

information, please contact Karen Migdail at (301) 427-1855.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact Mr. Donald L. Inniss, Director, Office of Equal Employment Opportunity Program, Program Support Center, on (301) 443-1144 no later than October 30, 2006. The agenda, roster, and minutes are available from Ms. Bonnie Campbell, Committee Management Officer, Agency for Healthcare Quality and Research, 540 Gaither Road, Rockville, Maryland 20850. Her phone number is (301) 427-1554.

#### SUPPLEMENTARY INFORMATION:

##### 1. Purpose

Section 921 of the Public Health Service Act (42 U.S.C. 299c) established the National Advisory Council for Healthcare Research and Quality. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director, Agency for Healthcare Research and Quality (AHRQ), on matters related to actions of the Agency to enhance the quality, improve the outcomes, reduce the costs of health care services, improve access to such services through scientific research, and to promote improvements in clinical practice and in the organization, financing, and delivery of health care services.

The Council is composed of members of the public appointed by the Secretary and Federal ex-officio members.

##### II Agenda

On Thursday, November 2, the Council meeting will begin at 4 p.m., with the call to order by the Council Chair and approval of previous Council minutes. The Director, AHRQ, will present her update on AHRQ's current research, programs, and initiatives. Following the update, the Council will discuss the topic *Visioning the Future*. The discussion of *Visioning the Future* will continue Friday morning, November 3. The official agenda will be available on AHRQ's Web site at <http://www.ahrq.gov> no later than November 1, 2006.

Dated: October 30, 2006.

**Carolyn M. Clancy,**

Director.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

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

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

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

**SUMMARY:** In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system titled, "Evaluation of Drug Usage Under the Staff Time and Resource Intensity Verification Study (STRIVE), System No. 09-70-0595." Section 1888(e)(G) of the Social Security Act (the Act) authorizes the Secretary of HHS to provide for payment adjustments to the skilled nursing facility (SNF) prospective payment system (PPS) through a resident classification system established by the Secretary that accounts for the relative resource utilization of different patient types. The case mix adjustment shall be based on resident assessment data and other data the Secretary considers appropriate. To accomplish this task, CMS is currently undertaking a national nursing home time study known as STRIVE, of which this data will be a part.

The purpose of this system is to collect and maintain during the STRIVE time study individually identifiable information on selected beneficiaries' medication utilization while in a nursing home, skilled nursing facility or swing bed hospital. Information retrieved from this system may be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor, grantee, or consultant. We have provided background information about the new system in the **SUPPLEMENTARY INFORMATION** section below. Although the Privacy Act requires only that CMS provide an opportunity for interested persons to comment on the proposed routine uses, CMS invites comments on all portions of this notice. See *Effective Date* section for comment period.

**DATES:** *Effective Date:* CMS filed a new SOR report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Homeland Security & Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of

Management and Budget (OMB) on October 27, 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 comment to the CMS Privacy Officer, Division of Privacy Compliance, Enterprise Architecture and Strategy Group, Office of Information Services, Mail-stop N2-04-27, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. Comments received will be available for review at this location by appointment during regular business hours, Monday through Friday from 9 a.m.-3 p.m., eastern time.

**FOR FURTHER INFORMATION CONTACT:** Julie Stankivic, Division of Institutional Post Acute Care, Chronic Care Policy Group, Center for Medicare Management, Mail Stop C5-06-27, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1849. She can be reached by telephone at 410-786-5725, or via e-mail at [Julie.Stankivic@cms.hhs.gov](mailto:Julie.Stankivic@cms.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Section 4008(k) of the Omnibus Reconciliation Act of 1990 (Public Law (Pub. L.) 101-508) required the Secretary to develop a proposal either to modify the then-current system under which SNFs received payment for extended care services under Part A of the Medicare program or to replace such a system with a system under which such payment would be made on the basis of a prospectively determined rate. In developing a proposal for the new system, the Secretary was required to "provide for adjustments to prospectively determined rates to account for changes in a facility's case mix, volume of cases, and the development of new technologies and standards for medical practice." Section 4432 of the Balanced Budget Act of 1997 (Pub. L. 105-33) mandated a PPS for all SNFs for cost reporting periods beginning on or after July 1, 1998.

Resident drug data may enable CMS to recalibrate the weights associated with the provision of non-therapy ancillary services to residents in SNFs and swing bed hospitals subject to the SNF PPS. In order to adjust the rates to account for changes in a facility's case mix, volume of cases and development of new technologies and standards of

medical practice, CMS must recalibrate the weights associated with the amount of time that nursing home staff spend caring for residents, as well as other elements of resident care. To do this, CMS has contracted with the Iowa Foundation for Medicare Care to conduct a study of staff time commonly referred to as STRIVE. This is the first national nursing home time study undertaken in the U.S. since 1997. As part of this process, CMS believes that collecting data on medication utilization in nursing homes is critical to analyzing the impact of the provision of non-therapy ancillary services to residents in SNFs and swing bed hospitals subject to the PPS.

## **I. Description of the Proposed System of Records**

### **A. Statutory and Regulatory Basis for SOR**

The statutory authority for this system is given under Section 1888(e)(G) of the Social Security Act.

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

This system will collect and maintain individually identifiable and other data collected by CMS and its contractors on Medicare participants and providers of service who are participating in STRIVE, in order to analyze relevant data to create adjustments based upon a resident classification system established by the Secretary that accounts for the relative resource utilization of different patient types. The collected information will include, but is not limited to: Facility name, Federal provider identification number, facility national provider identifier, beneficiary name, social security number, health insurance claim number, gender, date of birth, NDC Code, drug name, drug strength, dosage form (drops (gtts), gram (gm), *etc.*), quantity dispensed or returned, date drug dispensed or returned, dose and frequency, routine or PRN, compound code, and cost data if available.

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

A. The Privacy Act permits us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a "routine use." The Government will only release STRIVE 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 STRIVE.

CMS has the following policies and procedures concerning disclosures of information that will be maintained in the system. Disclosure of information from the system will be approved only to the extent necessary to accomplish the purpose of the disclosure and only after CMS:

1. Determines that the use or disclosure is consistent with the reason that the data is being collected; *e.g.*, to collect and maintain individually identifiable information on selected beneficiaries' medication utilization while in a nursing home, skilled nursing facility, or swing bed hospital.
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. The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a "routine use." The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. We are proposing to establish the following routine use disclosures of information maintained in the system:

5. To agency contractors, consultants or grantees, who have been engaged by

the agency to assist in the performance of a service related to this collection 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 believes that the disclosure of medication utilization data may enable CMS to better account for the relative resource utilization of different patient types for the purpose of updating SNF PPS.

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.

### **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 an individual 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 Proposed System of Records on Individual Rights

CMS proposes to establish this system in accordance with the principles and requirements of the Privacy Act and will collect, use, and disseminate information only as prescribed therein. Data in this system will be subject to the authorized releases in accordance with the routine uses identified in this system of records.

CMS will take precautionary measures 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 this 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: October 24, 2006.

**John R. Dyer,**

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

## SYSTEM NO. 09-70-0595

### SYSTEM NAME:

"Evaluation of Drug Usage Under the Staff Time and Resource Intensity Verification Study (STRIVE)," HHS/CMS/CMM.

### SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive Data.

### SYSTEM LOCATION:

Centers for Medicare & Medicaid Services (CMS) Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244-1850 and at various co-locations of CMS agents.

### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system will collect and maintain individually identifiable and other data collected by CMS and its contractors on Medicare participants and providers of service who are participating in STRIVE, in order to analyze relevant data to create adjustments based upon a resident classification system established by the Secretary that accounts for the relative resource utilization of different patient types.

### CATEGORIES OF RECORDS IN THE SYSTEM:

The collected information will include, but is not limited to: Facility name, Federal provider identification number, facility national provider identifier, beneficiary name, social security number, health insurance claim number, gender, date of birth, NDC Code, drug name, drug strength, dosage form (drops (gtts), gram (gm), etc.), quantity dispensed or returned, date drug dispensed or returned, dose and frequency, routine or PRN, compound code, and cost data if available.

### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The statutory authority for this system is given under Section 1888(e)(G) of the Social Security Act.

### PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to collect and maintain during the STRIVE time study individually identifiable information on selected beneficiaries' medication utilization while in a nursing home, skilled nursing facility or swing bed hospital. Information retrieved from this system may be disclosed to: (1) support regulatory, reimbursement, and policy functions

performed within the agency or by a contractor, grantee, or consultant.

### 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 proposing to establish the following routine use disclosures of information maintained in the system:

1. To agency contractors, consultants or grantees, who have been engaged by the agency to assist in the performance of a service related to this collection and who need to have access to the records in order to perform the activity.

### 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 an individual 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 will be stored electronically and on hard copy.

#### RETRIEVABILITY:

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

#### 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 will retain information for a total period not to exceed 5 years after the final report is released. 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 Institutional Post Acute Care, Chronic Care Policy Group, Center for Medicare Management, Mail Stop C5-06-27, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1849.

#### NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, employee identification number, tax identification number, national provider number, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), HICN, and/or 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 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).

#### RECORDS SOURCE CATEGORIES:

Data will be collected from OmniCare, pharmacies, nursing homes, and Long Term Care Minimum Data Set, System No. 09-70-1517.

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

None.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

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

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

**ACTION:** Notice of a new system of records.

**SUMMARY:** In accordance with the requirements of the Privacy Act of 1974, CMS is proposing to establish a new system of records (SOR) titled "One Program Integrity Data Repository (ODR)," System No. 09-70-0568. Section 1893 of the Social Security Act (the Act) established the "Medicare Integrity Program" that requires CMS to contract with eligible entities to "review activities of providers of services or other individuals and entities furnishing items and services for which payment may be made under this title" by utilizing equipment and software technologies. Likewise, section 1893 of the Act requires CMS to establish the Medicare Medicaid Data Match Program

(Medi-Medi) in which data from both the Medicare and Medicaid programs are analyzed together to better detect fraud, waste, and abuse existent in these programs. In order to comply with these requirements and enhance our ability to detect fraud, waste, and abuse in Medicare and Medicaid, CMS is proposing to construct the ODR.

CMS maintains numerous systems housing Medicare beneficiary Parts A, B, C, and D entitlement, enrollment, and utilization information. Additionally, CMS maintains data on physicians, providers, employer plans, Medicaid recipients and Medicare secondary payers. There are a large number of data sources, extraction tools, and access mechanisms. Users of the data often experience inconsistent, untimely, or duplicated information. The ODR will be an enterprise resource that will provide an integrated view of the data to all of CMS and its partners providing a single authoritative source of information and providing quality and timely data.

The ODR will provide an organized structure for reaching the data through a consistent application of access policies, processes and procedures, common services, governance, and framework. The ODR will integrate and load data from various CMS systems consisting of Medicare Parts A, B, C, and D, Medicaid and Retiree Drug Subsidy entitlement, enrollment and utilization data. The ODR will also contain demographic information on Medicaid beneficiaries, Medicare providers and physicians, and employer plans that are receiving a subsidy from CMS for providing creditable drug coverage to their retirees. It is through the integration of this Medicare data with other data; e.g., historic data, Part A and Part B data, and Medicaid data sets provided by state agencies that CMS fraud, waste, and abuse, quality improvement, research, and other analytic activities are maximized.

The data collected and maintained in this system are retrieved from the following databases: Medicare Drug Data Processing System, System No. 09-70-0553 (70 FR 58436 (October 6, 2005)); Medicare Beneficiary Database, System No. 09-70-0536 (66 FR 63392 (December 6, 2001)); Medicare Advantage Prescription Drug System, System No. 09-70-4001 (70 FR 60530 (October 18, 2005)); Medicaid Statistical Information System, System No. 09-70-6001 (67 FR 48906 (July 26, 2002)); Retiree Drug Subsidy Program, System No. 09-70-0550 (70 FR 41035 (July 15, 2005)); Common Working File, System No. 09-70-0526 (67 FR 3210 (January 23, 2002)); National Claims History,