Contact: Paul Boben, 410–786–6629
- Expansion of Coverage of Chiropractic Services Demonstration
  Contact: Carol Magee, 410–786–6611
- Frontier Extended Stay Clinic Demonstration Project
  Contact: Sid Mazumdar, 410–786–6673
- Home Health Agency Prospective Payment Demonstration
  Contact: J. Sherwood, 410–786–6651
- Impact of Payment Reform for Part B Covered Outpatient Drugs and Biologicals
  Contact: Usree Bandyopadhyay, 410–786–6650
- Informatics for Diabetes Education and Telemedicine Demonstration (IDEATel)
  Contact: Diana Ayres: 410–786–7203
- Inhalation Drug Therapy Demonstration
  Contact: Debbie Vanhoven, 410–786–6625
- Life Masters
  Contact: Linda Colantino, 410–786–3343
- Low Vision Rehabilitation Demonstration
  Contact: James Coan, 410–786–9168
- Massachusetts Senior Care Options
  Contact: William Clark, 410–786–1484
- Medical Adult Day Care Services Demonstration
  Contact: Armen Thoumaian, PhD, 410–786–6672
- Medicare + Choice Phase II—PPO Demonstration
  Contact: Debbie Vanhoven, 410–786–6625
- Medicare Advantage CCRC (Erickson) Demonstration
  Contact: Henry Bachofer, 410–786–0340
- Medicare Cancer Registry Record System
  Contact: Gerald Riley, 410–786–6699
- Medicare Care Management Performance Demonstration
  Contact: Jody Blatt, 410–786–6921
- Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project
  Contact: Linda Lebovic, 410–786–3402
- Medicare Coordinated Care Demonstration
  Contact: Cynthia Mason, 410–786–6680
- Medicare Drug Replacement Demonstration
  Contact: Jody Blatt, 410–786–6921
- Medicare Health Care Quality Demonstration Programs
  Contact: Cynthia Mason, 410–786–6680
- Medicare Home Health Independence Demonstration
  Contact: Armen Thoumaian, Ph.D., 410–786–6672
- Medicare Hospital Gainsharing Demonstration
  Contact: Lisa Waters, 410–786–6615
- Medicare Preventive Services—Medicare Lifestyle Modification Program Demonstration
  Contact: Armen Thoumaian, PhD, 410–786–6672
- Mercy Medicare Skilled Nursing Facility Payment Demonstration
  Contact: J. Sherwood, 410–786–6651
- Minnesota Senior Health Options
  Contact: Susan Radke, 410–786–4450
- Municipal Health Services Program Demonstration
  Contact: Michael Henesch, 410–786–6685
- New York Graduate Medical Education Demonstration
  Contact: Sid Mazumdar, 410–786–6673
- Nursing Home Value-Based Purchasing
  Contact: Ronald Lambert, 410–786–6624
- PACE-for-Profit Demonstration
  Contact: Michael Henesch, 410–786–6685
- Payment Development, Implementation and Monitoring for the BIPA Disease Management Demonstration
  Contact: J. Sherwood, 410–786–6651
- Person-Level Medicaid Data System
  Contact: Dave Baugh, 410–786–7716
- Physician Group Practice Demonstration
  Contact: John Pilotte, 410–786–6658
- Premier Hospital Quality Incentive Demonstration
  Contact: Katharine Pirotte, 410–786–6774
- Rural Community Hospital Demonstration
  Contact: Sid Mazumdar, 410–786–6673
- Rural Hospice Demonstration: Quality Assurance Metrics Implementation Support
  Contact: Cindy Massuda, 410–786–0652
- Senior Risk Reduction Demonstration
  Contact: Pauline Lapin, 410–786–6883
- Social Health Maintenance Organization for Long-Term Care Demonstration
  Contact: Thomas Theis, 410–786–6654
- State-based Home Health Agency TPL Payments
  Contact: J. Sherwood, 410–786–6651
- United Mine Workers of America Demonstration
  Contact: Jason Petroski, 410–786–4681
- Utah Graduate Medical Education
  Contact: Sid Mazumdar, 410–786–6673
- Wisconsin Partnership Program
  Contact: James Hawthorne, 410–786–6689

[FR Doc. E7–7403 Filed 4–18–07; 8:45 am]
BILLING CODE 4120–03–P

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, ''Post-Acute Care Payment Reform / Continuity of Assessment Report and Evaluation Demonstration and Evaluation (PAC–CARE), System No. 09–70–0569.'' The program is authorized under Section 5008 of the Deficit Reduction Act of 2005, which allows for the establishment of a demonstration program for purposes of understanding costs and outcomes across different post-acute care sites. The PAC–CARE will collect information that will enable CMS to better understand the relationships among patient needs, post-acute care placement, patient outcomes, and post-acute care related costs in the Medicare program. Anticipated results of the PAC–CARE include a standardized assessment instrument for post-acute care patients and a proposal for site-neutral payment for post-acute care services.

The purpose of this system is to collect and maintain demographic, health, and health resource use related data on the target population of Medicare beneficiaries who require treatment in a designated acute care or post-acute care facility. We will also collect certain identifying information on Medicare providers who provide services to such beneficiaries. 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, consultant or other legal agent; (2) assist another Federal or state agency with information to contribute to the accuracy of CMS's proper payment of Medicare benefits, enable such agency to administer a Federal health benefits program, or to enable such agency to fulfill a requirement of Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds; (3) support an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects; (4) support the functions of Quality Improvement Organizations; (5) support the functions of national accrediting organizations; (6) support litigation involving the agency; and (7) combat fraud, waste, and abuse in certain Federally-funded health benefits programs. 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 Dates'' 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 April 13, 2007. To ensure that all parties have adequate time in which to comment, the new system will become effective 30 days from the publication of

the notice, or 40 days from the date it was submitted to OMB and the Congress, whichever is later. We may defer implementation of this system or one or more of the routine use statements listed below if we receive comments that persuade us to defer implementation.

ADDRESSES: The public should address comments to the CMS Privacy Officer, Division of Privacy Compliance, Enterprise Architecture and Strategy Group, 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: Shannon Flood, Division of Payment Research, Research and Evaluation Group, Office of Research Development & Information, Mail Stop C3–19–26, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1849. She can be reached by telephone at 410–786–2583, or via e-mail at *Shannon.Flood@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION: Medicare beneficiaries frequently require post-acute care for rehabilitation and recovery following a hospital stay. The level and length of care required varies with the individual patient and the condition(s) requiring hospitalization. The type of care ranges from outpatient therapy to multi-day stays in a variety of post-acute care settings. The PAC–CARE will study Medicare beneficiaries as they are discharged from participating hospitals and move among post-acute care settings. Patient functional assessments will be performed at regular intervals beginning at hospital discharge and continuing as patients move among post-acute care settings until the episode of care has completed. Cost data will be collected from the post-acute care settings, combined with other cost information collected by Medicare Fiscal Intermediaries or Carriers, and combined with claims and patient outcome data to develop a payment reform proposal.

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 5008 of the Deficit Reduction Act of 2005.

B. Collection and Maintenance of Data in the System

This system will collect and maintain individually identifiable and other data collected on Medicare beneficiaries who require treatment in a designated acute care or post-acute care facility. We will also collect certain identifying information on Medicare providers who provide services to such beneficiaries. The collected information will include, but is not limited to: Medicare claims and eligibility data, name, address, telephone number, health insurance claims number, race/ethnicity, gender, date of birth, provider name, unique provider identification number, medical record number, as well as clinical, demographic, health/well-being, family and/or caregiver contact information, and background information relating to Medicare issues. Data will be collected from Medicare administrative and claims records, PAC–CARE site administrative data systems, patient medical charts, physician records, and via information submitted by beneficiaries and providers.

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 PAC-CARE 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 PAC–CARE.

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 demographic, health, and health resource use related data on the target population of Medicare beneficiaries who require treatment in a designated acute care or post-acute care facility. We will also collect certain identifying information on Medicare providers who provide services to such 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 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.

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 another Federal or state agency to:

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

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

c. Assist Federal/state Medicaid programs within the state.

Other Federal or state agencies, in their administration of a Federal health program, may require PAC–CARE 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 a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects.

The PAC–CARE data will provide for research or support of evaluation projects and a broader, longitudinal, national perspective of the status of Medicare beneficiaries. CMS anticipates that researchers may have legitimate requests to use these data in projects that could ultimately improve the care provided to Medicare beneficiaries and the policies that govern their 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 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 post acute care facilities that have an accreditation status with the requesting deemed organization;

b. Submission of a finder file identifying beneficiaries/patients receiving post acute care 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 PAC–CARE information to enable them to target potential identified problems during the organization's accreditation review process of the facility.

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

a. The agency or any component thereof, or

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

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

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

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

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

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual, grantee, cooperative agreement or consultant relationship 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 or makes grants or cooperative agreements when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor, grantee, consultant or other legal agent whatever information is necessary for the agent to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the agent from using or disclosing the information for any purpose other than that described in the contract and requiring the agent to return or destroy all information.

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

Other agencies may require PAC–CARE 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 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: April 12, 2007.

Charlene Frizzera,

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

SYSTEM NO. 09–70–0569

SYSTEM NAME:

''Post-Acute Care Payment Reform/ Continuity of Assessment Report and Evaluation Demonstration and Evaluation (PAC–CARE),'' HHS/CMS/ ORDI.

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 on Medicare beneficiaries who require treatment in a designated acute care or post-acute care facility. We will also collect certain identifying information on Medicare providers who provide services to such beneficiaries.

CATEGORIES OF RECORDS IN THE SYSTEM:

The collected information will include, but is not limited to: Medicare claims and eligibility data, name, address, telephone number, health insurance claims number, race/ ethnicity, gender, date of birth, provider name, unique provider identification number, medical record number, as well as clinical, demographic, health/well-being, family and/or caregiver contact information, and background information relating to Medicare issues. Data will be collected from Medicare administrative and claims records, PAC–CARE site administrative data systems, patient medical charts, physician records, and via information submitted by beneficiaries and providers.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The statutory authority for this system is given under Section 5008 of the Deficit Reduction Act of 2005.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to collect and maintain demographic, health, and health resource use related data on the target population of Medicare beneficiaries who require treatment in a designated acute care or post-acute care facility. We will also collect certain identifying information on Medicare providers who provide services to such beneficiaries. 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, consultant or other legal agent; (2) assist another Federal or state agency with information to contribute to the accuracy of CMS's proper payment of Medicare benefits, enable such agency to administer a Federal health benefits program, or to enable such agency to fulfill a requirement of Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds; (3) support an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects; (4) support the functions of Quality Improvement Organizations; (5) support the functions of national accrediting organizations; (6) support litigation involving the agency; and (7) combat fraud, waste, and abuse in certain Federally-funded health benefits programs.

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

A. The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a ''routine use.'' The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. We are 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.

2. To another Federal or state agency to:

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

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

c. Assist Federal/state Medicaid programs within the state.

3. To an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects.

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 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 post acute care facilities that have an accreditation status with the requesting deemed organization;

b. Submission of a finder file identifying beneficiaries/patients receiving post acute care 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.

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

a. The agency or any component thereof, or

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

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

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

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

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

B. Additional Provisions Affecting Routine Use Disclosures

To the extent this system contains Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, subparts A and E) 65 FR 82462 (12–28–00). Disclosures of such PHI that are otherwise authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.'' (See 45 CFR 164.512(a) (1)).

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

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

STORAGE:

All records are stored on electronic media.

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

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

RETENTION AND DISPOSAL:

Records will be retained until an approved disposition authority is obtained from the National Archives and Records Administration. 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, Research and Evaluation Group, Office of Research Development

& Information, Mail Stop C3–19–26, 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 Medicare administrative and claims records (Outcome and Assessment Information Set, Inpatient Rehabilitation Facilities Patient Assessment Instrument, Long Term Care Minimum Data Set), post-acute care site administrative data systems, patient medical charts, physician records, and via information submitted by beneficiaries and providers.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. E7–7404 Filed 4–18–07; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0077]

Withdrawal of Approval of New Animal Drug Applications; Pyrantel; Tylosin; Tylosin and Sulfamethazine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of three new animal drug applications (NADAs) for intermediate premixes used to manufacture Type C medicated feeds. In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to remove portions reflecting approval of these NADAs.

FOR FURTHER INFORMATION CONTACT: Pamela K. Esposito, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9067, e-mail: *pamela.esposito@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Custom Feed Services Corp., 2100 N. 13th St., Norfolk, NE 68701, has requested that FDA withdraw approval of NADA 121–200 for Tylosin 10 Premix (tylosin), NADA 129–159 for TYLAN 40 Sulfa-G (tylosin and sulfamethazine), and NADA 137–484 for Swine Guard-BN (pyrantel). All are intermediate premixes used to manufacture Type C medicated feeds. This action is requested because the products are no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs, redelegated to the Center for Veterinary Medicine, and in accordance with 21 CFR 514.115 *Withdrawal of approval of applications*, notice is given that approval of NADA 121–200, NADA 129–159, and NADA 137–484, and all supplements and amendments thereto, are hereby withdrawn, effective April 30, 2007.

In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the withdrawal of approval of these NADAs.

Dated: April 9, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–7461 Filed 4–18–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0078]

Withdrawal of Approval of New Animal Drug Applications; Estradiol Benzoate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has withdrawn approval of two new animal drug applications (NADAs) for a suspension implant of estradiol benzoate microspheres used in steers and heifers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency, and in suckling beef calves for increased rate of weight gain. In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to remove portions reflecting approval of these NADAs.

FOR FURTHER INFORMATION CONTACT: Pamela K. Esposito, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9067; e-mail: *pamela.esposito@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: PR Pharmaceuticals, Inc., 1716 Heath Pkwy., Fort Collins, CO 80524, has requested that FDA withdraw approval of NADA 141–040 for DURALEASE (estradiol benzoate), a suspension implant of estradiol benzoate microspheres used in steers and heifers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency and NADA 141–041 for CELERIN-C (estradiol benzoate), a similar product used in suckling beef calves for increased rate of weight gain. This action is requested because the products are no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs, redelegated to the Center for Veterinary Medicine, and in accordance with 21 CFR 514.115, notice is given that approval of NADA 141–040 and NADA 141–041 and all supplements and amendments thereto, were withdrawn as of September 29, 2006.

In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the withdrawal of approval of these NADAs.

Dated: April 9, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 07–1941 Filed 4–18–07; 8:45 am]

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