Dated: March 31, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E6–5038 Filed 4–5–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health (NIOSH); Advisory Board on Radiation and Worker Health (ABRWH); Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention announces the following committee meeting:

Name: Advisory Board on Radiation and Worker Health, National Institute for Occupational Safety and Health and Subcommittee for Dose Reconstruction and Site Profile Reviews (SDRSPR).

Subcommittee Meeting Time and Date:

9 a.m.–2 p.m., April 25, 2006.

Committee Meeting Times and Dates:

2:30 p.m.–5 p.m., April 25, 2006.

8:30 a.m.–5 p.m., April 26, 2006.

8:30 a.m.–4:30 p.m., April 27, 2006.

Public Comment Time and Date:

7 p.m.–8:30 p.m., April 26, 2006.

Place: Four Points by Sheraton Denver Cherry Creek Hotel, 600 South Colorado Boulevard, Denver, Colorado 80246. Phone 303.757.3341, Fax 303.756.6670.

Status: Open to the public, limited only by the space available. The meeting space accommodates approximately 75 people.

Background: The ABRWH was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Board include providing advice on the development of probability of causation guidelines which have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2007.

Purpose: This board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters to be Discussed: The agenda for the Subcommittee meeting includes Y–12 and Rocky Flats Site Profiles; Procedures Review Update; Selection of 5th and 6th Round of Individual Dose Reconstructions; and Individual Dose Reconstruction Reviews. The agenda for the Board meeting includes the Subcommittee Report on the following topics: Y–12 Site and Rocky Flats Site Profiles, Procedures Review Update, Selection of 5th and 6th Round of Individual Dose Reconstructions, and Individual Dose Reconstruction Reviews. There will be a report on the S. Cohen & Associates (SC&A) SEC Activities, specifically Ames, Procedures, Rocky Flats and Y–12; Board SEC Procedures; Conflict of Interest; Y–12 and Rocky Flats SEC Petitions; Program Updates from the Office of Compensation Analysis and Support on General Items, Bethlehem Steel Site Profile, and Science Issues; Program Updates from the Department of Labor; General SC&A Contract Issues; Board Correspondence; Future Schedules and Agendas; Nevada Test Site SEC Petition; and Pacific Proving Ground SEC Petition.

The agenda is subject to change as priorities dictate. In the event an individual cannot attend, written comments may be submitted. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Dr. Lewis V. Wade, Executive Secretary, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513.533.6825, fax 513.533.6826.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: March 30, 2006.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 06–3305 Filed 4–5–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services; Privacy Act of 1974; Report of a Modified or Altered System

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 requirements of the Privacy Act of 1974, we are proposing to modify or alter an existing SOR, ''Medicare Provider Analysis and Review (MEDPAR), System No. 09–70–0009.'' Notice for this system was published at 65 **Federal Register** (FR) 50548 (August 18, 2000). CMS is reorganizing its databases because of the impact of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law (Pub. L.) 108–173) provisions and the large volume of information the Agency collects to administer the Medicare program. 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 the system. The new assigned identifying number for this system should read: System No. 09–70–0514.

We propose to establish a new routine use to provide disclosure of data to hospitals that may be entitled to disproportionate share hospital payments. This new routine use will implement the disclosure provisions of Section 951 of the MMA. Section 951 will provide hospitals with a data set that will span the 2 Federal Fiscal Years that encompass the hospital's cost reporting period. This modification will carry out the purposes of the MEDPAR

and enable hospitals to calculate and verify their Supplemental Security Income (SSI) ratio without the need for additional processing on the part of CMS. This new routine use will be published at routine use number 3.

We are modifying the language in some of the remaining routine uses to provide clarity to CMS' 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 recent reorganizations and to update language in the administrative sections to correspond with language used in other CMS SORs.

The primary purpose of the system is to collect and maintain information for all services rendered during Medicare beneficiary stays in an inpatient hospital and/or Skilled Nursing Facilities (SNF), so as to enable CMS and its contractors to facilitate research on the quality and effectiveness of care provided, update annual hospital Inpatient Prospective Payment System (IPPS) rates, and to calculate Supplemental Security Income (SSI) ratios for hospitals that are paid under the hospital IPPS and serve a disproportionate share of low-income patients (hospitals that serve a disproportionate share of low-income patients are entitled to increased reimbursement under the IPPS). Information retrieved from this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant; (2) provide system data to a hospital that has an appeal properly pending before the Provider Reimbursement Review Board (PRRB) or before an intermediary; (3) provide system data when all requirements have been met to a hospital that may be entitled to disproportioned share hospital payments and makes a request in accordance with section 951 of the MMA; (4) assist another Federal or state agency with information to enable such agency to administer a Federal health benefits program, or 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; (5) support constituent requests made to a Congressional representative; (6) support litigation involving the agency; (7) facilitate research on the quality and effectiveness of care provided; and (8) combat fraud and abuse in certain Federally-funded health benefits programs. We have provided background information about the modified system in the ''Supplementary Information'' section below. Although the Privacy Act requires only that CMS provide an opportunity for interested persons to comment on the proposed routine uses, CMS invites comments on all portions of this notice. See ''Effective Dates'' section for comment period.

DATES: *Effective Dates:* CMS filed a modified or altered system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Homeland Security & Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on *3/30/2006*. 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 Data Development, 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: Molly Smith, Division of Acute Care, Hospital and Ambulatory Provider Group, Center for Medicare Management, CMS, Room C4–08–06, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. The telephone number is (410) 786–8354; she can also be reached via e-mail at *Molly.Smith@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION: Notice of this system was last published at 65 FR 50548 (August 18, 2000). The MEDPAR contains a summary of all services rendered to a Medicare beneficiary, from the time of admission through discharge, for a stay in an inpatient hospital and/or SNF, SSI eligibility information that CMS receives from the Social Security Administration (SSA) on Medicare beneficiaries who have had stays in inpatient hospitals and SNF, and enrollment data on Medicare beneficiaries.

Under section 1886 (d)(5)(F)(vi)(I) of the Social Security Act, 42 U.S.C. 1395ww(d)(5)(F)(vi)(I), hospitals that are paid under the IPPS and serve a disproportionate share of low-income patients may be entitled to increased reimbursement under Part A of the Medicare program. Such disproportionate share hospital payments, which became effective for discharges occurring on or after May 1, 1986, depend in part on a hospital's ''SSI ratio.'' CMS determines a hospital's SSI ratio by comparing, for the same period, (1) the hospital's total number of its Medicare inpatient days to (2) the hospital's ''Medicare/SSI days,'' *i.e.*, inpatient days attributable to Medicare patients who for such days were eligible for SSI payments under Title XVI of the Act. In determining a hospital's SSI ratio, CMS uses information from the National Claims History (CMS System No. 09–70–0005), in conjunction with SSI eligibility information that CMS receives from SSA. CMS notifies each hospital of the total number of its Medicare/SSI days for a given Federal fiscal year, or cost reporting period, but does not identify which of the hospital's Medicare patients had Medicare/SSI days.

Section 951 of the MMA requires the Secretary of HHS to arrange to furnish the data necessary for hospitals to compute the number of patient days used in calculating their disproportionate patient percentage. Beginning with cost reporting periods that include December 8, 2004, CMS will arrange to furnish, consistent with the Privacy Act, the MEDPAR limited data set data for a hospital's Medicare patients at the hospital's request, regardless of whether there is a properly pending appeal relating to disproportionate share hospital payments. We will make the information available for either the Federal fiscal year or, if the hospital's fiscal year differs from the Federal fiscal year, for the months included in the 2 Federal fiscal years that encompass the hospital's cost reporting period. Under this provision, the hospital will be able to use these data to calculate and verify its SSI ratio, and to decide whether it prefers to have the fraction determined on the basis of its fiscal year rather than a Federal fiscal year.

I. Description of the Modified or Altered System of Records

A. Statutory and Regulatory Basis for System of Records

Authority for maintenance of this system is given under sections 1102(a), 1871, and 1886(d)(5)(F) of the Social Security Act, (Title 42 United States Code (U.S.C.) §§ 1302(a), 1395hh, and 1395ww(d)(5)(F)). Authority is also given under section 951 of the Medicare Prescription Drug, Improvement, and

Modernization Act of 2003 (Pub. L. 108–173).

B. Scope of the Data Collected

The MEDPAR contains a summary of all services rendered to a Medicare beneficiary, from the time of admission through discharge, for a stay in an inpatient hospital and/or SNF, SSI entitlement information that CMS receives from SSA on Medicare beneficiaries who have had stays at inpatient hospitals and SNF, and enrollment data on Medicare beneficiaries. The MEDPAR contains information necessary for appropriate Medicare claim processing. It also contains, but is not limited to, the Medicare health insurance claim number, gender, race, age (no date of birth), zip code, state and county for Medicare beneficiaries who have received inpatient hospital and SNF services.

II. Collection and Maintenance of Data in the System

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 MEDPAR 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 MEDPAR. 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 collect and maintain information for all services rendered during Medicare beneficiary stays in an inpatient hospital and/or SNF, so as to enable CMS and its contractors to facilitate research on the quality and effectiveness of care provided, update annual hospital IPPS rates, and to calculate SSI ratios for hospitals that are paid under the hospital IPPS and serve a disproportionate share of low-income patients.

2. Determines:

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

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

c. That 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; and

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

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 who have been engaged by the agency to assist in the performance of a service related to this system of records 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 some of its functions when doing so would contribute to more effective and efficient operations. CMS must be able to give a contractor or consultant 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 or consultant from using or disclosing the information for any purpose other than that described in the contract and requires the contractor or consultant to return or destroy all information at the completion of the contract.

2. To a hospital that has an appeal properly pending before the Provider Reimbursement Review Board, or before an intermediary, on the issue of whether it is entitled to disproportionate share hospital payments, or the amount of such payments. As a condition of disclosure under this routine use, CMS will require the recipient of the information to:

a. Establish reasonable administrative, technical, and physical safeguards to prevent unauthorized access, use, or disclosure of the record or any part thereof;

b. Remove or destroy the information that allows the subject individual(s) to be identified at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the request;

c. Refrain from using or disclosing the information for any purpose other than the stated purpose under which the information was disclosed; and

d. Attest in writing that it understands the foregoing provisions, and is willing to abide by the foregoing provisions and any additional provisions that CMS deems appropriate in the particular circumstances.

Disclosure under this routine use shall be for the purpose of assisting the hospital to verify or challenge CMS' determination of the hospital's SSI ratio (*i.e.,* the total number of Medicare days compared to the number of Medicare/SSI days). Disclosure shall be limited to data concerning the total number of patient days, the number of SSI/Medicare days, if any, and the number of Medicare covered days, if any, associated with each stay at the hospital's facility during the cost reporting period under appeal or, where the hospital does not report on a Federal Fiscal Years basis, during the 2 Federal Fiscal Years in which the hospital's cost reporting period falls. The data disclosed will relate to stays at the hospital's IPPS units as well as any IPPS-excluded units in order to assist the hospital in verifying that all qualifying stays (*i.e.,* those in the IPPS units) were included in CMS' determination of the hospital's SSI ratio. The routine use would permit disclosure only to a hospital that has a proper appeal pending before the PRRB or before an intermediary. This routine use is applicable to appeals of determinations of a hospital's SSI ratio for cost reporting periods ending prior to December 8, 2004.

3. To a hospital that may be entitled to disproportionate share hospital

payments, or the amount of such payments, for cost reporting periods that span December 8, 2004, and beyond. As a condition of disclosure under this routine use, CMS will require the recipient of the information to:

a. Establish reasonable administrative, technical, and physical safeguards to prevent unauthorized access, use or disclosure of the record or any part thereof;

b. Remove or destroy the information that allows the subject individual(s) to be identified at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the request;

c. Refrain from using or disclosing the information for any purpose other than the stated purpose under which the information was disclosed; and

d. Attest in writing that it understands the foregoing provisions, and is willing to abide by the foregoing provisions and any additional provisions that CMS deems appropriate in the particular circumstances.

Disclosure under this routine use shall be for the purpose of assisting the hospital to verify or challenge CMS' determination of the hospital's SSI ratio (*i.e.,* the total number of Medicare days compared to the number of Medicare/SSI days). Disclosure shall be limited to data concerning the total number of patient days, the number of SSI/Medicare days, if any, and the number of Medicare covered days, if any, associated with each stay at the hospital's facility during the cost reporting period for which the hospital has requested the data, or, where the hospital does not report on a Federal Fiscal Years basis, during the 2 Federal Fiscal Years in which the hospital's cost reporting period falls. The data disclosed will relate to stays at the hospital's IPPS units as well as any IPPS-excluded units in order to assist the hospital in verifying that all qualifying stays (*i.e.*, those in the IPPS units) were included in CMS' determination of the hospital's SSI ratio. This routine use is applicable for cost reporting periods ending on or after December 8, 2004.

4. To another Federal or state agency to:

a. Contribute to the accuracy of CMS' proper payment of Medicare benefits, and/or

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 MEDPAR information in order to support evaluations and monitoring of Medicare claims information of beneficiaries who have had stays at inpatient hospitals and SNF, including proper reimbursement for services provided. In addition, other state agencies in their administration of a Federal health program may require MEDPAR information for the purpose of determining, evaluating and/or assessing cost effectiveness, and/or the quality of health care services provided in the state.

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

The MEDPAR data will provide the research, evaluation and epidemiological projects a broader, longitudinal, national perspective of the MEDPAR and inpatient data. CMS anticipates that many researchers will have legitimate requests to use these data in projects that could ultimately improve the care provided to Medicare patients and the policy that governs the care.

6. 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.

Beneficiaries sometimes request the help of a member of Congress in resolving an 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.

7. 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.

8. 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 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 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 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 agencies may require MEDPAR information for the purpose of combating fraud 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 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 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 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 the disclosure of information relating to individuals.

Dated: March 29, 2006.

Charlene Fizzera,

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

SYSTEM NO. 09–70–0514

SYSTEM NAME:

''Medicare Provider Analysis and Review (MEDPAR) HHS/CMS/OIS.''

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.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The MEDPAR contains a summary of all services rendered to a Medicare beneficiary, from the time of admission through discharge, for a stay in an inpatient hospital and/or Skilled Nursing Facilities (SNF), Supplemental Security Income (SSI) entitlement information that CMS receives from the Social Security Administration on Medicare beneficiaries who have had stays at inpatient hospitals and SNF, and enrollment data on Medicare beneficiaries.

CATEGORIES OF RECORDS IN THE SYSTEM:

The MEDPAR contains information necessary for appropriate Medicare claim processing. It also contains, but is not limited to, the Medicare health insurance claim number (HICN), gender, race, age (no date of birth), zip code, state and county for Medicare beneficiaries who have received inpatient hospital and SNF services.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for maintenance of this system is given under sections 1102(a), 1871, and 1886(d)(5)(F) of the Social Security Act, (Title 42 United States Code (U.S.C.) §§ 1302(a), 1395hh, and 1395ww(d)(5)(F)). Authority is also given under section 951 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173).

PURPOSE(S) OF THE SYSTEM:

The primary purpose of the system is to collect and maintain information for all services rendered during Medicare beneficiary stays in an inpatient hospital and/or Skilled Nursing Facilities, so as to enable CMS and its contractors to facilitate research on the quality and effectiveness of care provided, update annual hospital Inpatient Prospective Payment System (IPPS) rates, and to calculate Supplemental Security Income ratios for hospitals that are paid under the hospital IPPS and serve a disproportionate share of low-income patients, (hospitals that serve a disproportionate share of low-income patients are entitled to increased reimbursement under the IPPS). Information retrieved from this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant; (2) provide system data to a hospital that has an appeal properly pending before the Provider Reimbursement Review Board (PRRB) or before an intermediary; (3) provide system data when all requirements have been met to a hospital that may be entitled to disproportioned share hospital payments and makes a requests in accordance with section 951 of the MMA; (4) assist another Federal or state agency with information to enable such agency to administer a Federal health benefits program, or 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; (5) support constituent requests made to a Congressional representative; (6) support litigation involving the

agency; (7) facilitate research on the quality and effectiveness of care provided; and, (8) combat fraud 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, or consultants who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity.

2. To a hospital that has an appeal properly pending before the Provider Reimbursement Review Board, or before an intermediary, on the issue of whether it is entitled to disproportionate share hospital payments, or the amount of such payments. As a condition of disclosure under this routine use, CMS will require the recipient of the information to:

a. Establish reasonable administrative, technical, and physical safeguards to prevent unauthorized access, use, or disclosure of the record or any part thereof;

b. Remove or destroy the information that allows the subject individual(s) to be identified at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the request;

c. Refrain from using or disclosing the information for any purpose other than the stated purpose under which the information was disclosed; and

d. Attest in writing that it understands the foregoing provisions, and is willing to abide by the foregoing provisions and any additional provisions that CMS deems appropriate in the particular circumstances.

3. To a hospital that may be entitled to disproportionate share hospital payments, or the amount of such payments, for cost reporting periods that span December 8, 2004, and beyond. As a condition of disclosure under this routine use, CMS will require the recipient of the information to:

a. Establish reasonable administrative, technical, and physical safeguards to prevent unauthorized access, use or disclosure of the record or any part thereof;

b. Remove or destroy the information that allows the subject individual(s) to be identified at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the request;

c. Refrain from using or disclosing the information for any purpose other than the stated purpose under which the information was disclosed; and

d. Attest in writing that it understands the foregoing provisions, and is willing to abide by the foregoing provisions and any additional provisions that CMS deems appropriate in the particular circumstances.

4. To another Federal or state agency to:

a. Contribute to the accuracy of CMS' proper payment of Medicare benefits, and/or

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.

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

6. 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.

7. 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.

8. 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 or abuse in such program.

9. 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, 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 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 Medicare records are retrieved by HICN of the beneficiary.

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 MEDPAR data for a total period not to exceed 25 years. 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 Acute Care, Hospital and Ambulatory Provider Group, Center for Medicare Management, CMS, Room C4–08–06, 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, age, gender, and for verification purposes, the subject individual's name (woman's maiden name, if applicable) and social security number (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).

RECORD SOURCE CATEGORIES:

CMS's National Claims History system of records, enrollment data on Medicare beneficiaries, and SSI eligibility information from the Social Security Administration.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0112]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry and FDA entitled ''Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities.'' It was developed as a special control to support the reclassification of the topical oxygen chamber for extremities (TOCE) from class III (premarket approval) into class II (special controls). Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify the TOCE device from class III into class II (special controls). This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by July 5, 2006.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Charles N. Durfor, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301– 594–3090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled ''Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities.''

Following the effective date of any final reclassification rule based on this proposal, any firm submitting a premarket notification (510(k)) for the TOCE will need to address the issues covered in the special controls guidance document. However, the firm need only show that its device meets the recommendations of the guidance document or in some other way provides equivalent assurances of safety and effectiveness.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the TOCE. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.