

scientific misconduct by fabricating study research records for 15 subjects, including the patient interview data, the forms tracking data, and the medical record extraction data in a study on the management of cerebral aneurysms. The research was supported by National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), career development award K23 NS02159.

In a final decision dated November 23, 2005, the HHS Debarment Official, on behalf of the Secretary of HHS, issued the final debarment notice based on the PHS findings of scientific misconduct finding. The following actions have been implemented for a period of three (3) years, beginning on November 23, 2005:

(1) Ms. Grol has been debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility for or involvement in nonprocurement programs of the United States Government as defined in the debarment regulations at 45 CFR part 76; and

(2) Ms. Grol is prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Acting Director, Division of Research Investigations, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (240) 453-8800.

Chris B. Pascal,

Acting Director, Office of Research Integrity.

[FR Doc. E5-7470 Filed 12-16-05; 8:45 am]

BILLING CODE 4160-17-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: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

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, titled "Non-Medicare Beneficiary Workers' Compensation (WC) Set-aside File (WCSAF)," System No. 09-70-0537, last published at 67 FR 36892 (May 28, 2002). We propose to

expand the scope of this system to include non-Medicare beneficiaries whose applications for a WC Arrangement have not been approved (denied) as submitted. The disclosure provisions contained in published routine use number 2 and 3 are deemed to be duplicative of each other and as such require corrective action. This modified routine use will now be number 2 and will authorize disclosure to "another Federal and/or state agency, agency of a state government, an agency established by state law, or its fiscal agent."

We are modifying the language in the remaining routine uses 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 and to update language in the administrative sections to correspond with language used in other CMS SORs.

The primary purpose of the non-Medicare beneficiary WCSAF is to maintain a file of individuals who were injured while employed; are not currently Medicare beneficiaries; whose WC Settlement included a WC Medicare Set-aside Arrangement that is intended to pay for future medical expenses in place of future Medicare benefits; and was approved or not approved (denied) by CMS as submitted. The information retrieved from this system will be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant; (2) another Federal and/or state agency, agency of a state government, an agency established by state law, or its fiscal agent to contribute to the accuracy of CMS' proper payment of Medicare benefits, enable such agency to administer a Federal health benefits program, or 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; (3) an individual or organization for research, evaluation or epidemiological projects related to the prevention of disease or disability, the restoration or maintenance of health, or for understanding and improving payment projects; (4) support constituent requests made to a Congressional representative; (5) support litigation involving the agency; and (6) combat fraud and abuse in health benefits programs funded in whole or in part by Federal funds. We have provided

background information about the modified system in the **SUPPLEMENTARY INFORMATION** section, below. Although the Privacy Act requires only that the "routine use" portion of the system be published for comment, CMS invites comments on all portions of this notice. See **EFFECTIVE DATE** section for comment period.

EFFECTIVE DATE: 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 Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on December 13, 2005. We will not disclose any information under a routine use until 30 days after publication. We may defer implementation of this system or one or more of the routine use statements listed below if we receive comments that persuade us to defer implementation.

ADDRESSES: The public should address comment to the CMS Privacy Officer, 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 daylight time.

FOR FURTHER INFORMATION CONTACT: Donna Kettish, Division of Medicare Secondary Payer Policy Operations, Financial Services Group, Office of Financial Management, CMS, Mail stop C3-14-16, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. She can be reached by telephone at (410) 786-5462, or via e-mail at Donna.Kettish@cms.hhs.gov.

SUPPLEMENTARY INFORMATION: Notice for this system, "Non Medicare Beneficiary Workers' Compensation Set-aside File," System No. 09-70-0537, was most recently published in full at 67 **Federal Register** 36892 (May 28, 2002). CMS is responsible for safeguarding the fiscal integrity of the Medicare Program. The Health Insurance Portability and Accountability Act of 1996 established the "Medicare Integrity Program," enabling CMS to competitively award contracts with entities to promote the integrity of the Medicare Program. The Coordination of Benefit Contractor (COBC) is one of those specialized contractors hired to increase efficiency and effectiveness by ensuring that the appropriate payer makes benefit payments by coordinating Medicare and other benefit payments.

The Electronic Correspondence Referral System (ECRS) is currently used to transfer data between CMS's

Medicare contractors and the COBC to establish Medicare Secondary Payer (MSP) periods of coverage on CMS's Common Working File (CWF) and to update CWF with the results of a CMS review of a WC Medicare Set-aside Arrangement Proposal. The CWF is a CMS system, containing Medicare beneficiary eligibility information that is used for verification and validation purposes to ensure Medicare claims are paid properly and by the appropriate payer. The WC Case Control System is used to control the receipt of WC Medicare Set-aside Arrangement Proposals and tracking of each proposal through the review process to establishment of the MSP period of coverage via ECRS. ECRS is also used to transmit WC Medicare Set-aside Arrangement data from CMS Regional Offices (RO) to the COBC for Medicare beneficiaries and non-Medicare beneficiaries who have an approved or denied WC Medicare Set-aside Arrangement to cover future medical costs resulting from an injury incurred while employed. If the injury results in disability payments from the Social Security Administration, there is a reasonable expectation that the injured individual will also be eligible for Medicare benefits some time after the WC settlement is made.

The ROs or a CMS contractor will transmit the WC Medicare Set-aside Arrangement information via ECRS, or the WC Case Control System, for non-Medicare beneficiaries once they approve or deny the arrangement. The COBC will maintain ECRS and WC Case Control System transmitted data in the WCSAF for future matching purposes. The COBC will "match" non-beneficiary WCSAF data against the file it receives each month of new Medicare eligibles to identify any non-beneficiaries with impending Medicare entitlement. Once a match occurs, the existence of a WC Medicare Set-aside Arrangement will be reflected on the new beneficiary's CWF record and a Lead Medicare Contractor will be assigned for monitoring expenditures from the WC Medicare Set-aside Arrangement.

CMS is drawn into a civil action resulting from a WC claim in a consulting position to ensure that a legal settlement involving an injured worker considers Medicare's interest with respect to future claims. CMS RO approval of a WC Medicare Set-aside Arrangement helps direct the treatment of future disorders or health claims by the injured worker, ensuring he/she is adequately covered for long-term care resulting from their WC injury, first by the WC Medicare Set-aside Arrangement and then by Medicare if necessary.

I. Description of the Modified or Altered System of Records

A. Statutory and Regulatory Basis for SOR

Section 1862 (b)(2) of the Social Security Act (the Act) requires that Medicare payment may not be made for any item or service to the extent that payment has been made under a WC law or plan. This section of the Act and Title 42 Code of Federal Regulations (CFR) 411.46 require CMS to exclude payments once the injured individual becomes a Medicare beneficiary when payment should be made from WC funds that are always primary to Medicare payment.

B. Collection and Maintenance of Data in the System

The WCSAF includes standard data for identification including the name, address, date of birth, Social Security Number, date of the WC injury/incident, injury diagnosis code(s), effective date and amount of the WC Medicare Set-aside Arrangement. In addition, data will be included to enable CMS to manage the WC Medicare Set-aside Arrangement information when it becomes part of the beneficiary's record on the CWF. These data include the WC carrier, the administrator of the Set-aside Arrangement, and the attorney that prepared the arrangement.

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 WCSAF 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 WCSAF. 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 are being collected; *e.g.*, ensuring that benefit payments are made by the appropriate payer by coordinating Medicare and other benefit payments.

2. Determines that:

a. The purpose for which the disclosure is to be made can only be accomplished if the record is provided in individually identifiable form;

b. The purpose for which the disclosure is to be made is of sufficient importance to warrant the effect and/or risk on the privacy of the individual that additional exposure of the record might bring; and

c. There is a strong probability that the proposed use of the data would in fact accomplish the stated purpose(s).

3. Requires the information recipient to:

a. Establish administrative, technical, and physical safeguards to prevent unauthorized use of disclosure of the record;

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

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

4. Determines that the data are valid and reliable.

III. Proposed Routine Use Disclosures of Data in the System

A. 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, or consultants that have been contracted by the agency to assist in the performance of a service related to this system and that need to have access to the records in order to perform the activity.

CMS contemplates 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 agency business functions 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 whatever information is necessary for the contractor to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor from using or disclosing the information for any purpose other than that described in the contract and requires the contractor to return or destroy all information at the completion of the contract.

2. To another Federal and/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'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.

Other Federal or state agencies in their administration of a Federal health program may require WCSAF information in order to support evaluations and monitoring of Medicare claims information of beneficiaries, including proper payment for services provided. Releases of information would be allowed if the proposed use(s) for the information proved compatible with the purpose for which CMS collects the information.

WCSAF data may be released to the State only on those injured individuals who are not currently Medicare beneficiaries but who have a WC Medicare Set-aside Arrangement that is intended to pay for future medical expenses in place of future Medicare benefits that has been approved, or denied, by CMS.

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

The WCSAF data will provide the research and evaluations a broader, longitudinal, national perspective of the status of injured individuals that are not currently Medicare beneficiaries but have a WC Medicare Set-aside Arrangement that is intended to pay for future medical expenses in place of future Medicare benefits that has been approved, or denied, by CMS.

4. To a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional Office made at the written request of the constituent about whom the record is maintained.

Individuals sometimes request the help of a Member of Congress in resolving some issue relating to a matter before CMS. The Member of Congress then writes CMS, and CMS must be able to give sufficient information to be responsive to the inquiry.

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

a. The agency or any component thereof, or

b. Any employee of the agency in his or her official capacity; or

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

d. The United States Government is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation.

Whenever CMS is involved in litigation, or occasionally when another party is involved in litigation and CMS's policies or operations could be affected by the outcome of the litigation, CMS would be able to disclose information to the DOJ, court or adjudicatory body involved. A determination would be made in each instance that, under the circumstances involved, the purposes served by the use of the information in the particular litigation is compatible with a purpose for which CMS collects the information.

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

CMS contemplates 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 functions relating to the purpose of combating fraud and abuse.

CMS occasionally contracts out certain of its functions when this would contribute to effective and efficient operations. CMS must be able to give a contractor whatever information is necessary for the contractor to fulfill its duties. In these situations, safeguards (like ensuring that 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 those stated in II.B, above), are provided in the contract prohibiting the contractor from using or disclosing the information for any purpose other than that described in the contract and to return or destroy all information.

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

Other State agencies in their administration of a Federal health program may require WCSAF information for the purpose of preventing, deterring, discovering, detecting, investigating, examining, prosecuting, suing with respect to, defending against, correcting, remedying, or otherwise combating such fraud and abuse in such programs. Releases of information would be allowed if the proposed use(s) for the information proved compatible with the purpose for which CMS collects the information.

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, 65 FR 82462 (12-28-00), Subparts A and E. 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."

In addition, our policy will be to prohibit release even of data not directly identifiable, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals who are familiar with the enrollees could, because of the small size, use this information to deduce the identity of the beneficiary).

IV. Safeguards

CMS has safeguards in place for authorized users and monitors such

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

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations 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 or Altered 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: December 12, 2005.

Charlene Frizzera,

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

SYSTEM NO. 09-70-0537

SYSTEM NAME:

“Non-Medicare Beneficiary Workers’ Compensation (WC) Set-aside File, (WCSAF).”

SECURITY CLASSIFICATION:

Level 3 Privacy Act Sensitive.

SYSTEM LOCATION:

Group Health Incorporated, 25 Broadway, New York, New York 10004.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system of records will contain data on non-Medicare beneficiaries that receive an approval or a denial by the Centers for Medicare & Medicaid Services (CMS) of the adequacy of a WC Medicare Set-aside Arrangement, as part of a WC settlement that is intended to pay for future medical expenses in place of future Medicare benefits.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system of records will contain the individual-level identifying data including, but not limited to, name, address, date of birth, social security number (SSN), date of the WC injury/incident, injury diagnosis code(s), effective date and amount of the WC Medicare Set-aside Arrangement. In addition, data will be included to enable CMS to manage the WC Medicare Set-aside Arrangement information when it becomes part of a beneficiary's record on the Common Working File. These data include the WC carrier, the administrator of the WC Medicare Set-aside Arrangement, and the attorney that prepared the arrangement.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 1862(b)(2) of the Social Security Act (the Act) requires that Medicare payment may not be made for any item or service to the extent that payment has been made under a WC law or plan. This section of the Act and Title 42 Code of Federal Regulation (CFR) 411.46 require CMS to exclude payments once the injured individual becomes a Medicare beneficiary when payment should be made from WC funds that are always primary to Medicare payment.

PURPOSE(S) OF THE SYSTEM:

The primary purpose of the non-Medicare beneficiary WCSAF is to

maintain a file of individuals who were injured while employed; are not currently Medicare beneficiaries; whose WC Settlement included a WC Medicare Set-aside Arrangement that is intended to pay for future medical expenses in place of future Medicare benefits; and was approved or not approved (denied) by CMS as submitted. The information retrieved from this system will be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant; (2) another Federal and/or state agency, agency of a state government, an agency established by state law, or its fiscal agent to contribute to the accuracy of CMS' proper payment of Medicare benefits, enable such agency to administer a Federal health benefits program, or 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; (3) an individual or organization for research, evaluation or epidemiological projects related to the prevention of disease or disability, the restoration or maintenance of health, or for understanding and improving payment projects; (4) support constituent requests made to a Congressional representative; (5) support litigation involving the agency; and (6) combat fraud and abuse in health benefits programs funded in whole or in part by Federal funds.

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, or consultants that have been contracted by the agency to assist in the performance of a service related to this system and that need to have access to the records in order to perform the activity.

2. To another Federal and/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'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.

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

4. To a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional Office made at the written request of the constituent about whom the record is maintained.

5. 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.

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

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

B. Additional 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, 65 FR 82462 (12-28-00)), Subparts A and E. 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."

In addition, our policy will be to prohibit release even of data not directly identifiable, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals who are familiar with the enrollees could, because of the small size, use this information to deduce the identity of the beneficiary).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

All records are stored on magnetic media.

RETRIEVABILITY:

The records are retrieved alphabetically by the name and/or SSN of the subject of the records.

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 identifiable WCSAF data for a period of 6 years and 3 months unless the injured individual becomes a Medicare beneficiary prior to that period of time. When either of these criteria is met, the information stored on the injured individual will be deleted from the WCSAF. 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 Medicare Secondary Payer Policy Operations, Financial Services Group, Office of Financial Management, CMS, Mail Stop C3-14-16, 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, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), address, date of birth, date of WC injury/incident, diagnosis, effective date and amount of the WC Medicare Set-aside Arrangement. (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).

RECORD SOURCE CATEGORIES:

The Electronic Correspondence Referral System, Workers Comp Case

Control System, Medicare contractors and the Coordination of Benefit Contractor, Common Working File, CMS Regional Offices, an agency of a State government, Medicare beneficiaries and non-Medicare beneficiaries that have an approved or denied WC Medicare Set-aside arrangement to cover future medical costs resulting from an injury incurred while employed and the Social Security Administration.

SYSTEMS EXEMPTED FROM CERTAIN PROVISION OF THE ACT:

None.

[FR Doc. E5-7486 Filed 12-16-05; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Sanction Policies Task Order.
OMB No.: New Collection.

Description: This study is designed to determine how local welfare offices implement sanction policies in the Temporary Assistance for Needy Families program. This study will

survey local welfare staff to gather in-depth qualitative information on how workers interpret the policies and apply them in specific instances. The results of this study should give the Administration for Children and Families (ACF) a better understanding of possible outcomes of various sanction policies, which in turn will help ACF design a research program to study the effect of sanctions.

Respondents: A maximum of 324 welfare staff in local welfare offices.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|-----------------------|------------------------------------|-----------------------------------|--------------------|
| In-person Survey and Telephone Interviews | 324 | 1 | .85 | 275 |

Estimated Total Annual Burden Hours: 275.

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: December 12, 2005.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 05-24174 Filed 12-16-05; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1980N-0208]

Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Anthrax Vaccine Adsorbed; Final Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) proposed, among other things, to classify Anthrax Vaccine Adsorbed (AVA) on the basis of findings and recommendations of the Panel on Review of Bacterial Vaccines and Toxoids (the Panel) on December 13, 1985. The Panel reviewed the safety, efficacy, and labeling of bacterial vaccines and toxoids with standards of potency, bacterial antitoxins, and immune globulins. After the initial final rule and final order was vacated by the United States District Court for the District of Columbia on October 27, 2004, FDA published a new proposed rule and proposed order on December 29, 2004. The purpose of this final order is to categorize AVA according to the evidence of its safety and effectiveness,

thereby determining if it may remain licensed and on the market; issue a final response to recommendations made in the Panel's report, and; respond to comments on the previously published proposed order. The final rule and final order concerning bacterial vaccines and toxoids other than AVA is published elsewhere in this issue of the **Federal Register**.

DATES: The final order on categorization of AVA is effective December 19, 2005.

FOR FURTHER INFORMATION CONTACT: Kathleen Swisher, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Introduction
- II. Background
 - A. General Description of the "Efficacy Review" for Biological Products Licensed Before July 1972
 - B. The December 1985 Proposal
 - C. Additional Proceedings Following the December 1985 Proposal
- III. Categorization of Anthrax Vaccine Adsorbed—Final Order
 - A. Efficacy of Anthrax Vaccine Adsorbed
 - B. Safety of Anthrax Vaccine Adsorbed
 - C. The Panel's General Statement: Anthrax Vaccine, Adsorbed, Description of Product
 - D. The Panel's Specific Product