DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of a Modified or Altered System of Records

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

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

SUMMARY: In accordance with the Privacy Act of 1974, we are proposing to modify or alter an existing SOR, ''Inpatient Rehabilitation Facilities (IRF) Patient Assessment Instrument (IRF–PAI),'' System No. 09–70–1518, last published at 66 **Federal Register** 56681 (November 9, 2001). Information maintained in this system will continue to contain clinical assessment information for all Medicare Part A fee-for-service patients receiving the services of a Medicare approved IRF. This information will be useful in developing core measures that provide meaningful information on patient characteristics and outcomes across post-acute care settings and will be used by CMS to fulfill its responsibility for validating surveys conducted by accrediting agencies. We propose to assign a new CMS identification number to this system to simplify the obsolete and confusing numbering system originally designed to identify the Bureau, Office, or Center that maintained information in the Health Care Financing Administration systems of records. The new assigned identifying number for this system should read: System No. 09–70–0521.

We propose to modify existing routine use number 1 that permits disclosure to agency contractors and consultants to include disclosure to CMS grantees who perform a task for the agency. CMS grantees, charged 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 remain as routine use number 1. We will modify existing routine use number 2 that permits disclosure to Peer Review Organizations (PRO). Organizations previously referred to as PROs will be renamed to read: Quality Improvement Organizations (QIO). Information will be disclosed to QIOs relating to assessing and improving IRF quality of care. The modified routine use will be renumbered as routine use number 4.

We will delete routine use number 5 authorizing disclosure to support constituent requests made to a congressional representative. If an authorization for the disclosure has been obtained from the data subject, then no routine use is needed. The Privacy Act allows for disclosures with the ''prior written consent'' of the data subject. We will broaden the scope of published routine uses number 7 and 8, authorizing disclosures to combat fraud and abuse in the Medicare and Medicaid programs to include combating ''waste'' which refers increasingly more to specific beneficiary or recipient practices that result in unnecessary cost to federally-funded health benefit programs.

CMS proposes to broaden the scope of the disclosure requirement for routine use number 5, authorizing disclosure to national accrediting organizations that have been approved by CMS for deeming authority for Medicare requirements for home health services. Information will be released to these organizations for only those facilities that they accredit and that participate in the Medicare program and if they meet the following requirements: (1) Provide identifying information for IRFs that have an accreditation status with the requesting accrediting organization that has been granted deeming authority by CMS, (2) submission of a finder file identifying beneficiaries/patients receiving IRF services, (3) safeguard the confidentiality of the data and prevent unauthorized access, and (4) upon completion of a signed data exchange agreement or a CMS data use agreement.

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 this modified system is to support the IRF prospective payment system (PPS) for payment of the IRF Medicare Part A fee-for-services furnished by the IRF to Medicare beneficiaries. Information maintained in this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the Agency or by a contractor, consultant, or a CMS grantee; (2) assist another Federal and/or state agency, agency of a state government, an agency established by state law, or its fiscal agent, for evaluating and monitoring the quality of IRF health care and contribute to the accuracy of health insurance operations; (3) support 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) support the functions of Quality Improvement Organizations; (5) assist other insurers; (6) support the functions of national accrediting organizations; (7) support litigation involving the Agency; and (8) combat fraud, waste, and abuse in certain health care 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 modified or altered 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 14, 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: Georgia Johnson, Division of Continuing Care Providers, Survey and Certification Group, Center for Medicaid and State Operations, CMS, Mail Stop S2–12–25, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. She can also be reached by telephone at 410–786–6859,

or via e-mail at *Georgia.Johnson@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Description of the Modified or Altered System of Records

A. Statutory and Regulatory Basis for SOR

Authority for maintenance of the system is given under section 1886 (j) (2) (D) of the Social Security Act authorizing the secretary to collect the data necessary to establish and administer the payment system.

B. Collection and Maintenance of Data in the System

The IRF–PAI will be completed on all Medicare Part A fee-for-service patients who receive services under Part A from an IRF, it may also be completed on Medicare Advantage enrollees. Records in this system will include, but are not limited to, name, address, date of birth, gender, ethnicity, social security number, health insurance claim number, Medicaid number, patient identification number, patient history, diagnosis, and functional prognosis.

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

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

1. Determines that the use or disclosure is consistent with the reason that the data is being collected, e.g, to support the IRF prospective payment system (PPS) for payment of the IRF Medicare Part A fee-for-services furnished by the IRF to Medicare beneficiaries.

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 indivdual'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 support 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 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 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' 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. Improve the state survey process for investigation of complaints related to health and safety or quality of care and to implement a more outcome oriented survey and certification program.

Other Federal or state agencies in their administration of a Federal health program may require IRF–PAI information in order to support evaluations and monitoring of Medicare claims information of beneficiaries, including proper reimbursement for services provided.

3. To an individual or organization for research on the utilization of inpatient rehabilitation services as well as 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 IRF–PAI data will provide for research or in support of evaluation projects, a broader, national perspective of the status of Medicare beneficiaries. CMS anticipates that many researchers will have legitimate requests to use these data in projects that could ultimately improve the care provided to Medicare beneficiaries and the policy that governs the care.

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.

The QIO may use this data to support quality improvement activities and other QIO responsibilities as detailed in Title XI §§ 1151–1164.

The QIO will work to implement quality improvement programs, provide consultation to CMS, its contractors, and to state agencies. The QIO will

assist state agencies in related monitoring and enforcement efforts, assist CMS and intermediaries in program integrity assessment, and prepare summary information for release to CMS.

5. To assist insurance companies, third party administrators (TPA), employers, self-insurers, managed care organizations, other supplemental insurers, non-coordinating insurers, multiple employer trusts, group health plans (i.e., health maintenance organization (HMO) or a competitive medical plan (CMP)) with a Medicare contract, or a Medicare-approved health care payment plan (HCPP), directly or through a contractor, and other groups providing protection for their enrollees. Information to be disclosed shall be limited to Medicare entitlement data. In order to receive the information, they must agree to:

a. Certify that the individual about whom the information is being provided is one of its insured or employees, or is insured and/or employed by another entity for whom they serve as a third party administrator;

b. Utilize the information solely for the purpose of processing the individual's insurance claims; and

c. Safeguard the confidentiality of the data and prevent unauthorized access.

Other insurers, CMP, HMO and HCPP may require IRF–PAI information in order to support evaluations and monitoring of Medicare claims information of beneficiaries, including proper payment for services provided.

6. To assist national accrediting organization(s) whose accredited facilities are presumed to meet certain Medicare requirements for inpatient hospital rehabilitation services (e.g., the Joint Commission for the Accreditation of Healthcare Organizations, the American Osteopathic Association, or the Commission on Accreditation of Rehabilitation Facilities). Information will be released to these organizations for only those facilities that they accredit and that participate in the Medicare program and if they meet the following requirements:

a. Provide identifying information for IRFs that have an accreditation status with the requesting deemed organization;

b. Submission of a finder file identifying beneficiaries/patients receiving IRF services;

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

d. Upon completion of a signed data exchange agreement or a CMS data use agreement.

At this time, CMS anticipates providing accrediting organizations with IRF–PAI information to enable them to target potential identified problems during the organization's accreditation review process of the facility.

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

a. The agency or any component thereof, or

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

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

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

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

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

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

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

9. 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 IRF–PAI information for the purpose of combating fraud, waste, and abuse in such federally-funded programs.

B. Additional Provisions Affecting Routine Use Disclosures

To the extent this system contains Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, subparts A and E) 65 FR 82462 (12–28–00). Disclosures of such PHI that are otherwise authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.'' (See 45 CFR 164–512(a)(1)).

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

IV. Safeguards

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

information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent NIST publications; the DHHS 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 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 8, 2006.

John R. Dyer,

Chief Operating Officer, Centers for Medicare & Medicaid Services.

SYSTEM NO. 09–70–0521

SYSTEM NAME:

''Inpatient Rehabilitation Facilities Patient Assessment Instrument (IRF–PAI),'' HHS/CMS/CMSO.

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive Data.

SYSTEM LOCATION:

The Centers for Medicare & Medicaid Services (CMS) Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244–1850 and at various contractor sites and at CMS Regional Offices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The IRF–PAI will be completed on all Medicare Part A fee-for-service patients who receive services under Part A from an IRF, it may also be completed on Medicare Advantage enrollees.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records in this system will include, but are not limited to, name, address, date of birth, gender, ethnicity, social security number (SSN), health insurance claim number (HICN), Medicaid number, patient identification number, patient history, diagnosis, and functional prognosis.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for maintenance of the system is given under section 1886(j)(2)(D) of the Social Security Act authorizing the secretary to collect the data necessary to establish and administer the payment system.

PURPOSE(S) OF THE SYSTEM:

The primary purpose of this modified system is to support the IRF prospective payment system (PPS) for payment of the IRF Medicare Part A fee-for-services furnished by the IRF to Medicare beneficiaries. Information maintained in this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the Agency or by a contractor, consultant, or a CMS grantee; (2) assist another Federal and/or state agency, agency of a state government, an agency established by state law, or its fiscal agent, for evaluating and monitoring the quality of IRF health care and contribute to the accuracy of health insurance operations; (3) support 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) support the functions of Quality Improvement Organizations (QIO); (5) assist other insurers; (6) support the functions of national accrediting organizations; (7) support litigation involving the Agency; (8) combat fraud, waste, and abuse in certain health care programs.

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

A. The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a ''routine use.'' The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. We are proposing to establish 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 the performance of a service related to this collection and who need to have access to the records in order to perform the activity.

2. To assist 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' 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. Improve the state survey process for investigation of complaints related to health and safety or quality of care and to implement a more outcome oriented survey and certification program.

3. To an individual or organization for research on the utilization of inpatient rehabilitation services as well as 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 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 assist insurance companies, third party administrators (TPA), employers, self-insurers, managed care organizations, other supplemental insurers, non-coordinating insurers, multiple employer trusts, group health plans (i.e., health maintenance organization (HMO) or a competitive medical plan (CMP)) with a Medicare

contract, or a Medicare-approved health care payment plan (HCPP), directly or through a contractor, and other groups providing protection for their enrollees. Information to be disclosed shall be limited to Medicare entitlement data. In order to receive the information, they must agree to:

a. Certify that the individual about whom the information is being provided is one of its insured or employees, or is insured and/or employed by another entity for whom they serve as a third party administrator;

b. Utilize the information solely for the purpose of processing the individual's insurance claims; and

c. Safeguard the confidentiality of the data and prevent unauthorized access.

6. To assist national accrediting organization(s) whose accredited facilities are presumed to meet certain Medicare requirements for inpatient hospital rehabilitation services (e.g., the Joint Commission for the Accreditation of Healthcare Organizations, the American Osteopathic Association, or the Commission on Accreditation of Rehabilitation Facilities). Information will be released to these organizations for only those facilities that they accredit and that participate in the Medicare program and if they meet the following requirements:

a. Provide identifying information for IRFs that have an accreditation status with the requesting deemed organization;

b. Submission of a finder file identifying beneficiaries/patients receiving IRF services;

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

d. Upon completion of a signed data exchange agreement or a CMS data use agreement.

7. To support 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.

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

9. 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 Provisions Affecting Routine Use Disclosures.* To the extent this system contains Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, subparts A and E) 65 FR 82462 (12–28–00), disclosures of such PHI that are otherwise authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.'' (See 45 CFR 164–512(a)(1)).

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

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

STORAGE:

All records are stored on magnetic media.

RETRIEVABILITY:

The Medicare records are retrieved by the HICN and SSN.

SAFEGUARDS:

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

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

RETENTION AND DISPOSAL:

CMS will retain identifiable IRF–PAI data for a total period of 15 years. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from DOJ.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Survey and Certification Group, Center for Medicaid and State Operations, CMS, Mail Stop C3–20–01, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, HICN, address, date of birth, and gender, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), and SSN. Furnishing the SSN is voluntary, but it

may make searching for a record easier and prevent delay.

RECORD ACCESS PROCEDURE:

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

CONTESTING RECORDS PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the records and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These Procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORDS SOURCE CATEGORIES:

Information for this system is collected from the Inpatient Rehabilitation Facilities—Patient Assessment Instrument.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. E6–19506 Filed 11–17–06; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Delegation of Authority

Notice is hereby given that I have delegated to the Administrator, Health Resources and Services Administration (HRSA), with authority to re-delegate, the authority vested in the Secretary of Health and Human Services under Title III, Part B, Section 319F–4, titled ''Covered Countermeasure Process,'' of the Public Health Service Act, as amended, by the Public Readiness and Emergency Preparedness Act of 2006 (Pub. L. 109–148), only insofar as it pertains to the compensation program.

This delegation shall be exercised under the Department's existing delegation of authority and policy on regulations.

This delegation is effective upon signature. In addition, I hereby affirmed and ratified any actions taken by the HRSA Administrator or other HRSA officials which involved the exercise of this authority prior to the effective date of this delegation.

This delegation is effective upon date of signature.

Dated: November 8, 2006.

Michael O. Leavitt,

Secretary.

[FR Doc. 06–9264 Filed 11–17–06; 8:45 am]

BILLING CODE 4165–15–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute: Circulating Biomarkers of Cardiovascular Risk in the NHLBI's Framingham Heart Study

AGENCY: National Heart, Lung, and Blood Institute, NIH, HHS.

ACTION: Notice.

SUMMARY: National Heart, Lung, and Blood Institute (NHLBI) seeks partners in a biomarker consortium to promote research on novel serum/plasma/urine biomarkers of cardiovascular disease (CVD) and related risk factors including atherosclerosis, obesity, insulin resistance, hypertension, and metabolic syndrome. An immediate consequence of this project will be the development of new diagnostic tests to identify individuals at high risk for CVD and its risk factors at a time when intervention is most feasible. A downstream result of the identification of novel biomarkers of CVD (and its risk factors) will be the discovery of disease promoting pathways, which may serve as new therapeutic targets for treating and preventing our nation's leading cause of death.

Background: Despite steady declines in CVD mortality, CVD remains the leading cause of death in the developed world. The NHLBI's Framingham Heart Study (FHS) has been instrumental in the identification and elucidation of key modifiable risk factors for CVD, which in turn have facilitated modern approaches to the prevention and treatment of CVD. Because of its prospective study design, the NHLBI's FHS is ideally positioned to enable identification of novel risk factors for CVD. The availability of frozen serum/plasma/urine samples from over 7000 FHS participants in the Offspring and Third Generation cohorts, in concert with new high-throughput quantitative biomarker technology available from commercial collaborators, provides a unique opportunity to explore the biochemical signatures of key CVD phenotypes. In addition, by the end of 2007 genotyping of 550k SNPs will be completed in nearly all the FHS participants as part of the NHLBI's SHARe project and these data will permit analysis of the associations of gene variants with biomarker levels.

Scientific Scope: The proposed study will measure 150 or more evolving and novel biomarkers from the FHS in 7000 FHS subjects for whom subclinical and clinical CVD and its risk factors have been carefully characterized. Analyses will be conducted for association of biomarkers—individually and collectively—with clinically relevant phenotypes.

The aims of the project are to:

1. Identify the biochemical signature of atherosclerosis as determined by: (a) Aortic and coronary calcification on CT (data available in 3500 people), (b) aortic plaque burden by MRI (n=2000), (c) carotid intimal-medial thickness by ultrasound (n=3500), (d) clinical atherosclerotic CVD (n=500), and (e) the dynamic balance between arterial calcification and bone demineralization (n=3500).

2. Identify the biochemical signature of metabolic syndrome components including (a) systolic and diastolic blood pressure (n=7000), (b) obesity (n=7000) and visceral adiposity by CT (n=3500), (c) dyslipidemia (n=7000), and (d) impaired fasting glucose, diabetes, and insulin resistance.

Biomarkers for this project will be selected by expert consensus on the basis of (a) a careful review of the literature for biomarkers of atherosclerosis and metabolic syndrome, and (b) genes implicated in atherosclerosis and metabolic syndrome (and their constituent components and pathways), or showing evidence of association with the phenotypes of interest.

Technology: As part of this project, new quantitative tests will be developed to measure circulating biomarker levels using antibody sandwich assays and/or proteomic approaches that are amenable to high throughput application. Critical to this project is the implementation of methods to measure large numbers of biomarkers with minimal sample volume; proteomic, bead-linked immunoassays, and nanotechnology methods may be necessary to accomplish this aim. Pathways to be studied include but are not limited to: Adhesion/chemoattraction, adipokines, cytokines, growth factors, heat shock proteins, inflammation, lipoproteins, neurohormones, thrombosis/fibrinolysis, and vascular calcification. Demonstrated rigorous assay validation using non-FHS samples will be necessary before FHS biospecimens can be used for this project.

Study Sample: The NHLBI's FHS is community-based[N1], which should contribute to the generalizability of