Background and Brief Description

Cyanobacteria (blue-green algae) can be found in terrestrial, fresh, brackish, or marine water environments. Some species of cyanobacteria produce toxins that may cause acute or chronic illnesses (including neurotoxicity, hepatotoxicity, and skin irritation) in humans and animals (including other mammals, fish, and birds). A number of human health effects, including gastroenteritis, respiratory effects, skin irritations, allergic responses, and liver damage, are associated with the ingestion of or contact with water containing cyanobacterial blooms. Although the balance of evidence, in conjunction with data from laboratory animal research, suggests that cyanobacterial toxins are responsible for a range of human health effects, there have been few epidemiologic studies of this association.

During August 2006, we conducted our first study to assess exposure to microcystins in recreational waters with a bloom of *Microcystis aeruginosa.* We recruited 104 people who gave informed consent to participate. Ninety seven people did their recreational activities on Lake 1, which had a confirmed *M. aeruginosa* bloom, and 7 others did their activities on Lake 2, which had no bloom. Study participants completed a pre-activity questionnaire, a post-activity questionnaire, provided a 10-ml blood sample, and completed a telephone symptom survey 7–10 days after exposure. The concentrations of microcystins in Lake 1 ranged from 2 to 5 ug/L and in Lake 2 were all below the limit of detection (LOD). When we designed the study, we calculated that a person exposed to recreationally-generated aerosols from water containing 10 ug/L of microcystins should have levels of microcystins in their blood. However, the microcystin concentrations in Lake 2 were below the LOD and in Lake 1 were actually 2ug/L to 5ug/L, much lower than we anticipated based on data from the previous week. Thus, the recreational exposures were not likely high enough for us to quantify microcystins in blood and the serum samples were all below the LOD for microcystins.

For the new data collection, we will conduct two separate studies in different lakes. In total, we will recruit 200 study participants who are at risk for swallowing water or inhaling spray (i.e., water skiers, jet skiers, people sailing small boats) and who would normally be doing these activities, even in the presence of a bloom. We may recruit people who train for organized swimming events (e.g., triathlons) in lakes. In addition, we will recruit 50 study participants from lakes with no blooms as a comparison group to assess the health effects associated with recreational activities on ''clean'' lakes. Study participants will be asked to sign a consent form, complete a symptom survey before and after doing their recreational water activities, provide one 10-ml whole blood sample after their recreational activities, and complete a telephone symptom survey 8–10 days after doing study activities.

The purpose of the new data collection is to continue assessing the public health impact of exposure to the cyanobacterial toxins, microcystins, during recreational activities. We will examine the extent of human exposure to microcystins present in recreational waters and associated aerosols and whether serum levels of microcystins can be used as a biomarker of exposure.

There is no cost to the respondents other than their time. The total estimated annualized burden hours are 69.

ESTIMATED ANNUALIZED BURDEN HOURS

Forms	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Screening questionnaire	125	1	5/60
Consent and pre-exposure questionnaire	100	1	10/60
Post-exposure questionnaire	100	1	15/60
10-day post exposure questionnaire	100	1	10/60

Dated: September 6, 2007.

Maryam I. Daneshvar,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–17962 Filed 9–11–07; 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 New System of Records

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

ACTION: Notice of a New System of Records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, CMS is proposing to establish a new system of records (SOR) titled, ''Performance Measurement and Reporting System (PMRS),'' System No. 09–70–0584. PMRS will serve as a master system of records to assist in projects that provide transparency in health care on a broad-scale enabling consumers to compare the quality and price of health care services so that they can make informed choices among individual physicians, practitioners and providers of services. In cooperation with local or regional public-private collaborative stakeholders; individuals assigned to provider groups; insurance and provider associations; government agencies; employers; accrediting and quality organizations; Chartered Value Exchanges (CVE), data aggregators, and other community leaders who are committed to improving the quality of services, CMS is laying the foundation for pooling and analyzing information about the quality of medical services and performance provided by physicians and health care providers. PMRS will further assist in developing existing strategies to improve health care quality including transparency of cost and/or price information, quality and utilization information; and patient safety for Medicare beneficiaries by collecting and aggregating data, by measuring performance at the individual physician level, and by reporting meaningful information to Medicare beneficiaries in order to make informed choices and improve outcomes.

Pursuant to the ''routine use'' promulgated under this system of records notice, CMS or a non-Quality Improvement Organization (non-QIO)

contractor would make the individual physician-level performance measurement results available to Medicare beneficiaries by posting it on a public Web site and by various other methods of data dissemination. If local Web sites are used by a local or regional collaborative, CMS would have links to these Web sites on its main Web site. This information would be made available for the purpose of, and in a manner that would promote more informed choices by Medicare beneficiaries among their Medicare coverage options (i.e., the Medicare Advantage, local or regional plans offered in their area, and original fee-for-service Medicare). The routine uses established with this system contain a proper explanation as to the need for the disclosure provisions and provide clarity to CMS's intention to disclose individual-specific information contained in this system.

The primary purpose of this system is to support the collection, maintenance, and processing of information promoting the effective, efficient, and economical delivery of health care services, and promoting the quality of services of the type for which payment may be made under title XVIII by allowing for the establishment and implementation of performance measures, and the provision of feedback to physicians. Information in this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed for the Agency or by a contractor, consultant, or a CMS grantee; (2) assist another Federal and/or state agency, agency of a state government, or an agency established by state law; (3) promote more informed choices by Medicare beneficiaries among their Medicare group options by making physician performance measurement information available to Medicare beneficiaries through a Web site and other forms of data dissemination; (4) provide CVEs and data aggregators with information that will assist in generating single or multi-payer performance measurement results to promote transparency in health care to members of their community; (5) assist individual physicians, practitioners, providers of services, suppliers, laboratories, and others health care professionals who are participating in health care transparency projects; (6) assist individuals or organizations with projects that provide transparency in health care on a broad-scale enabling consumers to compare the quality and price of health care services; or for research, evaluation, and epidemiological projects related to the prevention of disease or disability; restoration or maintenance of health or for payment purposes; (7) assist Quality Improvement Organizations; (8) support litigation involving the agency; and (9) combat fraud, waste, and abuse in certain health benefits programs. We have provided background information about this 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.

EFFECTIVE DATES: CMS filed a new 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 9/05/2007. To ensure that all parties have adequate time in which to comment, the new 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. to 3 p.m., eastern time zone.

FOR FURTHER INFORMATION CONTACT: Aucha Prachanronarong, Health Insurance Specialist, Division of Ambulatory Care and Measure Management, Quality Measurement and Health Assessment Group, Office of Clinical Standards and Quality, CMS, Room C1–23–14, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. The telephone number is (410) 786–1879 or contact *Aucha.Prachanronarong@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION: The Value-driven Health Care Initiative is designed to achieve four cornerstones: Interoperable health information technology (HIT); transparency of price information; transparency of quality information; and the use of incentives to promote high-quality and cost-efficient health care. Regional/local public-private collaboration is essential to the success of this Initiative. As such, the Initiative is encouraging the growth of regional public-private collaboratives that will be chartered by the Agency for Health Research and Quality (AHRQ) to support and achieve the four cornerstones. Only mature, sustainable, multi-stakeholder entities that are committed to achieving the four cornerstones, including publicly reporting physician-level and other provider performance measurement information and facilitating the use of this information to improve the quality and efficiency of health care delivery, will become Chartered Value Exchanges (CVE).

Provided they meet certain criteria established by CMS and disclosure is consistent with the Privacy Act, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and other applicable laws, CMS will provide CVEs with patient de-identified Medicare-inclusive individual physician-level performance measurement results. CMS also may provide physician and patient identifiable protected health claims data information to data aggregators that are HIPAA business associates of CMS (including working with providers, payers, or other HIPAA covered entities) for purposes for generating these results. The patient de-identified results will be calculated using Medicare claims data based on consensus-based measures as determined by CMS, including but not limited to quality, efficiency and utilization metrics. Available results may include single payer (i.e., Medicare only and private payer only performance measurement results) and/or multi-payer (i.e., results generated from merging or aggregating Medicare results with other private payer results) patient de-identified, individual physician-level performance measurement results. CMS also plans to make the patient de-identified and individual physician-level performance measurement results available to Medicare beneficiaries, and others that meet CMS requirements for disclosure.

CMS also has implemented a pilot project known as, ''The Better Quality Information to Improve Care for Medicare Beneficiaries (BQI) Project'' to develop a model for data aggregation, quality measurement, and public reporting. Through the BQI project, each pilot collaborative, as a QIO subcontractor, is aggregating private claims data with Medicare claims data and, in some cases, Medicaid claims data to produce single payer and/or multi-payer, patient de-identified, individual physician-level performance

measurement results using quality measures that are approved by CMS. These performance measurement results will be made available to Medicare beneficiaries by CMS or a CMS contractor.

In addition, as required by the Tax Relief and Health Care Act of 2006, CMS is implementing a voluntary Physician Quality Reporting Initiative (PQRI). Under PQRI, eligible professionals who choose to participate and successfully report on a designated set of quality measures for services paid under the Medicare Physician Fee Schedule and provided to Medicare beneficiaries under the traditional fee-for-service program, may earn a bonus payment subject to a cap. Participating eligible professionals whose Medicare patients in the traditional fee-for-service program fit the specifications of the PQRI quality measures will report the corresponding appropriate Common Procedural Terminology (CPT) Category II codes or G-codes on their claims. In the future, CMS may publicly release the performance information that is reported by physicians pursuant to PQRI.

I. Description of the Proposed System of Records

A. Statutory and Regulatory Basis for System

Authority for the collection, maintenance, and disclosures from this system is given under provisions of §§ 1152, 1153(c), 1153(e), 1154, 1160, 1851(d) and 1862(g) of the Social Security Act; § 101 of the Tax Relief and Health Care Act of 2006; and §§ 901, 912, and 914 of the Public Health Service Act.

B. Collection and Maintenance of Data in the System

The system contains single and multi-payer, patient de-identified, individual physician-level performance measurement results as well as, patient identifiable clinical and claims information provided by individual physicians, practitioners and providers of services, individuals assigned to provider groups, insurance and provider associations, government agencies, accrediting and quality organizations, and others who are committed to improving the quality of physician services. This system contains the patient's or beneficiary's name, sex, health insurance claim number (HIC), Social Security Number (SSN), address, date of birth, medical record number(s), prior stay information, provider name and address, physician's name, and/or identification number, date of admission or discharge, other health insurance, diagnosis, surgical procedures, and a statement of services rendered for related charges and other data needed to substantiate claims. The system contains provider characteristics, prescriber identification number(s), assigned provider number(s) (facility, referring/servicing physician), and national drug code information, total charges, and Medicare payment amounts.

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

A. The Privacy Act permits us to disclose information without an individual's consent/authorization 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 PMRS 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 disclose the minimum individually identifiable data necessary to achieve the purpose of PMRS. CMS has the following policies and procedures concerning disclosures of information that will be maintained in the system. In general, disclosure of information from the system will be approved only for the minimum information 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, maintain, and process information promoting the effective, efficient, and economical delivery of health care services, and promoting the quality of services of the type for which payment may be made under title XVIII;

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 reasonable probability that the proposed use of the data would in fact accomplish the stated purpose(s) of the disclosure.

3. Requires the information recipient to:

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

b. Remove or destroy the information that allows the individual to be identified at the earliest time; and

c. Generally 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. Entities Who May Receive Disclosures Under Routine Use

These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974, under which CMS may release information from the PMRS without the consent/authorization of the individual to whom such information pertains. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure is legally permissible, including but not limited to ensuring that the purpose of the disclosure is compatible with the purpose for which the information was collected. We propose to establish the following routine use disclosures of information maintained in the system:

1. To support Agency contractors, consultants, or CMS grantees who have been engaged by the Agency to assist in accomplishment of a CMS function relating to the purposes for this SOR and who need to have access to the records in order to assist CMS.

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 a CMS function relating to purposes for this SOR.

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

2. Pursuant to agreements with CMS to assist another Federal or state agency,

agency of a state government, or an agency established by state law to:

a. Contribute to projects that provide transparency in health care on a broad-scale enabling consumers to compare the quality and price of health care services,

b. Contribute to the accuracy of CMS's proper payment of Medicare benefits,

c. 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

d. Assist Federal/state Medicaid programs which may require PMRS information for purposes related to this system.

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

3. To assist in making the individual physician-level performance measurement results available to Medicare beneficiaries, through a Web site and other forms of data dissemination, in order to promote more informed choices by Medicare beneficiaries among their Medicare coverage options.

This information would be made available to Medicare beneficiaries for the purpose of, and in a manner that would promote more informed choices by Medicare beneficiaries among their Medicare coverage options (i.e., the Medicare Advantage local or Regional plans offered in their area, and original fee-for-service Medicare).

4. To provide Chartered Value Exchanges (CVE) and data aggregators with information that will assist in generating single or multi-payer performance measurement results that will assist beneficiaries in making informed choices among individual physicians, practitioners and providers of services; enable consumers to compare the quality and price of health care services; and assist in providing transparency in health care at the local level if CMS:

a. Determines that the use or disclosure does not violate legal limitations under which the record was provided, collected, or obtained;

b. Determines that the purpose for which the disclosure is to be made:

(1) 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

(2) There is reasonable probability that the objective for the use would be accomplished;

c. Requires the recipient of the information to establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record;

d. Make no further use or disclosure of the record except:

(1) For use in another project providing transparency in health care, under these same conditions, and with written authorization of CMS; and

(2) When required by law.

e. Secures a written statement attesting to the information recipient's understanding of and willingness to abide by these provisions. CVEs and data aggregators should complete a Data Use Agreement (CMS Form 0235) in accordance with current CMS policies.

The disclosure of PMRS information to CVEs or data aggregators will support the generation of single or multi-payer performance measurement results that will provide a more comprehensive view of physician performance for Medicare beneficiaries. Both identifiable physician level information and patient de-identified information may be made available to CVEs to enable them to provide transparency in health care on a local level. Identifiable physician and patient level information may be provided to data aggregators that are HIPAA business associates of CMS to conduct CMS' health care operations (including working with other providers, payers, or other HIPAA covered entities to generate single and multi-payer performance information).

5. To assist individual physicians, practitioners, providers of services, suppliers, laboratories, and other health care professionals who are participating in health care transparency projects.

PMRS data will be released to the individual physician only on those individuals who received services ordered or provided by the individual physician and shall be limited to claims and utilization data necessary to perform that specific project function whose information was provided for the PMRS project. Individual physicians, practitioners, providers of services, suppliers, laboratories, and other health care professionals require PMRS information for the purpose of direct feedback with respect to their individual patients on a non-aggregated basis.

PMRS information is needed in order to support evaluations, establish the validity of evidence, or to verify the accuracy of information presented by the individual physician as it concerns the patient's entitlement to benefits and for services provided.

6. To assist an individual or organization with projects that provide transparency in health care on a broad-scale enabling consumers to compare the quality and price of health care services; or for research, evaluation, and epidemiological projects related to the prevention of disease or disability; restoration or maintenance of health or for payment purposes if CMS:

a. Determines that the use or disclosure does not violate legal limitations under which the record was provided, collected, or obtained;

b. Determines that the purpose for which the disclosure is to be made:

(1) Cannot be reasonably accomplished unless the record is provided in individually identifiable form,

(2) 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

(3) There is reasonable probability that the objective for the use would be accomplished;

c. Requires the recipient of the information to:

(1) Establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, and

(2) Remove or destroy the information that allows the individual to be identified at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the project, unless the recipient presents an adequate justification of a research or health nature for retaining such information, and

(3) Make no further use or disclosure of the record except:

(a) For disclosure to a properly identified person, for purposes of providing transparency in health care enabling consumers to compare the quality and price of health care services so that they can make informed choices among individual physicians, practitioners and providers of services;

(b) In emergency circumstances affecting the health or safety of any individual;

(c) For use in another research project, under these same conditions, and with written authorization of CMS;

(d) For disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit; or

(e) When required by law.

d. Secures a written statement attesting to the information recipient's understanding of and willingness to abide by these provisions. Researchers should complete a Data Use Agreement (CMS Form 0235) in accordance with current CMS policies.

PMRS data will provide data for projects that provide transparency in health care on a broad-scale enabling consumers to compare the quality and price of health care services; and research evaluation; and epidemiological projects with a broader, longitudinal, national perspective of the status of health care provided to 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.

7. 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.

QIOs will work to implement quality improvement programs, provide consultation to CMS, its contractors, and to state agencies. QIOs will assist the state agencies in related monitoring and enforcement efforts, assist CMS and intermediaries in program integrity assessment, and prepare summary information for release to CMS.

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

9. To assist a CMS contractor (including, but not limited to MACs, 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 contract or grant with a third party to assist in accomplishing CMS functions relating to the purpose of combating fraud, waste or abuse.

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 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.

10. 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 PMRS information for the purpose of combating fraud, waste or abuse in such Federally-funded programs.

B. Additional Circumstances 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 Fed. Reg. 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)).

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 National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

V. Effects of the New System on the Rights of Individuals

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. We will only disclose the minimum personal data necessary to achieve the purpose of PMRS.

Disclosure of information from the system will be approved only to the extent necessary to accomplish the purpose of the disclosure. CMS has assigned a higher level of security clearance for the information maintained in this system in an effort to

provide added security and protection of data in this system.

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. 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: September 4, 2007.

Charlene Frizzera,

Chief Operating Officer, Centers for Medicare & Medicaid Services.

SYSTEM No. 09–70–0584

SYSTEM NAME:

• ''Performance Measurement and Reporting System (PMRS),'' HHS/CMS/OCSQ

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive

SYSTEM LOCATION:

CMS Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244–1850 and at various contractor sites.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system contains single and multi-payer, patient de-identified, individual physician-level performance measurement results as well as, clinical and claims information provided by individual physicians, practitioners and providers of services, individuals assigned to provider groups, insurance and provider associations, government agencies, accrediting and quality organizations, and others who are committed to improving the quality of physician services.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains the patient's or beneficiary's name, sex, health insurance claim number (HIC), Social Security Number (SSN), address, date of birth, medical record number(s), prior stay information, provider name and address, physician's name, and/or identification number, date of admission or discharge, other health insurance, diagnosis, surgical procedures, and a statement of services rendered for related charges and other data needed to substantiate claims. The system contains provider characteristics, prescriber identification number(s), assigned provider number(s) (facility, referring/servicing physician), and national drug code information, total charges, and Medicare payment amounts.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for the collection, maintenance, and disclosures from this system is given under provisions of §§ 1152, 1153 (c), 1153(e), 1154, 1160, 1851 (d) and 1862 (g) of the Social Security Act; § 101 of the Tax Relief and Health Care Act of 2006; and §§ 901, 912, and 914 of the Public Health Service Act.

PURPOSE (S) OF THE SYSTEM:

The primary purpose of this system is to support the collection, maintenance, and processing of information promoting the effective, efficient, and economical delivery of health care services, and promoting the quality of services of the type for which payment may be made under title XVIII by allowing for the establishment and implementation of performance measures, and the provision of feedback to physicians. Information in this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed for the Agency or by a contractor, consultant, or a CMS grantee; (2) assist another Federal and/or state agency, agency of a state government, or an agency established by state law; (3) promote more informed choices by Medicare beneficiaries among their Medicare group options by making physician performance measurement information available to Medicare beneficiaries through a Web site and other forms of data dissemination; (4) provide Charted Value Exchanges (CVE) and data aggregators with information that will assist in generating single or multi-payer performance measurement results to promote transparency in health care to members of their community; (5) assist individual physicians, practitioners, providers of services, suppliers, laboratories, and other health care professionals who are participating in health care transparency projects; (6) assist individuals or organizations with projects that provide transparency in health care on a broad-scale, enabling consumers to compare the quality and price of health care services; or for research, evaluation, and epidemiological projects related to the prevention of disease or disability; restoration or maintenance of health or for payment purposes; (7) assist Quality Improvement Organizations; (8) support litigation involving the agency; and (9) combat fraud, waste, and abuse in certain health benefits programs

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

A. *Entities Who May Receive Disclosures Under Routine Use.* These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974, under which CMS may release information from the PMRS without the consent/authorization of the individual to whom such information pertains. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure is legally permissible, including but not limited to ensuring that the purpose of the disclosure is compatible with the purpose for which the information was collected. We propose to establish the following routine use disclosures of information maintained in the system:

1. To support Agency contractors, consultants, or CMS grantees who have been engaged by the Agency to assist in accomplishment of a CMS function relating to the purposes for this SOR and who need to have access to the records in order to assist CMS.

2. Pursuant to agreements with CMS to assist another Federal or state agency, agency of a state government, or an agency established by state law to:

a. Contribute to projects that provide transparency in health care on a broad-scale enabling consumers to compare the quality and price of health care services,

b. Contribute to the accuracy of CMS's proper payment of Medicare benefits,

c. 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

d. Assist Federal/state Medicaid programs which may require PMRS information for purposes related to this system.

3. To assist in making the individual physician-level performance measurement results available to Medicare beneficiaries, through a Web site and other forms of data dissemination, in order to promote more informed choices by Medicare beneficiaries among their Medicare coverage options.

4. To provide Chartered Value Exchanges (CVE) and data aggregators with information that will assist in generating single or multi-payer

performance measurement results that will assist beneficiaries in making informed choices among individual physicians, practitioners and providers of services; enable consumers to compare the quality and price of health care services; and assist in providing transparency in health care at the local level if CMS:

a. Determines that the use or disclosure does not violate legal limitations under which the record was provided, collected, or obtained;

b. Determines that the purpose for which the disclosure is to be made:

(1) Is of sufficient importance to warrant the effect on and/or risk to the privacy of the individual that additional exposure of the record might bring, and

(2) There is reasonable probability that the objective for the use would be accomplished;

c. Requires the recipient of the information to establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record,

d. Make no further use or disclosure of the record except:

(1) For use in another project providing transparency in health care, under these same conditions, and with written authorization of CMS;

(2) When required by law.

e. Secures a written statement attesting to the information recipient's understanding of and willingness to abide by these provisions. CVEs and data aggregators should complete a Data Use Agreement (CMS Form 0235) in accordance with current CMS policies.

5. To assist individual physicians, practitioners, providers of services, suppliers, laboratories, and other health care professionals who are participating in health care transparency projects.

6. To assist an individual or organization with projects that provide transparency in health care on a broad scale, enabling consumers to compare the quality and price of health care services; or for research, evaluation, and epidemiological projects related to the prevention of disease or disability; restoration or maintenance of health or for payment purposes if CMS:

a. Determines that the use or disclosure does not violate legal limitations under which the record was provided, collected, or obtained;

b. Determines that the purpose for which the disclosure is to be made:

(1) Cannot be reasonably accomplished unless the record is provided in individually identifiable form,

(2) 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

(3) There is reasonable probability that the objective for the use would be accomplished;

c. Requires the recipient of the information to:

(1) Establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, and

(2) Remove or destroy the information that allows the individual to be identified at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the project, unless the recipient presents an adequate justification of a research or health nature for retaining such information, and

(3) Make no further use or disclosure of the record except:

(a) For disclosure to a properly identified person, for purposes of providing transparency in health care enabling consumers to compare the quality and price of health care services so that they can make informed choices among individual physicians, practitioners and providers of services;

(b) In emergency circumstances affecting the health or safety of any individual;

(c) For use in another research project, under these same conditions, and with written authorization of CMS;

(d) For disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit; or

(e) When required by law.

d. Secures a written statement attesting to the information recipient's understanding of and willingness to abide by these provisions. Researchers should complete a Data Use Agreement (CMS Form 0235) in accordance with current CMS policies.

7. 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.

8. 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.

9. To assist a CMS contractor (including, but not limited to MACs, 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.

10. To assist another Federal agency or 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 Circumstances 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 Fed. Reg. 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)).

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

STORAGE:

Records are stored on both tape cartridges (magnetic storage media) and

in a DB2 relational database management environment (DASD data storage media).

RETRIEVABILITY:

Information is most frequently retrieved by HICN, provider number (facility, physician, IDs), service dates, and beneficiary state code.

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 National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

Records are maintained with identifiers for all transactions after they are entered into the system for a period of 20 years. Records are housed in both active and archival files. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from the Department of Justice.

SYSTEM MANAGER AND ADDRESS:

Director, Quality Measurement and Health Assessment Group, Office of Clinical Standards and Quality, CMS, Room C1–23–14, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

For purpose of notification, the subject individual should write to the system manager who will require the system name, and the retrieval selection criteria (e.g., HICN, Provider number, etc.).

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:

Medicare Beneficiary Database (09–70–0536), National Claims History File (09–70–0558), and private physicians, private providers, laboratories, other providers and suppliers who are participating in health care transparency projects sponsored by the Agency.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. E7–17907 Filed 9–11–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0230]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Information From United States Processors That Export to the European Community

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 12, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0320. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Information From U.S. Processors That Export to the European Community—(OMB Control Number 0910–0320)—Extension

The European Community (EC) is a group of 27 European countries that have agreed to harmonize their commodity requirements to facilitate commerce among member states. EC legislation for intra-EC trade has been extended to trade with non-EC countries, including the United States. For certain food products, including those listed in this document, EC legislation requires assurances from the responsible authority of the country of origin that the processor of the food is in compliance with applicable regulatory requirements.

FDA requests information from processors that export certain animal-derived products (e.g., shell eggs, dairy products, game meat, game meat products, animal casings, and gelatin) to the EC. FDA uses the information to maintain lists of processors that have demonstrated current compliance with U.S. requirements and provides the lists to the EC quarterly. Inclusion on the list is voluntary. EC member countries refer to the lists at ports of entry to verify that products offered for importation to the EC from the United States are from processors that meet U.S. regulatory requirements. Products processed by firms not on the lists are subject to