist of the transaction validation processing, storing and maintaining the drug event data in a large-scale database, and staging the data into data marts to support beneficiary and plan analysis of incurred payment. Information in 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 Quality Improvement Organizations; (3) assist Part D prescription drug plans; (4) support an individual or organization for a research, evaluation or epidemiological project; (5) support constituent requests made to a congressional representative; (6) support litigation involving the agency; and (7) combat fraud and abuse in certain health benefits programs.

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

A. 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 DDPS 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 system

and who need to have access to the records in order to assist CMS.

2. To Quality Improvement Organization (QIO) in connection with review of claims, or in connection with studies or other review activities conducted pursuant to Part B of Title XI of the Act and in performing affirmative outreach activities to individuals for the purpose of establishing and maintaining their entitlement to Medicare benefits or health insurance plans.

3. To Part D Prescription Drug Plans and their Prescription Drug Event submitters, providing protection against medical expenses of their enrollees without the beneficiary's authorization, and 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 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 Third Party Administrator;

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.

4. To an individual or organization for a research, evaluation, or epidemiological project related to the prevention of disease or disability, the restoration or maintenance of health, or payment-related projects.

5. 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.

6. 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.

7. 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.

8. 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 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, 65 FR 82462 (Dec. 28, 00), as amended by 66 FR 12434 (Feb. 26, 01)). 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 non-identifiable information, except pursuant to one of the routine uses, if 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:

Records are stored on both tape cartridges (magnetic storage media) and in a DB2 relational database management environment (DASD data storage media).

RETRIEVABILITY:

Information is most frequently retrieved by HICN, provider number (facility, physician, IDs), service dates, and beneficiary state code.

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:

Records are maintained with identifiers for all transactions after they

are entered into the system for a period of 20 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 AND ADDRESS:

Director, Division of Program Analysis and Performance, Medicare Drug Benefit Group, Centers for Beneficiary Choices, CMS, Room S1-06-14, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

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., HICN, facility/pharmacy number, service dates, 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:

Summary prescription drug claim information contained in this system is obtained from the Prescription Benefit Package (PBP) Plans and Medicare Advantage (MA-PBP) Plans daily and monthly drug event transaction reports, Medicare Beneficiary Database (09-70-0530), and other payer information to be provided by the TROOP Facilitator.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 05-19905 Filed 10-5-05; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Deletion of System of Records

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

ACTION: Notice to delete 14 systems of records.

SUMMARY: CMS proposes to delete 14 systems of records from its inventory subject to the Privacy Act of 1974 (Title 5 United States Code 552a).

DATES: *Effective Date:* The deletions will be effective on September 27, 2005.

ADDRESSES: The public should address comments to: CMS Privacy Officer, Division of Privacy Compliance Data Development, Enterprise Databases Group, Office of Information Services, CMS, Room N2-04-27, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. The telephone number is (410) 786-5357. 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.

SUPPLEMENTARY INFORMATION: CMS is reorganizing its databases because of the amount of information it collects to administer the Medicare program. Retention and destruction of the data contained in these systems will follow the schedules listed in the system notice. CMS is deleting the following systems of records.

Deletions

System No.	Title	System manager
09-70-0030	National Long-Term Care Study Follow-up	HHS/CMS/ORDI
09-70-0039	Evaluation of the Medicare Alzheimer's Disease Demonstration	HHS/CMS/ORDI
09-70-0040	Health Care Financing Administration Medicare Heart Transplant Data File	HHS/CMS/ORDI
09-70-0045	Evaluation of the Arizona Health Care Cost Containment and Long Term Care Systems Demonstration	HHS/CMS/ORDI
09-70-0046	Home Health Quality Indicator System	HHS/CMS/ORDI
09-70-0049	Evaluation of the Home Health Agency Prospective Payment Demonstration	HHS/CMS/ORDI
09-70-0050	The Medicare/Medicaid Multi-State Case Mix and Quality Data Base for Nursing Home Residents	HHS/CMS/ORDI
09-70-0051	Quality Assurance for the Home Health Agency Prospective Payment Demonstration	HHS/CMS/ORDI
09-70-0052	Post-Hospitalization Outcomes Studies	HHS/CMS/ORDI
09-70-0057	Evaluation of the Medicaid Extension of Eligibility to Certain Low Income Families Not Otherwise Qualified to Receive Medicaid Benefits Demonstration.	HHS/CMS/ORDI
09-70-0058	Evaluation of the Medicare SELECT Program	HHS/CMS/ORDI
09-70-0059	The Medicaid Necessity Appropriateness and Outcomes of Care Study	HHS/CMS/ORDI