

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services****Privacy Act of 1974; Report of Modified or Altered System**

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

**ACTION:** Notice of Proposed Modification or Alteration to a System of Records (SOR).

**SUMMARY:** In accordance with the requirements of the Privacy Act of 1974, we are proposing to modify an existing system of records titled, "Unique Physician/Practitioner Identification Number (UPIN)," System No. 09-70-0525, most recently modified at 69 FR 75316 (December 16, 2004). We propose to delete published routine use number 1 that permits the release of the identification of each physician or non-physician practitioner who has been assigned a UPIN and who is participating in the Medicare program. Selected UPIN information to carry out this requirement is available as a public use file, and as such, should not be treated as a routine use disclosure. We will broaden the "Purpose" section of this notice to include this requirement as one of the primary purposes of this system.

We propose to modify existing routine use number 2 that permits disclosure to agency contractors and consultants to include disclosure to CMS grantees who perform a task for the agency. CMS grantees, charges with completing projects or activities that require CMS data to carry out that activity, are classified separate from CMS contractors and/or consultants. The modified routine use will be renumbered as routine use number 1. We will delete routine use number 6 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 routine uses number 8 and 9, authorizing disclosures to combat fraud and abuse in the Medicare and Medicaid programs to include combating "waste" which refers to specific beneficiary/recipient practices that result in unnecessary cost to all Federally-funded health benefit programs. We also propose to add a

routine use for the release of information to assist an individual or organization for research, evaluation or epidemiological projects related to the prevention of disease or disability, or the restoration or maintenance of health, and for payment-related projects. The added routine use will be numbered as routine use number 3.

We are modifying the language in the remaining routine uses to provide a proper explanation as to the need for the routine use and to provide clarity to CMS's intention to disclose individual-specific information contained in this system. The routine uses will then be prioritized and reordered according to their usage. We will also take the opportunity to update any sections of the system that were affected by the recent reorganization or because of the impact of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) provisions and to update language in the administrative sections to correspond with language used in other CMS SORs.

The primary purpose of the SOR is to: (1) Collect and maintain a unique identification of each physician, non-physician practitioner, or medical group practice requesting or receiving Medicare payment, and (2) provide beneficiaries and other interested entities with the identification of each physician or non-physician practitioner assigned an UPIN and who are participating in the Medicare program. Information retrieved from this SOR will be used to: (1) Support regulatory, reimbursement, and policy functions performed within the Agency or by a contractor or consultant, or CMS grantee; (2) assist another Federal and/or State agency, agency of a State government, an agency established by State law, or its fiscal agent; (3) facilitate research on the quality and effectiveness of care provided, as well as payment related projects; (4) assist Quality Improvement Organizations; (5) provide the American Medical Association with information needed for them to assist us in identifying physicians; (6) support litigation involving the Agency; and (7) 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 proposed 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 system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Homeland Security & Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on November 7, 2006. To ensure that all parties have adequate time in which to comment, the modified system, including routine uses, will become effective 30 days from the publication of the notice, or 40 days from the date it was submitted to OMB and Congress, whichever is later, unless CMS receives comments that require alterations to this notice.

**ADDRESSES:** The public should address comments to: CMS Privacy Officer, Division of 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:** Kimberly Brandt, Director, Program Integrity Group, Office of Financial Management, CMS, 7500 Security Boulevard, C3-02-17, Baltimore, Maryland 21244-1850. The telephone number is (410) 786-5704.

**SUPPLEMENTARY INFORMATION:****Description of the Modified System of Records***A. Statutory and Regulatory Basis For System of Records*

In 1988, CMS modified an SOR under the authority of §§ 1842 (r)-(42 U.S.C. 1395u) of Public Law 101-508; 1861(s)(1)-(42 U.S.C. 1395x); §§ 1833 (q)(1)-(42 U.S.C. 1395l); 1842(b)(18)-(42 U.S.C. 1395u); 1842 (h)(4) & (5)-(42 U.S.C. 1395u); and 4164 of Omnibus Budget Reconciliation Act of 1990 (OBRA). Section 1871 (a)(1)-(42 U.S.C. 1395hh) provides that the Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance program under Title XVIII. Section 1833 (d)-(42 U.S.C. 1395l), prohibits making payment under Part B for services which are payable under Part A. It contains records of all physicians, non-physician practitioners and medical group practice as defined by section 1861(r)-(42 U.S.C. 1395x), 1877(h)(4)-(42 U.S.C. 1395) of Title XVIII of the Act, who provide services for which payment is made under Medicare. By

uniquely identifying all Part B health professional and practitioners and groups, CMS believes we will eliminate the possibility of double payment.

Medicare carriers currently identify physicians, non-physician practitioners and groups using their own systems of assigned numbers. These individualized systems allow for Physician Identification Numbers (PIN) ranging from 4 to 16 alphabetic and or numeric characters. Some carriers assign separate PIN to the same physician providing medical services in more than one locality, office or practice and lack the capability to cross reference the PIN and related physician data (e.g., group affiliation).

Other carriers maintain a single PIN or cross-referenced PIN for each physician practicing within the carrier's geographic area of responsibility. The assignment of a unique identification number will help eliminate the possibility of double billing where physicians, non-physician practitioners, and groups can furnish medical services in, as well as bill for these services from several locations or States which are in different carrier jurisdictions. In addition, independent physicians who have been found to be ineligible for Medicare payments in one area, location or State are prevented from receiving inappropriate or illegal payment in one or more other areas, locations or States.

In order to rectify the problems inherent in these individualized identification systems, CMS proposed to expand the Registry under Congressional mandate (Section 9202 of the Consolidated Omnibus Reconciliation Act of 1985, Pub. L. 99-272) that created uniform record system under UPIN. The proposed changes to this national system or Registry of Unique Physician/Practitioner Identification Number will enable CMS to more readily identify all physicians, non-physician practitioners, and group practices deemed ineligible for Medicare payments and maintain more comprehensive data on physician credentials.

#### *B. Collection and Maintenance of Data in the System*

The records contain a UPIN for each physician, non-physician practitioner, and medical group practices defined by §§ 1124(A)—(42 U.S.C. 1320A-3), 1861(r), 1842(b)(18)(ii)(iii)(iv)(v)(r), and 1877(h)(4) of the Act who request or receive Medicare reimbursement for medical services. The system contains a UPIN, tax identification, and social security number for each physician, non-physician practitioner and medical group. Also, the system contains

information concerning a provider's birth, residence, medical education, and eligibility information necessary for Medicare reimbursement.

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

A. The Privacy Act permits us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a "routine use." The government will only release UPIN information that can be associated with each physician, non-physician practitioner and medical group practices 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. Identifiable data includes individual records with UPIN information and identifiers. Non-identifiable data includes individual records with UPIN information and masked identifiers or UPIN information with identifiers stripped out of the file.

We will only disclose the minimum personal data necessary to achieve the purpose of UPIN. 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 of records will be approved only for the minimum information necessary to accomplish the purpose of the disclosure after CMS:

1. Determines that the use or disclosure is consistent with the reason that the data is being collected; e.g., maintain unique identification of each physician, non-physician practitioner, or medical group practice requesting or receiving Medicare payment.

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 or disclosure of the record;

- b. Remove or destroy at the earliest time all patient-identifiable information; and

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

4. Determines that the data are valid and reliable.

#### **III. Proposed Routine Use Disclosures of Data in the System**

##### *A. Entities Who May Receive Disclosures Under Routine Use*

These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974, under which CMS may release information from the UPIN 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 support Agency contractors, consultants, or grantees who have been engaged by the Agency to assist in accomplishment of a CMS function relating to the purposes for this SOR and who need to have access to the records in order to assist CMS.

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

CMS occasionally contracts out certain of its functions when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor, consultant, or grantee whatever information is necessary for the contractor or consultant to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor, consultant, 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 pursuant to agreements with CMS to:

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

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

c. Assist Federal/State Medicaid programs within may require UPIN information for purposes related to this system.

The RRB requires UPIN information to enable them to assist in the implementation and maintenance of the Medicare program.

SSA requires UPIN data to enable them to assist in the implementation and maintenance of the Medicare program.

The Internal Revenue Service may require UPIN 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).

Disclosure under this routine use shall be used by State Medicaid agencies pursuant to agreements with HHS for administration of State supplementation payments for determinations of eligibility for Medicaid, for enrollment of welfare recipients for medical insurance under section 1843 of the Act, for quality control studies, for determining eligibility of recipients of assistance under Titles IV and XIX of the Act, and for the complete administration of the Medicaid program. UPIN data will be released to the State only on those individuals who are patients under the services of a Medicaid program within the State or who are residents of that State.

Occasionally State licensing boards require access to the UPIN data for review of unethical practices or nonprofessional conduct.

We also contemplate disclosing information under this routine use in situations in which State auditing agencies require UPIN information for auditing of Medicare eligibility considerations. Disclosure of physicians' customary charge data are made to State audit agencies in order to ascertain the corrections of Title XIX charges and payments. CMS may enter into an agreement with State auditing agencies to assist in accomplishing functions relating to purposes for this SOR.

State and other governmental worker's compensation agencies working with CMS to assure that workers' compensation payments are

made where Medicare has erroneously paid and workers' compensation programs are liable.

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

The collected data will provide the research, evaluation and epidemiological projects a broader, longitudinal, national perspective of the data. CMS anticipates that many researchers will have legitimate requests to use these data in projects that could ultimately improve the care provided to Medicare patients and the policy that governs the care. CMS understands the concerns about the privacy and confidentiality of the release of data for a research use. Disclosure of data for research and evaluation purposes may involve aggregate data rather than individual-specific data.

4. 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.

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

5. To support the American Medical Association (AMA), for the purpose of assisting CMS to identify medical doctors when CMS is unable to establish an identity, provided the AMA agrees to:

a. Use the information provided by CMS solely to identify a medical doctor;

b. Make no copies of the information it receives from the CMS, except for one back-up copy;

c. Return such information to CMS upon completion of its matching operation, and erase the back-up copy;

d. Establish appropriate administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the records; and,

e. Sign a written statement attesting to its understanding of, and willingness to abide by these provisions.

CMS exchanges information with the AMA for the purpose of attempting to identify medical doctors when the UPIN Registry is unable to establish identity

after matching carrier-submitted data to the data extract provided by the AMA. The AMA would attempt to establish medical doctor identity by matching the UPIN data to data maintained in the AMA Physician Master File.

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

a. The Agency or any component thereof, or

b. any employee of the Agency in his or her official capacity, or

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

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

Whenever CMS is involved in litigation, or occasionally when another party is involved in litigation and CMS's policies or operations could be affected by the outcome of the litigation, CMS would be able to disclose information to the DOJ, court or adjudicatory body involved.

7. To assist 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, waste or abuse in such program.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contract or grant with a third party to assist in accomplishing CMS functions relating to the purpose of combating fraud, waste or abuse.

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

8. To assist another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud, waste or abuse in a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such programs.

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

#### *B. Additional Circumstances 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 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 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 Modified 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 (see item IV above) to minimize the risks of unauthorized access to the records and the potential harm to individual privacy or other personal or property rights of patients whose data are maintained in the system. CMS will collect only that information necessary to perform the system's functions. In addition, CMS will make disclosure from the proposed system only with consent of the subject individual, or his/her legal representative, or in accordance with an applicable exception provision of the Privacy Act. CMS, therefore, does not anticipate an unfavorable effect on individual privacy as a result of information relating to individuals.

Dated: November 1, 2006.

**Charlene Frizzera,**

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

#### **SYSTEM NO. 09–70–0525**

##### **SYSTEM NAME:**

"Unique Physician/Practitioner Identification Number" (UPIN), HHS/CMS/OFM.

##### **SECURITY CLASSIFICATION:**

Level Three Privacy Act Sensitive.

##### **SYSTEM LOCATION:**

CMS Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244–1850. The system is also located at CMS contractors and agents at various locations (see Appendix A).

##### **CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

All physicians, non-practitioners and medical groups practices, defined by §§ 1124(A), 1861(r), 1842(b)(1)(ii)(iii)(iv)(v)(r), and 1877(h)(4) of the Social Security Act who request or receive Medicare reimbursement for medical services.

##### **CATEGORIES OF RECORDS IN THE SYSTEM:**

The system contains an UPIN, tax identification, and social security number (SSN) for each physician, non-physician practitioner and medical group. Also, the system contains information concerning a provider's birth, residence, medical education, and eligibility information for Medicare reimbursement.

##### **AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Authority for the collection and maintenance of this system is given under the provisions of §§ 1842(r)–(42 U.S.C. 1395u) of Pub. L. 101–508; 1861(s)(1)–(42 U.S.C. 1395x); §§ 1833(q)(1)–(42 U.S.C. 1395l); 1842(b)(18)–(42 U.S.C. 1395u); § 1842(h)(4) & (5)–(42 U.S.C. 1395u); and 4164 of Omnibus Budget Reconciliation Act of 1990 (OBRA).

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

The primary purpose of the SOR is to: (1) Collect and maintain an unique identification of each physician, non-physician practitioner, or medical group practice requesting or receiving Medicare payment, and (2) provide beneficiaries and other interested entities with the identification of each physician or non-physician practitioner assigned an UPIN and who are participating in the Medicare program. Information retrieved from this SOR will be used to: (1) Support regulatory, reimbursement, and policy functions performed within the Agency or by a contractor or consultant, or CMS grantee; (2) assist another Federal and/or State agency, agency of a State government, an agency established by State law, or its fiscal agent; (3) facilitate research on the quality and effectiveness of care provided, as well as payment related projects; (4) assist Quality Improvement Organizations; (5) provide the American Medical Association with

information needed for them to assist us in identifying physicians; (6) support litigation involving the Agency; and (7) 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. 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 UPIN 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 support Agency contractors, consultants, or grantees who have been engaged by the Agency to assist in accomplishment of a CMS function relating to the purposes for this SOR and who need to have access to the records in order to assist CMS.

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

- a. Contribute to the accuracy of CMS's proper payment of Medicare benefits,
- b. Enable such agency to administer a Federal health benefits program, or as necessary to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds, and/or
- c. Assist Federal/State Medicaid programs within may require UPIN information for purposes related to this system.

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

4. 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.

5. To support the American Medical Association (AMA), for the purpose of assisting CMS to identify medical doctors when CMS is unable to establish an identity, provided the AMA agrees to:

- a. Use the information provided by CMS solely to identify a medical doctor;
- b. Make no copies of the information it receives from the CMS, except for one back-up copy;
- c. Return such information to CMS upon completion of its matching operation, and erase the back-up copy;
- d. Establish appropriate administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the records; and,
- e. Sign a written statement attesting to its understanding of, and willingness to abide by these provisions.

6. To assist 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.

7. To assist 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, waste or abuse in such program.

8. To assist another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud, waste or abuse in a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine,

prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such programs.

**B. Additional Circumstances 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 on magnetic media.

**RETRIEVABILITY:**

The records are retrieved alphabetically by the provider name, social security number or by their assigned UPIN.

**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 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:

CMS and the repository of the National Archive and Records Administration will retain identifiable UPIN assessment data for a total period not to exceed fifteen (15) years.

#### SYSTEM MANAGER AND ADDRESS:

Director, Program Integrity Group, Office of Financial Management, CMS, 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, health insurance claim number, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), social security number (SSN) (furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay), address, date of birth, and sex.

#### 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:

CMS obtains the identifying information in this system from carriers. Information in these records concerning the eligibility of physicians, practitioners, and medical groups for Medicare reimbursement is obtained either directly from such entities through Medicare Regional Offices, contractors, PRO, Department of Justice, State or local judicial systems, medical licensing and certification agencies or organizations, medical societies and medical associations.

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

None.

#### Appendix A. Health Insurance Claims

Medicare records are maintained at the CMS Central Office (*see* section 1 below for the address). Health Insurance Records of the Medicare program can also be accessed through a representative of the CMS Regional Office (*see* section 2 below for addresses). Medicare claims records are also maintained by private insurance organizations that share in administering provisions of the health insurance programs. These private insurance organizations, referred to as carriers and intermediaries, are under contract to the Centers for Medicare & Medicaid Services and the Social Security Administration to perform specific tasks in the Medicare program (*see* section three below for addresses for intermediaries, section four addresses the carriers, and section five addresses the Payment Safeguard Contractors).

##### 1. Central Office Address

CMS Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244-1850.

##### 2. CMS Regional Offices

*Boston Region*—Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont. John F. Kennedy Federal Building, Room 1211, Boston, Massachusetts 02203. Office Hours: 8:30 a.m.–5 p.m.

*New York Region*—New Jersey, New York, Puerto Rico, Virgin Islands. 26 Federal Plaza, Room 715, New York, New York 10007. Office Hours: 8:30 a.m.–5 p.m.

*Philadelphia Region*—Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia. Post Office Box 8460, Philadelphia, Pennsylvania 19101. Office Hours: 8:30 a.m.–5 p.m.

*Atlanta Region*—Alabama, North Carolina, South Carolina, Florida, Georgia, Kentucky, Mississippi, Tennessee. 101 Marietta Street, Suite 702, Atlanta, Georgia 30223. Office Hours: 8:30 a.m.–4:30 p.m.

*Chicago Region*—Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin. Suite A-824, Chicago, Illinois 60604. Office Hours: 8 a.m.–4:45 p.m.

*Dallas Region*—Arkansas, Louisiana, New Mexico, Oklahoma, Texas. 1200 Main Tower Building, Dallas, Texas. Office Hours: 8 a.m.–4:30 p.m.

*Kansas City Region*—Iowa, Kansas, Missouri, Nebraska. New Federal Office Building, 601 East 12th Street—Room 436, Kansas City, Missouri 64106. Office Hours: 8 a.m.–4:45 p.m.

*Denver Region*—Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming. Federal Office Building, 1961 Stout St.—Room 1185, Denver, Colorado 80294. Office Hours: 8 a.m.–4:30 p.m.

*San Francisco Region*—American Samoa, Arizona, California, Guam, Hawaii, Nevada. Federal Office Building, 10 Van Ness Avenue, 20th Floor, San Francisco, California 94102. Office Hours: 8 a.m.–4:30 p.m.

*Seattle Region*—Alaska, Idaho, Oregon, Washington. 1321 Second Avenue, Room 615, Mail Stop 211, Seattle, Washington 98101. Office Hours 8 a.m.–4:30 p.m.

#### 3. Intermediary Addresses (Hospital Insurance)

Medicare Coordinator, Assoc. Hospital Serv. Maine (ME BC), 2 Gannett Drive South, Portland, ME 04106-6911.

Medicare Coordinator, Anthem New Hampshire, 300 Goffs Falls Road, Manchester, NH 03111-0001.

Medicare Coordinator, BC/BS Rhode Island (RI BC), 444 Westminster Street, Providence, RI 02903-3279.

Medicare Coordinator, Empire Medicare Services, 400 S. Salina Street, Syracuse, NY 13202.

Medicare Coordinator, Cooperativa, P.O. Box 363428, San Juan, PR 00936-3428.

Medicare Coordinator, Maryland B/C, P.O. Box 4368, 1946 Greenspring Ave., Timonium, MD 21093.

Medicare Coordinator, Highmark, P5103, 120 Fifth Avenue Place, Pittsburgh, PA 15222-3099.

Medicare Coordinator, United Government Services, 1515 N. Rivercenter Dr., Milwaukee, WI 53212.

Medicare Coordinator, Alabama B/C, 450 Riverchase Parkway East, Birmingham, AL 35298.

Medicare Coordinator, Florida B/C, 532 Riverside Ave., Jacksonville, FL 32202-4918.

Medicare Coordinator, Georgia B/C, P.O. Box 9048, 2357 Warm Springs Road, Columbus, GA 31908.

Medicare Coordinator, Mississippi B/C MS, P.O. Box 23035, 3545 Lakeland Drive, Jackson, MS 39225-3035.

Medicare Coordinator, North Carolina B/C, P.O. Box 2291, Durham, NC 27702-2291.

Medicare Coordinator, Palmetto GBA A/RHHI, 17 Technology Circle, Columbia, SC 29203-0001.

Medicare Coordinator, Tennessee B/C, 801 Pine Street, Chattanooga, TN 37402-2555.

Medicare Coordinator, Anthem Insurance Co. (ANTHM IN), P.O. Box 50451, 8115 Knue Road, Indianapolis, IN 46250-1936.

Medicare Coordinator, Arkansas B/C, 601 Gaines Street, Little Rock, AR 72203.

Medicare Coordinator, Group Health of Oklahoma, 1215 South Boulder, Tulsa, OK 74119-2827.

Medicare Coordinator, Trailblazer, P.O. Box 660156, Dallas, TX 75266-0156.

Medicare Coordinator, Cahaba GBA, Station 7, 636 Grand Avenue, Des Moines, IA 50309-2551.

Medicare Coordinator, Kansas B/C, P.O. Box 239, 1133 Topeka Ave., Topeka, KS 66629-0001.

Medicare Coordinator, Nebraska B/C, P.O. Box 3248, Main PO Station, Omaha, NE 68180-0001.

Medicare Coordinator, Mutual of Omaha, P.O. Box 1602, Omaha, NE 68101.

Medicare Coordinator, Montana B/C, P.O. Box 5017, Great Falls Div., Great Falls, MT 59403-5017.

Medicare Coordinator, Noridian, 4510 13th Avenue SW., Fargo, ND 58121-0001.

Medicare Coordinator, Utah B/C, P.O. Box 30270, 2455 Parleys Way, Salt Lake City, UT 84130-0270.

Medicare Coordinator, Wyoming B/C, 4000 House Avenue, Cheyenne, WY 82003.

Medicare Coordinator, Arizona B/C, P.O. Box 37700, Phoenix, AZ 85069.

Medicare Coordinator, UGS, P.O. Box 70000, Van Nuys, CA 91470-0000.

Medicare Coordinator, Regents BC, P.O. Box 8110 M/S D-4A, Portland, OR 97207-8110.

Medicare Coordinator, Premera BC, P.O. Box 2847, Seattle, WA 98111-2847.

#### 4. Medicare Carriers

Medicare Coordinator, NHIC, 75 Sargent William Terry Drive, Hingham, MA 02044.

Medicare Coordinator, B/S Rhode Island (RI BS), 444 Westminster Street, Providence, RI 02903-2790.

Medicare Coordinator, Trailblazer Health Enterprises, Meriden Park, 538 Preston Ave., Meriden, CT 06450.

Medicare Coordinator, Upstate Medicare Division, 11 Lewis Road, Binghamton, NY 13902.

Medicare Coordinator, Empire Medicare Services, 2651 Strang Blvd., Yorktown Heights, NY, 10598.

Medicare Coordinator, Empire Medicare Services, NJ, 300 East Park Drive, Harrisburg, PA 17106.

Medicare Coordinator, Triple S, #1441 F.D., Roosevelt Ave., Guaynabo, PR 00968.

Medicare Coordinator, Group Health Inc., 4th Floor, 88 West End Avenue, New York, NY 10023.

Medicare Coordinator, Highmark, P.O. Box 89065, 1800 Center Street, Camp Hill, PA 17089-9065.

Medicare Coordinator, Trailblazers Part B, 11150 McCormick Drive, Executive Plaza 3 Suite 200, Hunt Valley, MD 21031.

Medicare Coordinator, Trailblazer Health Enterprises, Virginia, P.O. Box 26463, Richmond, VA 23261-6463.

United Medicare Coordinator, Tricenturion, 1 Tower Square, Hartford, CT 06183.

Medicare Coordinator, Alabama B/S, 450 Riverchase Parkway East, Birmingham, AL 35298.

Medicare Coordinator, Cahaba GBA, 12052 Middleground Road, Suite A, Savannah, GA 31419.

Medicare Coordinator, Florida B/S, 532 Riverside Ave, Jacksonville, FL 32202-4918.

Medicare Coordinator, Administar Federal, 9901 Linnstation Road, Louisville, KY 40223.

Medicare Coordinator, Palmetto GBA, 17 Technology Circle, Columbia, SC 29203-0001.

Medicare Coordinator, CIGNA, 2 Vantage Way, Nashville, TN 37228.

Medicare Coordinator, Railroad Retirement Board, 2743 Perimeter Parkway, Building 250, Augusta, GA 30999.

Medicare Coordinator, Cahaba GBA, Jackson, Miss, P.O. Box 22545, Jackson, MS 39225-2545.

Medicare Coordinator, Administar Federal (IN), 8115 Knue Road, Indianapolis, IN 46250-1936.

Medicare Coordinator, Wisconsin Physicians Service, P.O. Box 8190, Madison, WI 53708-8190.

Medicare Coordinator, Nationwide Mutual Insurance Co., P.O. Box 16788, 1 Nationwide Plaza, Columbus, OH 43216-6788.

Medicare Coordinator, Arkansas B/S, 601 Gaines Street, Little Rock, AR 72203.

Medicare Coordinator, Arkansas—New Mexico, 601 Gaines Street, Little Rock, AR 72203.

Medicare Coordinator, Palmetto GBA—DMERC, 17 Technology Circle, Columbia, SC 29203-0001.

Medicare Coordinator, Trailblazer Health Enterprises, 901 South Central Expressway, Richardson, TX 75080.

Medicare Coordinator, Noridian, 636 Grand Avenue, Des Moines, IA 50309-2551.

Medicare Coordinator, Kansas B/S, P.O. Box 239, 1133 Topeka Ave., Topeka, KS 66629-0001.

Medicare Coordinator, Kansas B/S—NE, P.O. Box 239, 1133 Topeka Ave., Topeka, KS 66629-0239.

Medicare Coordinator, Montana B/S, P.O. Box 4309, Helena, MT 59601.

Medicare Coordinator, Nordinan, 4305 13th Avenue South, Fargo, ND 58103-3373.

Medicare Coordinator, Noridian Bcbnd (CO), 730 N. Simms #100, Golden, CO 80401-4730.

Medicare Coordinator, Noridian Bcbnd (WY), 4305 13th Avenue South, Fargo, ND 58103-3373.

Medicare Coordinator, Utah B/S, P.O. Box 30270, 2455 Parleys Way, Salt Lake City, UT 84130-0270.

Medicare Coordinator, Transamerica Occidental, P.O. Box 54905, Los Angeles, CA 90054-4905.

Medicare Coordinator, NHIC—California, 450 W. East Avenue, Chico, CA 95926.

Medicare Coordinator, Cigna, Suite 254, 3150 Lakeharbor, Boise, ID 83703.

Medicare Coordinator, Cigna, Suite 506, 2 Vantage Way, Nashville, TN 37228.

#### Payment Safeguard Contractors

Medicare Coordinator, Aspen Systems Corporation, 2277 Research Blvd., Rockville, MD 20850.

Medicare Coordinator, DynCorp Electronic Data Systems (EDS), 11710 Plaza America Drive, 5400 Legacy Drive, Reston, VA 20190-6017.

Medicare Coordinator, Lifecare Management Partners Mutual of Omaha Insurance Co., 6601 Little River Turnpike, Suite 300, Mutual of Omaha Plaza, Omaha, NE 68175.

Medicare Coordinator, Reliance Safeguard Solutions, Inc., P.O. Box 30207, 400 South

Salina Street, 2890 East Cottonwood Pkwy., Syracuse, NY 13202.

Medicare Coordinator, Science Applications International, Inc., 6565 Arlington Blvd. P.O. Box 100282, Falls Church, VA.

Medicare Coordinator, California Medical Review, Inc., Integriguard Division Federal Sector Civil Group One, Sansome Street, San Francisco, CA 94104-4448.

Medicare Coordinator, Computer Sciences Corporation, Suite 600, 3120 Timanus Lane, Baltimore, MD 21244.

Medicare Coordinator, Electronic Data Systems (EDS), 11710 Plaza America Drive, 5400 Legacy Drive, Plano, TX 75204.

Medicare Coordinator, TriCenturion, L.L.C., P.O. Box 100282, Columbia, SC 29202.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0328]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Additive Petitions

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by December 15, 2006.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.