4. Should fees collected from industry be used to pay for other costs FDA incurs to ensure that drugs in the American marketplace are safe and effective? Such additional costs might include monitoring adverse drug reactions, monitoring drug advertising, and routine surveillance, inspection and testing of drug manufacturers.

III. Comments

Interested persons may submit written comments to the Dockets Management Branch (address above), or via e-mail to FDADockets@oc.fda.gov, or via the Internet at http://www.accessdata.fda.gov/scripts/oc/dockets/commentsdocket.cfm. by October 31, 2000. Comments are to be identified with the docket number found in brackets in the heading of this document. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Transcripts

You may request a transcript of the PDUFA public meeting in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 10 cents per page. You may also examine the transcript of the meeting after September 30, 2000, at the Dockets Management Branch between 9 a.m. and 4 pm., Monday through Friday, as well as on the Internet at http://www.fda.gov/oc/pdufa2/meeting2000.html.

Dated: July 25, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–19301 Filed 8–3–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–10015]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection;

Title of Information Collection: Evaluation of the Qualified Medicare Beneficiary (QMB) and Specified Low-Income Medicare Beneficiary (SLMB) Programs—Beneficiary Survey;

Form No.: HCFA–10015 (OMB #0938–NEW);

Use: Medicare beneficiaries eligible for the Qualified Medicare Beneficiary (QMB) and Specified Low-Income Medicare Beneficiary (SLMB) Programs will be surveyed. Numerous studies have shown that large numbers of potentially eligible QMB's and SLMB's do not participate in these programs. To further its goals under GPRA, the Health Care Financing Administration (HCFA) needs information on the effects of the QMB and SLMB programs. This project will help HCFA to develop a better understanding of the reasons for the low participation rates among the potential eligibles for both programs. Also, it will provide HCFA with information on the awareness of the QMB and SLMB programs; the paths and barriers to QMB and SLMB enrollment and the benefits of the QMB and SLMB coverage;

Frequency: Other: One-Time;

Affected Public: Individuals or Households;

Number of Respondents: 1,500;

Total Annual Responses: 1,500;

Total Annual Hours: 500.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan (HCFA–10015), Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

July 13, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–19308 Filed 8–3–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Privacy Act of 1974; Report of New System

AGENCY: Health Care Financing, Department of Health and Human Services (HHS), Administration (HCFA).

ACTION: Notice of new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system of records, ''National Emphysema Treatment Trial (NETT) System, HHS/HCFA/CHPP, 09–70–0531.'' HCFA and the National Heart, Lung and Blood Institute, which is part of the National Institutes of Health, are collaborating on an effort to study the effectiveness of lung volume reduction surgery. The study is called ''National Emphysema Treatment Trial.'' The purpose of this multi-center randomized study is to evaluate the long-term outcomes of lung volume reduction surgery on function, morbidity and mortality, and to define appropriate patient selection criteria in order to determine which patients will likely benefit from lung volume reduction surgery.

The primary purpose of the system of records is to maintain data that will allow HCFA to collect and provide secure data on participants in the randomized phase of the study, pay claims, and to monitor and evaluate the clinical trial. Information retrieved from this system of records will also be disclosed to: support regulatory, reimbursement and policy functions performed within the agency or by a contractor or consultant, another federal or state agency 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, support research, evaluation, or epidemiological projects related to the prevention of disease or disability, or the restoration or maintenance of health, and for payment related projects, support constituent requests made to a congressional representative, support litigation involving the agency, and, combat fraud and abuse in certain health benefits programs. We have provided background information about the proposed system in the ''Supplementary Information'' section below. Although the Privacy Act requires only that HCFA provide an opportunity for interested persons to comment on the proposed routine uses, HCFA invites comments on all portions of this notice. See ''Effective Dates'' section for comment period.

EFFECTIVE DATES: HCFA filed a new system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on July 18, 2000. To ensure that all parties have adequate time in which to comment, the new system of records, including routine uses, will become effective 40 days from the publication of the notice, or from the date it was submitted to OMB and the Congress, whichever is later, unless HCFA receives comments that require alterations to this notice.

ADDRESSES: The public should address comments to: Director, Division of Data Liaison and Distribution (DDLD), HCFA, 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: Steven Sheingold, Ph.D., HCFA, Center for Health Plans and Providers, 7500 Security Boulevard, C4–10–07, Baltimore, Maryland 21244–1850. His telephone number is (410) 786–5896.

SUPPLEMENTARY INFORMATION:

I. Description of the Modified System of Records

A. Background

HCFA and the National Heart, Lung and Blood Institute, which is part of the National Institutes of Health, are collaborating on an effort to study the effectiveness of lung volume reduction surgery. The purpose of this multi-center randomized study is to evaluate the long-term outcomes of lung volume reduction surgery on function, morbidity and mortality, and to define appropriate patient selection criteria. Data related to health care services furnished to Medicare beneficiaries participating in the NETT will be collected and used to monitor and evaluate the trial and its interventions. The trial is designed to:

- Establish a multi-center randomized clinical trial in association with a prospective registry to evaluate the long-term efficacy, morbidity and mortality associated with intensive medical therapy with lung volume reduction surgery as compared with intensive medical therapy alone.
- Define patient selection criteria in order to determine which patients will likely benefit from lung volume reduction surgery.

The NETT contains information on beneficiaries participating in the study. HCFA and its evaluation contractor will use this information to monitor and evaluate the trial and its interventions. Individual patient data will be collected on the HCFA claim forms for fee-for-services and Medicare managed-care beneficiaries. The trial was scheduled to began in 1997 and will continue for 7 years from its actual start date or until the recruitment goal of 2600 patients is attained, whichever comes first.

B. Statutory and Regulatory Basis for System of Records

Authority for maintenance of the system is given under Section 1862(a)(1)(A) of the Social Security Act, and 42 U.S.C. 1395, which states that Medicare must provide coverage for items and services that are ''reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.''

II. Collection and Maintenance of Data in the System.

A. Scope of the Data Collected

The system of records will contain information about Medicare beneficiaries with emphysema, as well as referring and servicing physicians. Utilization and frequency of specific health care services, the provider, and the sites of services are provided as part of the trial. The system will also contain the beneficiary's name, address, date of birth, sex, health insurance claim number (HIC), telephone number, marital status, clinical outcomes, and morbidity and mortality rates.

B. 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 which 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 NETT information that can be associated with an individual as provided for under ''Section III. Entities Who May Receive Disclosures Under Routine Use.'' Both identifiable and non-identifiable data may be disclosed under a routine use.

We will only disclose the minimum personal data necessary to achieve the purpose of NETT. HCFA has the following policies and procedures concerning disclosures of information which will be maintained in the system. In general, disclosure of information from the system of records will be approved only to the extent necessary to accomplish the purpose of the disclosure and only after HCFA:

(a) Determines that the use or disclosure is consistent with the reason that the data is being collected, e.g., developing and monitoring the quality of care provided to patients in the study, to monitor and evaluate the trial and its interventions.

(b) Determines:

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

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

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

(c) Requires the information recipient to:

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

(2) Remove or destroy at the earliest time all patient-identifiable information.

(d) Determines that the data are valid and reliable.

III. Proposed Routine Use Disclosures of Data in the System

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 HCFA may release

information from the NETT without the consent 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. In addition, our policy will be to prohibit release even of non-identifiable data, except pursuant to one of the routine uses, if 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). 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 HCFA may enter into a contractual or similar agreement with a third party to assist in accomplishing HCFA function relating to purposes for this system of records.

HCFA occasionally contracts out certain of its functions when this would contribute to effective and efficient operations. HCFA 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 to return or destroy all information at the completion of the contract.

2. To another federal or state agency:

(1) To contribute to the accuracy of HCFA's proper payment of Medicare benefits, and/or

(2) To 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 NETT information in order to support evaluations and monitoring of Medicare claims information of beneficiaries who are participating in the study, including proper reimbursement for services provided.

3. 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 NETT data will provide the research, evaluations and epidemiological projects a broader, longitudinal, national perspective of the status of patients participating in the study. HCFA 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. HCFA understands the concerns about the privacy and confidentiality of the release of data for a research use.

4. To a member of congress or to a congressional staff member in response to an inquiry of the congressional office made at the written request of the constituent about whom the record is maintained.

Beneficiaries sometimes request the help of a member of congress in resolving some issue relating to a matter before HCFA. The member of congress then writes HCFA, and HCFA must be able to give sufficient information to be responsive to the inquiry.

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

(a) The agency or any component thereof, or

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

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

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

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

6. To HCFA contractors, including but not necessarily limited to fiscal intermediaries and carriers under Title XVIII of the Social Security Act; to administer some aspect of a HCFA-administered health benefits program, or to a grantee of a HCFA-administered grant program, which program is or could be affected by fraud and abuse, for the purpose of preventing, deterring, discovering, detecting, investigating, examining, prosecuting, suing with respect to, defending against, correcting, remedying, or otherwise combating such fraud and abuse in such programs.

We contemplate disclosing information under this routine use only in situations in which HCFA may enter into a contractual or similar agreement with a third party to assist in accomplishing HCFA functions relating to purposes for this system of records.

HCFA occasionally contracts out certain of its functions when this would contribute to effective and efficient operations. HCFA must be able to give a contractor whatever information is necessary for the contractor to fulfill its duties. In these situations, safeguards (like ensuring that the purpose for which the disclosure is to be made is of sufficient importance to warrant the effect and/or risk on the privacy of the individual that additional exposure of the record might bring and those stated in II.B above), are provided in the contract prohibiting the contractor from using or disclosing the information for any purpose other than that described in the contract and to return or destroy all information.

7. To another federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States, including any state or local government agency, for the purpose of preventing, deterring, discovering, detecting, investigating, examining, prosecuting, suing with respect to, defending against, correcting, remedying, or otherwise combating such fraud and abuse in health benefits program funded in whole or in part by federal funds.

Other state agencies in their administration of a Federal health program may require NETT information for the purpose of preventing, deterring, discovering, detecting, investigating, examining, prosecuting, suing with respect to, defending against, correcting, remedying, or otherwise combating such fraud and abuse in such programs.

IV. Safeguards

A. Authorized Users

Personnel having access to the system have been trained in Privacy Act requirements. Employees who maintain records in the system are instructed not to release any data until the intended recipient agrees to implement appropriate administrative, technical, procedural, and physical safeguards

sufficient to protect the confidentiality of the data and to prevent authorized access to the data. Records are used in a designated work area and system location is attended at all times during working hours.

To assure security of the data, the proper level of class user is assigned for each individual user level. This prevents unauthorized users from accessing and modifying critical data. The system database configuration includes five classes of database users:

- Database Administrator class owns the database objects (*e.g.*, tables, triggers, indexes, stored procedures, packages) and has database administration privileges to these objects.
- Quality Control Administrator class has read and write access to key fields in the database;
- Quality Indicator (QI) Report Generator class has read-only access to all fields and tables;
- Policy Research class has query access to tables, but are not allowed to access confidential patient identification information; and
- Submitter class has read and write access to database objects, but no database administration privileges. This class is used by the NETT data submission applications to receive and validate file uploads.

B. Physical Safeguards

All server sites have implemented the following minimum requirements to assist in reducing the exposure of computer equipment and thus achieve an optimum level of protection and security for the NETT system.

Access to all servers is controlled, with access limited to only those support personnel with a demonstrated need for access. Servers are to be kept in a locked room accessible only by specified management and system support personnel. Each server requires a specific log on process. All entrance doors are identified and marked. A log is kept of all personnel who were issued a security card, key and/or combination which grants access to the room housing the server, and all visitors are escorted while in this room. All servers are housed in an area where appropriate environmental security controls are implemented, which include measures implemented to mitigate damage to AIS resources caused by fire, electricity, water and inadequate climate controls.

Protection applied to the workstations, servers and databases include:

- User Log-ons—Authentication is performed by the Primary Domain Controller/Backup Domain Controller of the log-on domain.
- Workstation Names—Workstation naming conventions may be defined and implemented at the agency level.
- Hours of Operation—May be restricted by Windows NT. When activated all applicable processes will automatically shut down at a specific time and not be permitted to resume until the predetermined time. The appropriate hours of operation are determined and implemented at the agency level.
- Inactivity Log-out—Access to the NT workstation is automatically logged out after a specified period of inactivity.
- Warnings—Legal notices and security warnings display on all servers and workstations.
- Remote Access Services (RAS)—Windows NT RAS security handles resource access control. Access to NT resources is controlled for remote users in the same manner as local users, by utilizing Windows NT file and sharing permissions. Dial-in access can be granted or restricted on a user-by-user basis through the Windows NT RAS administration tool.

There are several levels of security found in the NETT system. Windows NT provides much of the overall system security. The Windows NT security model is designed to meet the C2-level criteria as defined by the U.S. Department of Defense's Trusted Computer System Evaluation Criteria document (DoD 5200.28–STD, December 1985). Netscape Enterprise Server is the security mechanism for all NETT transmission connections to the system. As a result, Netscape controls all NETT information access requests. Anti-virus software is applied at both the workstation and NT server levels.

Access to different areas on the Windows NT server are maintained through the use of file, directory and share level permissions. These different levels of access control provide security that is managed at the user and group level within the NT domain. The file and directory level access controls rely on the presence of an NT File System (NTFS) hard drive partition. This provides the most robust security and is tied directly to the file system. Windows NT security is applied at both the workstation and NT server levels.

C. Procedural Safeguards

All automated systems must comply with federal laws, guidance, and policies for information systems security. These include, but are not limited to: the Privacy Act of 1974, the Computer Security Act of 1987, OMB Circular A–130, revised, IRM Circular #10, HHS Automated Information Systems Security Program, the HCFA Information Systems Security Policy and Program Handbook, and other HCFA systems security policies. Each automated information system should ensure a level of security commensurate with the level of sensitivity of the data, risk, and magnitude of the harm that may result from the loss, misuse, disclosure, or modification of the information contained in the system.

V. Effects of the Proposed System of Records on Individual Rights

HCFA 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.

HCFA will take precautionary measures (see item IV. above) to minimize the risks of unauthorized access to the records and the potential harm to individual privacy or other personal or property rights of patients whose data is maintained in the system. HCFA will collect only that information necessary to perform the system's functions. In addition, HCFA 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.

HCFA, therefore, does not anticipate an unfavorable effect on individual privacy as a result of the disclosure of information relating to individuals.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

09–70–0531

SYSTEM NAME:

''National Emphysema Treatment Trial (NETT) System, HHS/HCFA/CHPP''.

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive Data.

SYSTEM LOCATION:

HCFA Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244–1850.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system of records will contain information about Medicare beneficiaries with emphysema enrolled

in the randomized phase of the trial, as well as referring and servicing physicians.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system of records will contain information about Medicare utilization and frequency of specific health care services, the provider and provider's speciality, provider's location or sites of services, cost of surgery, medical or pulmonary rehabilitation, extra-site therapy, medical services necessary for treatment, and self-administered drug therapy. The system will also contain the beneficiary's name, address, date of birth, sex, health insurance claim number (HIC), telephone number, marital status, clinical outcomes, and morbidity and mortality rates.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for maintenance of the system is given under section 1862 (a)(1)(A) of the Social Security Act (the Act), and 42 U.S.C. 1395.

PURPOSE(S):

The primary purpose of the system of records is to maintain data that will allow HCFA to collect and provide secure data on participants in the randomized phase of the study, pay claims, and to monitor and evaluate the clinical trial. Information retrieved from this system of records will also be disclosed to: support regulatory, reimbursement and policy functions performed within the agency or by a contractor or consultant, another federal or state agency 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, support research, evaluation, or epidemiological projects related to the prevention of disease or disability, or the restoration or maintenance of health, and for payment related projects, support constituent requests made to a congressional representative, support litigation involving the agency, and, combat fraud and abuse in certain health benefits programs.

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

The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose which 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 use in this system meets the compatibility requirement of the Privacy Act. We are proposing to establish the following routine use disclosures of information which will be 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 another federal or state agency:

(1) To contribute to the accuracy of HCFA's proper payment of Medicare benefits, and/or

(2) To enable such agency to administer a federal health benefits program, or as necessary to enable such agency to fulfill a requirement of a federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds.

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

4. To a member of congress or to a congressional staff member in response to an inquiry of the congressional office made at the written request of the constituent about whom the record is maintained.

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

(a) The agency or any component thereof, or

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

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

(d) The United States Government

is a party to litigation or has an interest in such litigation, and by careful review, HCFA determines that the records are both relevant and necessary to the litigation.

6. To HCFA contractors, including but not necessarily limited to fiscal intermediaries and carriers under title XVIII of the Social Security Act; to administer some aspect of a HCFA-administered health benefits program, or to a grantee of a HCFA-administered grant program, which program is or could be affected by fraud and abuse, for the purpose of preventing, deterring, discovering, detecting, investigating, examining, prosecuting, suing with respect to, defending against, correcting, remedying, or otherwise combating such fraud and abuse in such programs.

7. To another federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States, including any state or local government agency, for the purpose of preventing, deterring, discovering, detecting, investigating, examining, prosecuting, suing with respect to, defending against, correcting, remedying, or otherwise combating such fraud and abuse in health benefits program funded in whole or in part by Federal funds.

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

STORAGE:

The records are stored in file folders, magnetic tapes and computer disks.

RETRIEVABILITY:

The Medicare and Medicaid records are retrieved by health insurance claim number.

SAFEGUARDS:

HCFA has safeguards 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 systems security requirements. Employees who maintain records in the system are instructed not to release any data until the intended recipient agrees to implement appropriate administrative, technical, procedural, and physical safeguards sufficient to protect the confidentiality of the data and to prevent unauthorized access to the data.

In addition, HCFA has physical safeguards in place to reduce the exposure of computer equipment and thus achieve an optimum level of protection and security for the NETT system. For computerized records, safeguards have been established in accordance with HHS standards and National Institute of Standards and Technology guidelines, *e.g.,* security codes will be used, limiting access to authorized personnel. System securities are established in accordance with HHS, Information Resource Management (IRM) Circular #10, Automated Information Systems Security Program, HCFA Automated Information Systems (AIS) Guide, Systems Securities Policies, and OMB Circular No. A–130 (revised), Appendix III.

RETENTION AND DISPOSAL:

HCFA will retain identifiable data for a total period of fifteen (15) years from the date the information was last updated.

SYSTEM MANAGER AND ADDRESS:

HCFA, Director, Center for Health Plans and Providers, Program Analysis

and Performance Measurement Group, 7500 Security Blvd., 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, health insurance claim number, address, date of birth, sex, 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:

The NETT will use Medicare enrollment records, Medicare beneficiaries or proxies, and medical providers (such as physicians, medical facilities, home health care providers) for a sample of enrollees.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 00–18548 Filed 8–3–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Privacy Act of 1974; Report of Modified or Altered System

AGENCY: Health Care Financing Administration (HCFA), Department of Health and Human Services (HHS).

ACTION: Notice of 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 a SOR, ''Explanation of Medicare Benefits Records (EOMB), HHS/HCFA/BPO, System No. 09–70–0513.'' We are proposing to change the name of the SOR to ''Medicare Benefits Notices (MBN), HHS/HCFA/CBS, System No. 09–70–0513.'' We are also proposing to add one new routine use for contractors and consultants, update any sections of the SOR that were affected by the recent reorganization, and to update language in the administrative sections to correspond with language used in other HCFA SOR. The primary purpose of the SOR to provide an explanation of Medicare claims processed and to advise beneficiaries of supplemental insurance, deductible status, appeals information and general Medicare information. Information retrieved from this SOR will be used to support regulatory and policy functions performed within the agency or by a contractor or consultant, support constituent requests made to a congressional representative, and to support litigation involving the agency related to this SOR. We have provided background information about the proposed system in the ''Supplementary Information'' section below. Although the Privacy Act requires only that HCFA provide an opportunity for interested persons to comment on the proposed routine uses, HCFA invites comments on all portions of this notice. See ''Effective Dates'' section for comment period.

EFFECTIVE DATES: HCFA 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 Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on July 18, 2000. To ensure that all parties have adequate time in which to comment, the modified or altered SOR, including routine uses, will become effective 40 days from the publication of the notice, or from the date it was submitted to OMB and the Congress, whichever is later, unless HCFA receives comments that require alterations to this notice.

ADDRESSES: The public should address comments to: Director, Division of Data Liaison and Distribution (DDLD), HCFA, 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: Maria Ramirez, Division of Contractor Customer Service Operations, Center for Beneficiary Services, HCFA, C2–02–10, 7500 Security Boulevard, Baltimore, Maryland, 21244–1850. The telephone number is 410–786–1122.

SUPPLEMENTARY INFORMATION:

I. Description of the Modified SOR

Statutory and Regulatory Basis for SOR

In 1981, HCFA established a SOR under the authority of sections 205, 226, 1811, and 1832 of Title XVIII of the Social Security Act (42 U.S.C. 405, 426, 1395c, and 1395k). Notice of this system, ''Explanation of Medicare Benefits Records, (EOMB),'' HHS/HCFA/BPO, System No. 09–70–0513, was published in the **Federal Register** on October 27, 1981 (46 FR 52706). These regulations established the requirement that an explanation of Medicare benefits be sent to beneficiaries advising them of Medicare benefits remaining, and whether the various deductible requirements have been satisfied.

II. Collection and Maintenance of Data in the System.

A. Scope of the Data Collected

The system includes Medicare hospital insurance benefits records, Part B benefits records, home health benefits records, and Medicare hospital benefits records. These are notices of utilization and explanation of Medicare benefits. They also advise beneficiaries of supplementary insurance, deductible status, appeals information, and general Medicare information.

B. 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 MBN information as provided for under ''Section III. Entities Who May Receive Disclosures Under Routine Use.''

We will only disclose the minimum personal data necessary to achieve the purpose of MBN. HCFA has the following policies and procedures concerning disclosures of information which will be maintained in the system. In general, disclosure of information from the SOR will be approved only for the minimum information necessary to accomplish the purpose of the disclosure after HCFA:

(a) Determines that the use or disclosure is consistent with the reason that the data is being collected, *e.g.,*