Dated:November 28, 2006.

Joan F. Karr,

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

[FR Doc. E6–20417 Filed 12–1–06; 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 Modified or Altered System of Records

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

ACTION: Notice of a Modified or Altered System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to modify or alter an existing SOR, ''Medicare Beneficiary Database (MBD),'' System No. 09–70–0536, established at 66 **Federal Register** (FR) 63392 (December 6, 2001), and modified at 71 FR 11420 (March 7, 2006). The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) authorizes Medicare payment to Part D sponsors (including Medicare Advantage prescription drug plan sponsors) that contract with CMS to provide qualified Part D prescription drug coverage as described in 42 CFR Parts 417, 422 and 423. The MBD will include data necessary to process certain activities associated with the new Part D benefit including, but not limited to, the following activities: (1) Determination of the status of Medicare beneficiaries who are eligible for the Low Income Subsidy Program (LIS) and are deemed to receive certain drug benefits; and (2) auto-assignment/auto-enrollment of beneficiaries as required by the MMA, and regulation, to include all LIS and deemed individuals who are not voluntarily enrolled in a drug plan, will automatically be assigned to a Prescription Drug Plan (PDP) or Medicare Advantage (MA) Prescription Drug Plan (MA–PD).

We propose to broaden the scope of the disclosure provisions of this system by adding a new routine use to permit the release of Part D enrollment data maintained in the MBD to support Patient Assistance Programs (PAP) and other groups providing pharmaceutical assistance to the Medicare beneficiary. The new routine use will be published as routine use number 8. Specifically, the new routine use will facilitate the sharing of information between PAPs and Part D plans to meet the MMA provisions for drug utilization reviews, drug medication therapy management, and quality of care that can only be addressed through the cooperation between the PAP and the Part D Plan. Information may be released to these organizations upon a specific request, and only if the requester meets the following requirements. They must (1) Provide an attestation or other qualifying information that they are providing pharmaceutical assistance to Medicare beneficiaries; (2) submit a finder file identifying Medicare beneficiaries receiving pharmaceutical assistance and/or services; (3) safeguard the confidentiality of any CMS data received and prevent unauthorized access; and, (4) complete a written statement attesting to the information recipient's understanding of and willingness to abide by CMS provisions regarding Privacy protections and information security. Recipients of CMS data must complete the Coordination of Benefits PAP Data Sharing Agreement prior to the release of CMS data. The finder file submitted by the PAP must provide the following data elements: (a) First initial of the first name, (b) first 6 letters of the last name, (c) social security number or health insurance claims number, (d) date of birth, and (e) sex. Part D data maintained in the MBD that will be released to a PAP or a group providing pharmaceutical assistance will consist of the verification of Medicare status and the identification of the current Part D Plan selected by the Medicare beneficiary.

We will delete published routine use number 8 authorizing disclosure to support constituent requests made to a congressional representative. If an authorization for the disclosure has been obtained from the data subject, then no routine use is needed. The Privacy Act allows for disclosures with the ''prior written consent'' of the data subject. We will broaden the scope of published routine uses number 10 and 11 authorizing disclosures to combat fraud and abuse in the Medicare and Medicaid programs to include combating ''waste'' which shall refer to specific beneficiary/recipient practices that result in unnecessary cost to all federally-funded health benefit programs.

The primary purpose of this modified system is to provide CMS with a singular, authoritative, database of comprehensive enrollment data on individuals in the Medicare program to support ongoing and expanded program administration, service delivery modalities, and payment coverage options. This collection will contain a complete ''beneficiary insurance profile'' that reflects the individual's Medicare health insurance coverage and Medicare health plan and demonstration enrollment. Information retrieved from this system of records will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor, consultant or a CMS grantee; (2) assist another Federal or State agency, agency of a State government, an agency established by State law, or its fiscal agent; (3) support providers and suppliers of services for administration of Title XVIII; (4) assist third parties where the contact is expected to have information relating to the individual's capacity to manage his or her own affairs; (5) support Quality Improvement Organizations (QIO); (6) assist other insurers for processing individual insurance claims; (7) facilitate research on the quality and effectiveness of care provided, as well as payment related projects; (8) support Patient Assistance Programs and other groups providing pharmaceutical assistance or services to Medicare beneficiaries; (9) support litigation involving the agency; and (10) combat fraud, waste, and abuse in certain health benefits programs. We have provided background information about the modified system in the **SUPPLEMENTARY INFORMATION** section below. Although the Privacy Act requires only that CMS provide an opportunity for interested persons to comment on the routine uses, CMS invites comments on all portions of this notice. See **EFFECTIVE DATES** section for comment period.

DATES: *Effective Dates*: CMS filed a modified or altered SOR report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Homeland Security & Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on 11/28/2006. 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 40 days from the date it was submitted to OMB and the Congress, whichever is later. 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 comments to: CMS Privacy Officer, Division of Privacy Compliance, Enterprise Architecture and Strategy Group, Office of Information Services, 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 Time zone.

FOR FURTHER INFORMATION CONTACT: Danielle Moon, Director, Division of Enrollment and Eligibility Policy, Medicare Enrollment and Appeals Group, Center for Beneficiary Choices, CMS, Mail Stop S1–05–06, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Her telephone number is 410–786–5724, and via e-mail at *Danielle.Moon@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Description of the Modified or Altered System of Records

A. Statutory and Regulatory Basis for SOR

Authority for maintenance of the system is given under §§ 226, 226A, 1811, 1818, 1818A, 1831, 1833(a)(1)(A), 1836, 1837, 1838, 1843, 1866, 1876, 1881, and 1902(a)(6) of the Act and Title 42 United States Code (U.S.C.) 426, 426–1, 1395c, 1395cc, 1395i–2, 1395i–2a, 1395j, 13951, 1395mm, 1395o, 1395p, 1395q, 1395rr, 1395v, 1396a, and Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) (Regulations at 42 CFR Parts 403, 411, 417 and 423).

B. Collection and Maintenance of Data in the System

This system contains information on individuals age 65 or over who have been, or currently are, entitled to health insurance (Medicare) benefits under Title XVIII of the Social Security Act (the Act) or under provisions of the Railroad Retirement Act; individuals under age 65 who have been, or currently are, entitled to such benefits on the basis of having been entitled for not less that 24 months to disability benefits under Title II of the Act or under the Railroad Retirement Act; individuals who have been, or currently are, entitled to such benefits because they have End-Stage Renal Disease (ESRD); individuals age 64 and 8 months or over who are likely to become entitled to health insurance (Medicare) benefits upon attaining age 65, and individuals under age 65 who have at least 21 months of disability benefits who are likely to become entitled to Medicare upon the 25th month or entitlement to such benefits and those populations that are dually eligible for both Medicare and Medicaid (Title XIX of the Act).

Information maintained in the system include, but are not limited to: Standard data for identification such as health insurance claim number, social security number, gender, race/ethnicity, date of birth, geographic location, Medicare enrollment and entitlement information, MSP data necessary for appropriate Medicare claim payment, hospice election, MA plan elections and enrollment, End Stage Renal Disease (ESRD) entitlement, historic and current listing of residences, and Medicare eligibility and Managed Care institutional status.

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 MBD 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 MBD. CMS has the following policies and procedures concerning disclosures of information that will be maintained in the system. Disclosure of information from this 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 provide CMS with a singular, authoritative, database of comprehensive data on individuals in the Medicare program to support ongoing and expanded program administration, service delivery modalities, and payment coverage options.

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. Modified 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 modifying/altering the routine use disclosures of information maintained in the system so that the routine uses include the following:

1. To support agency contractors, consultants or grantees 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, consultant or grantee whatever information is necessary for the contractors, consultants or grantees to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor, consultant or grantee from using or disclosing the information for any purpose other than that described in the contract and requires the contractor, consultant or grantee to return or destroy all information at the completion of the contract.

2. To assist another Federal or State agency, agency of a State government,

an agency established by State law, or its fiscal agent to:

a. Contribute to the accuracy of CMS' 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 MBD 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 MBD 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, other State agencies in their administration of a Federal health program may require MBD information for the purpose of determining, evaluating and/or assessing cost effectiveness, and/or the quality of health care services provided in the State.

The Railroad Retirement Board requires MBD information to administer provisions of the Railroad Retirement Act and Social Security Act relating to railroad employment and/or the administration of the Medicare program.

The Social Security Administration requires MBD data to enable them to assist in the implementation and maintenance of the Medicare program.

Disclosure under this routine use shall be used by State Medicaid agencies pursuant to agreements with 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 who are residents of that State.

3. To assist providers and suppliers of services directly or through fiscal intermediaries or carriers for the administration of Title XVIII of the Act.

Providers and suppliers of services require MBD 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 benefits under the Medicare program, including proper reimbursement for services provided.

4. To assist third party contact in situations where the party to be contacted has, or is expected to have information relating to the individual's capacity to manage his or her affairs or to his or her eligibility for, or an entitlement to, benefits under the Medicare program and;

a. The individual is unable to provide the information being sought (an individual is considered to be unable to provide certain types of information when any of the following conditions exists: the individual is confined to a mental institution, a court of competent jurisdiction has appointed a guardian to manage the affairs of that individual, a court of competent jurisdiction has declared the individual to be mentally incompetent, or the individual's attending physician has certified that the individual is not sufficiently mentally competent to manage his or her own affairs or to provide the information being sought, the individual cannot read or write, cannot afford the cost of obtaining the information, a language barrier exists, or the custodian of the information will not, as a matter of policy, provide it to the individual), or

b. The data are needed to establish the validity of evidence or to verify the accuracy of information presented by the individual, and it concerns one or more of the following: the individual's entitlement to benefits under the Medicare program, the amount of reimbursement, and in cases in which the evidence is being reviewed as a result of suspected fraud and abuse, program integrity, quality appraisal, or evaluation and measurement of activities.

Third parties contacts require MBD information in order to provide support for the individual's entitlement to benefits under the Medicare program; to establish the validity of evidence or to verify the accuracy of information presented by the individual, and assist in the monitoring of Medicare claims information of beneficiaries, including proper reimbursement of services provided.

5. To support Quality Improvement Organizations (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. As established by the Part D Program, QIOs will conduct reviews of prescription drug events data, or in connection with studies or other review activities conducted pursuant to Part D of Title XVIII of the Act.

QIOs will work to implement quality improvement programs, provide consultation to CMS, MA–PD, PDPs, and State agencies, to assist CMS in prescription drug event assessments, and prepare summary information for release to CMS.

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

6. To other insurers, underwriters, third party administrators (TPAs), self-insurers, group health plans, employers, health maintenance organizations, health and welfare benefit funds, Federal agencies, a State or local government or political subdivision of either (when the organization has assumed the role of an insurer, underwriter, or third party administrator, or in the case of a State that assumes the liabilities of an insolvent insurers pool or fund), multiple-employers trusts, no-fault medical, automobile insurers, workers' compensation carriers plans, liability insurers, and other groups providing protection against medical expenses who are primary payers to Medicare in accordance with 42 U.S.C. 1395y(b), or 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 or continued right to any such benefit or payment (for example, a State Medicaid Agency, State Workers' Compensation Board, or Department of Motor Vehicles) for the purpose of coordination of benefits with the Medicare program and implementation of the MSP provisions at 42 U.S.C. 1395y(b). The information CMS may disclose will be:

- Beneficiary Name
- Beneficiary Address
- Beneficiary Health Insurance Claim Number
- Beneficiary Social Security Number
- Beneficiary Gender
- Beneficiary Date of Birth
- Amount of Medicare Conditional Payment
- Provider Name and Number
- Physician Name and Number
- Supplier Name and Number
- Dates of Service

- Nature of Service
- Diagnosis

To administer the MSP provision at 42 U.S.C. 1395y(b) (2), (3), and (4) more effectively, CMS would receive (to the extent that it is available) and may disclose the following types of information from insurers, underwriters, third party administrator, self-insurers, etc.:

- Subscriber Name and Address
- Subscriber Date of Birth
- Subscriber Social Security number
- Dependent Name
- Dependent Date of Birth
- Dependent Social Security Number
- Dependent Relationship to Subscriber
- Insurer/Underwriter/TPA Name and Address
- Insurer/Underwriter/TPA Group Number
- Insurer/Underwriter/Group Name
- Prescription Drug Coverage
- Policy Number
- Effective Date of Coverage
- Employer Name, Employer Identification Number (EIN) and Address
- Employment Status
- Amounts of Payment

To administer the MSP provision at 42 U.S.C. 1395y(b)(1) more effectively for entities such as Workers' Compensation carriers or boards, liability insurers, no-fault and automobile medical policies or plans, CMS would receive (to the extent that it is available) and may disclose the following information:

- Beneficiary's Name and Address
- Beneficiary's Date of Birth
- Beneficiary's Social Security Number
- Name of Insured
- Insurer Name and Address
- Type of coverage; automobile medical, no-fault, liability payment, or workers' compensation settlement
- Insured's Policy Number
- Effective Date of Coverage
- Date of accident, injury or illness
- Amount of payment under liability, no-fault, or automobile medical policies, plans, and workers' compensation settlements
- Employer Name and Address (Workers' Compensation Only)
- Name of insured could be the driver of the car, a business, the beneficiary (*i.e.*, the name of the individual or entity which carries the insurance policy or plan)

In order to receive this information the entity must agree to the following conditions:

c. To utilize the information solely for the purpose of coordination of benefits with the Medicare program and other third party payer in accordance with Title 42 U.S.C. 1395y(b);

d. To safeguard the confidentiality of the data and to prevent unauthorized access to it; and,

e. To prohibit the use of beneficiary-specific data for the purposes other than for the coordination of benefits among third party payers and the Medicare program.

This agreement would allow the entities to use the information to determine cases where they or other third party payers have primary responsibility for payment. Examples of prohibited uses would include but are not limited to: creation of a mailing list, sale or transfer of data.

To administer the MSP provisions more effectively, CMS may receive or disclose the following types of information from or to entities including insurers, underwriters, TPAs, and self-insured plans, concerning potentially affected individuals:

- Subscriber HICN
- Dependent Name
- Funding arrangements of employer group health plans, for example, contributory or non-contributory plan, self-insured, re-insured, HMO, TPA insurance
- Claims payment information, for example, the amount paid, the date of payment, the name of the insurers or payer
- Dates of employment including termination date, if appropriate
- Number of full and/or part-time employees in the current and preceding calendar years
- Employment status of subscriber, for example, full or part time or self-employed

Other insurers, HMO, and Health Care Prepayment Plans may require MBD information in order to support evaluations and monitoring of Medicare claims information of beneficiaries, including proper reimbursement for services provided.

1860D–23 and 1860D–24 of the Act require that the Secretary establish requirements for prescription drug plans (Part D plans) to ensure the effective coordination between a Part D plan and a State Pharmaceutical Assistance Program (SPAP), as well as other payers of prescription drug benefits, including enrollment file sharing. CMS, using its coordination of benefits contractor, allows this to happen by having payers that will be secondary to Part D submit their enrollment data in exchange for Part D enrollment data. The data shared is mainly enrollment information (date of enrollment into Part D, what Part D plan they are enrolled with). SPAPs, but not other payers, will also receive data indicating whether the beneficiary qualifies for a low-income subsidy to pay for drug costs.

7. To assist 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 MBD 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.

8. To support Patient Assistance Programs and other groups providing pharmaceutical assistance to a Medicare beneficiary. Medicare Part D enrollment information may be released to these organizations upon specific request, and then only if they meet the following requirements, they must:

a. Provide an attestation or other qualifying information that they are providing pharmaceutical assistance to Medicare beneficiaries;

b. Submit a finder file to CMS to identify Medicare beneficiaries receiving pharmaceutical assistance and/or services consisting of the following data elements:

(1) First initial of the first name,

(2) First 6 letters of the last name,

(3) Social security number or health insurance claims number,

(4) Date of birth, and

(5) Sex;

c. Safeguard the confidentiality of any data received and prevent unauthorized access to the data; and,

d. Complete a written statement attesting to the information recipient's understanding of and willingness to abide by CMS provisions regarding Privacy protections and information security. Recipients of CMS data must complete the PAP Data Sharing Agreement prior to the release of CMS data.

Part D data maintained in the MBD that will be released to PAPs or a group providing pharmaceutical assistance will consist of the verification of Medicare status and the name of the current Part D Plan selected by the Medicare beneficiary.

9. 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.

10. To a CMS contractor (including, but not necessarily limited to fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste 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, waste or 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.

11. 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, waste or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such programs.

Other agencies may require MBD information for the purpose of combating fraud, waste or abuse in such Federally-funded programs.

B. Additional Provisions Affecting Routine Use Disclosures

To the extent this system contains Protected Health Information (PHI) 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 such PHI that are otherwise 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.'' (See 45 CFR 164.512 (a) (1).)

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 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 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 may apply but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

V. Effects of the System of Records on Individual Rights

CMS proposes to modify 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 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.

Dated: November 24, 2006.

John R. Dyer,

Chief Operating Officer, Centers for Medicare & Medicaid Services.

System No. 09–70–0536

SYSTEM NAME:

''Medicare Beneficiary Database (MBD), HHS/CMS/CBC.''

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive Data.

SYSTEM LOCATION:

The Centers for Medicare & Medicaid Services (CMS) Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244–1850.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals age 65 or over who have been, or currently are, entitled to health insurance (Medicare) benefits under

Title XVIII of the Social Security Act (the Act) or under provisions of the Railroad Retirement Act; individuals under age 65 who have been, or currently are, entitled to such benefits on the basis of having been entitled for not less that 24 months to disability benefits under Title II of the Act or under the Railroad Retirement Act; individuals who have been, or currently are, entitled to such benefits because they have End-Stage Renal Disease (ESRD); individuals age 64 and 8 months or over who are likely to become entitled to health insurance (Medicare) benefits upon attaining age 65, and individuals under age 65 who have at least 21 months of disability benefits who are likely to become entitled to Medicare upon the 25th month or entitlement to such benefits and those populations that are dually eligible for both Medicare and Medicaid (Title XIX of the Act).

CATEGORIES OF RECORDS IN THE SYSTEM:

Information maintained in the system include, but are not limited to: Standard data for identification such as health insurance claim number, social security number, gender, race/ethnicity, date of birth, geographic location, Medicare enrollment and entitlement information, MSP data necessary for appropriate Medicare claim payment, hospice election, MA plan elections and enrollment, End Stage Renal Disease (ESRD) entitlement, historic and current listing of residences, and Medicare eligibility and Managed Care institutional status.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM

Authority for maintenance of the system is given under §§ 226, 226A, 1811, 1818, 1818A, 1831, 1833(a)(1)(A), 1836, 1837, 1838, 1843, 1866, 1876, 1881, and 1902(a)(6) of the Act and Title 42 United States Code (U.S.C.) 426, 426–1, 1395c, 1395cc, 1395i-2, 1395i-2a, 1395j, 13951, 1395mm, 1395o, 1395p, 1395q, 1395rr, 1395v, 1396a, and Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) (Regulations at 42 CFR Parts 403, 411, 417 and 423).

PURPOSE(S) OF THE SYSTEM:

The primary purpose of this modified system is to provide CMS with a singular, authoritative, database of comprehensive enrollment data on individuals in the Medicare program to support ongoing and expanded program administration, service delivery modalities, and payment coverage options. This collection will contain a complete ''beneficiary insurance profile'' that reflects the individual's Medicare health insurance coverage and Medicare health plan and demonstration enrollment. Information retrieved from this system of records will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor, consultant or a CMS grantee; (2) assist another Federal or State agency, agency of a State government, an agency established by State law, or its fiscal agent; (3) support providers and suppliers of services for administration of Title XVIII; (4) assist third parties where the contact is expected to have information relating to the individual's capacity to manage his or her own affairs; (5) support Quality Improvement Organizations (QIO); (6) assist other insurers for processing individual insurance claims; (7) facilitate research on the quality and effectiveness of care provided, as well as payment related projects; (8) support Patient Assistance Programs and other groups providing pharmaceutical assistance or services to Medicare beneficiaries; (9) support litigation involving the agency; and (10) combat fraud, waste, 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. 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 modifying/altering the routine use disclosures of information maintained in the system so that the routine uses include the following:

1. To support agency contractors, consultants or grantees 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 assist another Federal or State agency, agency of a State government, an agency established by State law, or its fiscal agent to:

a. Contribute to the accuracy of CMS' 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 assist providers and suppliers of services directly or through fiscal intermediaries or carriers for the administration of Title XVIII of the Act.

4. To assist third party contact in situations where the party to be contacted has, or is expected to have information relating to the individual's capacity to manage his or her affairs or to his or her eligibility for, or an entitlement to, benefits under the Medicare program and;

a. The individual is unable to provide the information being sought (an individual is considered to be unable to provide certain types of information when any of the following conditions exists: The individual is confined to a mental institution, a court of competent jurisdiction has appointed a guardian to manage the affairs of that individual, a court of competent jurisdiction has declared the individual to be mentally incompetent, or the individual's attending physician has certified that the individual is not sufficiently mentally competent to manage his or her own affairs or to provide the information being sought, the individual cannot read or write, cannot afford the cost of obtaining the information, a language barrier exists, or the custodian of the information will not, as a matter of policy, provide it to the individual), or

b. The data are needed to establish the validity of evidence or to verify the accuracy of information presented by the individual, and it concerns one or more of the following: The individual's entitlement to benefits under the Medicare program, the amount of reimbursement, and in cases in which the evidence is being reviewed as a result of suspected fraud and abuse, program integrity, quality appraisal, or evaluation and measurement of activities.

5. To support Quality Improvement Organizations (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. As established by the Part D Program, QIOs will conduct reviews of prescription drug events data, or in connection with studies or other review activities conducted pursuant to Part D of Title XVIII of the Act.

6. To other insurers, underwriters, third party administrators (TPAs), self-insurers, group health plans, employers, health maintenance organizations, health and welfare benefit funds, Federal agencies, a State or local government or political subdivision of either (when the organization has assumed the role of an insurer, underwriter, or third party administrator, or in the case of a State that assumes the liabilities of an insolvent insurers pool or fund), multiple-employers trusts, no-fault medical, automobile insurers, workers' compensation carriers plans, liability insurers, and other groups providing protection against medical expenses who are primary payers to Medicare in accordance with 42 U.S.C. 1395y(b), or 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 or continued right to any such benefit or payment (for example, a State Medicaid Agency, State Workers' Compensation Board, or Department of Motor Vehicles) for the purpose of coordination of benefits with the Medicare program and implementation of the MSP provisions at 42 U.S.C. 1395 y(b). The information CMS may disclose will be:

- Beneficiary Name
- Beneficiary Address
- Beneficiary Health Insurance Claim Number
- Beneficiary Social Security Number
- Beneficiary Gender
- Beneficiary Date of Birth
- Amount of Medicare Conditional Payment
- Provider Name and Number
- Physician Name and Number
- Supplier Name and Number
- Dates of Service
- Nature of Service
- Diagnosis

To administer the MSP provision at 42 U.S.C. 1395 y(b)(2), (3), and (4) more effectively, CMS would receive (to the extent that it is available) and may disclose the following types of information from insurers, underwriters, third party administrator, self-insurers, etc.:

- Subscriber Name and Address
- Subscriber Date of Birth
- Subscriber Social Security number
- Dependent Name
- Dependent Date of Birth
- Dependent Social Security Number
- Dependent Relationship to Subscriber
- Insurer/Underwriter/TPA Name and Address
- Insurer/Underwriter/TPA Group Number
- Insurer/Underwriter/Group Name
- Prescription Drug Coverage
- Policy Number
- Effective Date of Coverage
- Employer Name, Employer Identification Number (EIN) and Address
- Employment Status
- Amounts of Payment

To administer the MSP provision at 42 U.S.C. 1395y(b)(1) more effectively for entities such as Workers' Compensation carriers or boards, liability insurers, no-fault and automobile medical policies or plans, CMS would receive (to the extent that it is available) and may disclose the following information:

- Beneficiary's Name and Address
- Beneficiary's Date of Birth
- Beneficiary's Social Security number
- Name of Insured
- Insurer Name and Address
- Type of coverage; automobile medical, no-fault, liability payment, or workers' compensation settlement
- Insured's Policy Number
- Effective Date of Coverage
- Date of accident, injury or illness
- Amount of payment under liability, no-fault, or automobile medical policies, plans, and workers' compensation settlements
- Employer Name and Address (Workers' Compensation Only)
- Name of insured could be the driver of the car, a business, the beneficiary (*i.e.*, the name of the individual or entity which carries the insurance policy or plan)

In order to receive this information the entity must agree to the following conditions;

c. To utilize the information solely for the purpose of coordination of benefits with the Medicare program and other third party payer in accordance with Title 42 U.S.C. 1395y(b);

d. To safeguard the confidentiality of the data and to prevent unauthorized access to it; and

e. To prohibit the use of beneficiary-specific data for the purposes other than for the coordination of benefits among third party payers and the Medicare program. This agreement would allow the entities to use the information to determine cases where they or other third party payers have primary responsibility for payment. Examples of prohibited uses would include but are not limited to; creation of a mailing list, sale or transfer of data.

To administer the MSP provisions more effectively, CMS may receive or disclose the following types of information from or to entities including insurers, underwriters, TPAs, and self-insured plans, concerning potentially affected individuals:

- Subscriber HICN
- Dependent Name
- Funding arrangements of employer group health plans, for example, contributory or non-contributory plan, self-insured, re-insured, HMO, TPA insurance
- Claims payment information, for example, the amount paid, the date of payment, the name of the insurers or payer
- Dates of employment including termination date, if appropriate
- Number of full and/or part-time employees in the current and preceding calendar years
- Employment status of subscriber, for example, full or part time or self-employed

7. To assist 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.

8. To support Patient Assistance Programs and other groups providing pharmaceutical assistance to a Medicare beneficiary. Medicare Part D enrollment information may be released to these organizations upon specific request, and then only if they meet the following requirements, they must:

a. Provide an attestation or other qualifying information that they are providing pharmaceutical assistance to Medicare beneficiaries;

b. Submit a finder file to CMS to identify Medicare beneficiaries receiving pharmaceutical assistance and/or services consisting of the following data elements:

(1) First initial of the first name,

(2) First 6 letters of the last name,

(3) Social security number or health insurance claims number,

(4) Date of birth,

(5) Sex;

c. Safeguard the confidentiality of any data received and prevent unauthorized access to the data; and

d. Complete a written statement attesting to the information recipient's understanding of and willingness to abide by CMS provisions regarding Privacy protections and information security. Recipients of CMS data must complete the PAP Data Sharing Agreement prior to the release of CMS data.

9. 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.

10. To a CMS contractor (including, but not necessarily limited to fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such program.

11. 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, waste or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such programs.

B. Additional Provisions Affecting Routine Use Disclosures

To the extent this system contains Protected Health Information (PHI) 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 such PHI that are otherwise 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.'' (See 45 CFR 164.512 (a)(1).)

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 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:

All Medicare records are accessible by HICN, and SSN search. This system supports both on-line and batch access.

SAFEGUARDS:

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

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply 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 in the active files for a period of 15 years. The records are then retired to archival files maintained at the Health Care Data Center. 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, Division of Enrollment and Eligibility Policy, Medicare Enrollment and Appeals Group, Center for Beneficiary Choices, CMS, Mail Stop S1–05–06, 7500 Security Boulevard, 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, HICN, address, date of birth, and gender, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), and SSN. Furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay.

RECORD ACCESS PROCEDURE:

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

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 CATEGORIES:

The data contained in this system of records are extracted from other CMS systems of records: Enrollment Database, Medicare Advantage Prescription Drug System, and the Medicaid Statistical Information System. Information will also be provided from the application submitted by the individual through State Medicaid agencies, the Social Security Administration and through other entities assisting beneficiaries.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. E6–20408 Filed 12–1–06; 8:45 am]

BILLING CODE 4120–03–P