

(unapproved) full or abbreviated applications received by the agency prior to February 19, 1998, sponsors have until the time of next revision of their labels or by February 19, 2003, whichever comes first, to comply with the amendments and they must report these minor changes in their next annual report. The guidance also advises that full or abbreviated applications received by FDA after February 19, 1998, should provide labels and labeling in compliance with the amendments.

This revised guidance document represents the agency's current thinking on implementation of the elimination of certain labeling requirements. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 10, 1998.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 98-19317 7-20-98; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[HCFA-R-193]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

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, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the 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:** Extension of a currently approved collection; **Title of Information Collection:** "An Important Message from Medicare." and Supporting Regulations 42 CFR 466.78, 489.27, .20; **Form No.:** HCFA-R-193, OMB # 0938-0692; **Use:** Hospitals participating in the Medicare program have agreed to distribute "An Important Message from Medicare" to beneficiaries during each admission. Receiving this information will provide the beneficiary with some ability to participate and/or initiate discussions concerning discussions affecting Medicare coverage or payment and about his or her appeal rights in response to any hospitals notice to the effect that Medicare will no longer cover continued care in the hospital. **Frequency:** Other, as needed; **Affected Public:** Individuals or Households, Business or other for-profit, Not-for-profit, Federal Government, State, Local, or Tribal Government; **Number of Respondents:** 6,700; **Total Annual Responses:** 11,000,000.; **Total Annual Hours:** 183,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, E-mail your request, including your address and phone number, to [Paperwork@hcfa.gov](mailto: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 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: July 9, 1998.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.*

[FR Doc. 98-19386 Filed 7-20-98; 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:** Department of Health and Human Services (HHS), Health Care Financing 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, called "End-Stage Renal Disease (ESRD) Managed Care Demonstration System," HHS/HCFA/OSP No. 09-70-0067. We have provided background information about the proposed new system in the **SUPPLEMENTARY INFORMATION** section below. Although the Privacy Act requires only that the "routine uses" portion of the system be published for comment, HCFA invites comments on all portions of this notice.

**DATES:** HCFA filed a new system report with the Chairman of the Committee on Government Reform and Oversight of the House of Representatives, the Chairman of the Committee on Governmental Affairs of the Senate, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), on July 9, 1998. The new system of records, including routine uses, will become effective 40 days from the date submitted to OMB and the Congress, unless HCFA receives comments which require alteration to this notice.

**ADDRESSES:** The public should address comments to the HCFA Privacy Act Officer, Division of Freedom of Information & Privacy, Office of Information Services, Health Care Financing Administration, 7500 Security Boulevard, C2-01-11, Baltimore, Maryland 21244-1850. Comments received will be available for review at this location by appointment, Monday through Friday 9 a.m.-3 p.m., eastern time zone.

**FOR FURTHER INFORMATION CONTACT:** Paul Eggers, Office of Strategic Planning, Health Care Financing Administration, 7500 Security Boulevard, C3-24-07, Baltimore, Maryland 21244-1850. His telephone number is (410) 786-6691.

**SUPPLEMENTARY INFORMATION:** The ESRD Managed Care Demonstration System data file contains information on beneficiaries enrolled in the ESRD Managed Care Demonstration. This information will be used by HCFA and its evaluation contractor to monitor and evaluate the demonstration. The system

will include information on utilization of specific health care services, cost and quality of those services, clinical outcomes and effectiveness of care, and patient satisfaction.

Primary data collected by the evaluator and the managed care organizations will be linked to HCFA administrative data to provide information necessary for monitoring and evaluating the demonstration and its interventions. The demonstration is designed to test the feasibility and effectiveness of the following:

- Removal of the barrier to ESRD enrollment. At present, ESRD-eligible beneficiaries cannot enroll in Medicare health maintenance organizations (HMOs) (although they may remain enrolled if they develop ESRD subsequent to enrollment). Under the demonstration, the sites will have year-round open enrollment of ESRD beneficiaries.

- ESRD-focused case management, and the potential benefits to patient, provider, and payer, with particular emphasis on whether outcomes of care are improved.

- Preventive and supportive interventions and more comprehensive benefit coverage for ESRD patients. Section 2355 of the Deficit Reduction Act of 1989, as amended, requires that HCFA pay the demonstration sites a capitation rate based on 100 percent of fee-for-service costs, rather than 95 percent. In order to justify receiving the additional 5 percent, the HMO is obliged to offer extra, non-Medicare-covered benefits beyond those that would have been available in the absence of the demonstration.

- An ESRD capitation rate that adjusts for patient age, cause of renal failure, treatment status, and services as an alternative to both fee-for-service and the current capitation rate for ESRD patients in HMOs, that is unadjusted for demographic or treatment factors.

Individual patient-level data will be collected and linked from a variety of sources, including, but not limited to: Surveys conducted by the evaluation contractor, including those using the Kidney Disease Quality of Life (KDQOL) instrument; data from the End-Stage Renal Disease (ESRD) Program Management and Medical Information System (PMMIS) maintained by HCFA; no-pay claims data submitted by the sites during the course of the demonstration; claims data on fee-for-service comparison patients; and clinical data in regard to dialysis adequacy measures, such as those collected by HCFA's core indicators studies.

The Privacy Act permits us to disclose information without the written consent of individuals for "routine uses"—that is, disclosures that are compatible with the purpose for which we collected the information. The proposed routine uses in the new system meet the compatibility criterion of the statute. We anticipate the disclosures under the routine uses will not result in any unwarranted adverse effects on personal privacy.

Dated: July 9, 1998.

**Nancy-Ann Min DeParle,**  
*Administrator.*

**09-70-0067**

**SYSTEM NAME:**

End-Stage Renal Disease (ESRD) Managed Care Demonstration System, HHS/HCFA/OSP.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Health Care Financing Administration, Office of Information Services, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Medicare ESRD beneficiaries enrolled in the ESRD Managed Care Demonstration and Medicare ESRD beneficiaries in comparison groups.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Individual-level information on demographics, utilization of specific health care services, cost and quality of those services, clinical outcomes and effectiveness of care, and patient satisfaction will be collected.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Authority for maintenance of the system is section 2355 of the Deficit Reduction Act of 1984, Pub. L. 98-369, as amended by section 4207(b)(4) of the Omnibus Budget Reconciliation Act (OBRA) of 1990, Pub. L. 101-508, and as amended by section 13567(b) of OBRA 1993, Pub. L. 103-66.

**PURPOSE(S):**

To collect and maintain information on beneficiaries enrolled in the ESRD Managed Care Demonstration, and ESRD beneficiaries in comparison groups, in order to monitor and evaluate the demonstration.

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

These routine uses specify additional circumstances under which HCFA may

release information from the ESRD Managed Care Demonstration System 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. Also, HCFA will require each prospective recipient of such information to agree in writing to certain conditions to ensure the continuing confidentiality and physical safeguards of the information. More specifically, as a condition of each disclosure under these routine uses, HCFA will, as necessary and appropriate:

(a) Determine that no other Federal statute specifically prohibits disclosure of the information;

(b) Determine that the use or disclosure does not violate legal limitations under which the information was provided, collected, or obtained;

(c) Determine that the purpose for which the disclosure is to be made:

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

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

(3) There is a reasonable probability that the purpose of the disclosure will be accomplished.

(d) Require the recipient of the information to:

(1) Establish reasonable administrative, technical, and physical safeguards to prevent unauthorized access, use, or disclosure of the record or any part thereof. The physical safeguards shall provide a level of security that is at least the equivalent of the level of security contemplated in OMB Circular No. A-130 (revised), Appendix III—*Security of Federal Automated Information Systems* which sets forth guidelines for security plans for automated information systems in Federal agencies;

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

(3) Refrain from using or disclosing the information for any purpose other than the stated purpose under which the information was disclosed; and

(4) Make no further uses or disclosure of the information, except:

(i) To prevent or address an emergency directly affecting the health or safety of an individual;

(ii) For use on another project under the same conditions, provided HCFA has authorized the additional use(s) in writing; or

(iii) When required by law;

(e) Secure a written statement or agreement from the prospective recipient of the information whereby the prospective recipient attests to an understanding of, and willingness to abide by the foregoing provisions and any additional provisions that HCFA deems appropriate in the particular circumstances; and

(f) Determine whether the disclosure constitutes a computer "matching program" as defined in 5 U.S.C. 552a(a)(8). If the disclosure is determined to be a computer "matching program," the procedures for matching agreements as contained in 5 U.S.C. 552a(o) must be followed.

Disclosure may be made:

1. To a Congressional office, from the record of an individual, in response to an inquiry from the Congressional office made at the request of that individual;

2. To the Bureau of Census for use in processing research and statistical data directly related to the programs administered in whole or in part by HCFA;

3. To the Department of Justice, to a court or other tribunal, or to another party before such tribunal, when:

(a) HHS, or any component thereof; or  
(b) Any HHS employee in his or her official capacity; or

(c) Any HHS employee in his or her individual capacity, where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or

(d) The United States, or any agency thereof, where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, the tribunal, or the other party is relevant and necessary to the litigation and would help in the effective representation of the governmental party or interest, provided, however, that in each case HHS determines that such disclosure is compatible with the purpose for which the records were collected.

4. To an individual or organization for a research, demonstration, evaluation, or epidemiological project related to the prevention of disease or disability, the restoration or maintenance of health, or for purposes of determining, evaluating and/or assessing cost, effectiveness,

and/or the quality of health care services provided.

5. To a contractor for the purpose of collating, analyzing, aggregating or otherwise refining or processing records in this system, or for developing, modifying, and/or manipulating automated information systems (ADP) software. Data would also be disclosed to contractors incidental to consultation, programming, operation, user assistance, or maintenance for ADP or telecommunications systems containing or supporting records in the system.

6. To a peer review organization or ESRD network for health care quality improvement projects conducted in accordance with its contract with HCFA.

7. To state Medicaid agencies pursuant to agreements with the Department of Health and Human Services for determining Medicaid and Medicare eligibility of recipients of assistance under titles IV, XVIII, and XIX of the Social Security Act, and for the complete administration of the Medicaid program.

8. To an agency of a state Government, or established by state law, for purposes of determining, evaluating and/or assessing cost, effectiveness, and/or the quality of health care services provided in the state.

9. To another Federal or state agency:

(a) To contribute to the accuracy of HCFA's proper payment of Medicare health benefits, including release to the Social Security Administration for its assistance in the implementation of HCFA's Medicare and Medicaid programs, or

(b) As necessary to enable such agency to fulfill a requirement of a Federal statute or regulation, or a state statute or regulation that implements a program funded in whole or in part with Federal funds.

10. To a HCFA contractor, including but not limited to, fiscal intermediaries and carriers under title XVIII of the Social Security Act, to administer some aspect of a HCFA-administered grant program, which program is or could be affected by fraud or 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 or abuse in such programs.

11. 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 or abuse in a health benefits program funded in whole or in part by Federal funds.

12. To any entity that makes payment for, or oversees administration of, health services, for the purpose of preventing, deterring, discovering, detecting, investigating, examining, prosecuting, suing with respect to, defending against, correcting, remedying, or otherwise combating such fraud or abuse against such entity or the program or services administered by such entity, provided:

(a) Such entity enters into an agreement with HCFA to share knowledge and information regarding actual or potential fraudulent or abusive practices or activities regarding the delivery or receipt of health care services, or regarding securing payment or reimbursement for health care services, or any practice or activity that, if directed toward a HCFA-administered program, might reasonably be construed as actually or potentially fraudulent or abusive;

(b) Such entity does, on a regular basis, or at such times as HCFA may request, fully and freely share such knowledge and information with HCFA, or as directed by HCFA, with HCFA's contractors; and

(c) HCFA determines that it may reasonably conclude that the knowledge or information it has received or is likely to receive from such entity could lead to preventing, deterring, discovering, detecting, investigating, examining, prosecuting, suing with respect to, defending against, correcting, remedying, or otherwise combating fraud or abuse in the Medicare, Medicaid, or other health benefits program administered by HCFA or 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 on magnetic tapes and computer disks.

##### **RETRIEVABILITY:**

The records are retrieved by health insurance claim number.

##### **SAFEGUARDS:**

Access is limited to authorized HCFA personnel and HCFA contractor employees in the performance of their duties. HHS contractors and collaborating researchers are required to comply with the provisions of the Privacy Act, and are required to sign Assurance of Confidentiality Forms (or

Data Security Statements) that are kept on file by the contractor. For computerized records, safeguards established in accordance with Department 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; and HCFA Automated Information Systems (AIS) Guide, Systems Securities Policies, and OMB Circular No. A-130 (revised), Appendix III.

#### RETENTION AND DISPOSAL:

Records are maintained with identifiers as long as needed for program research.

#### SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Strategic Planning (OSP), Health Care Financing Administration, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

#### NOTIFICATION PROCEDURE:

The subject individual should write the system manager, who will require the system name, health insurance claim number, and, for verification purposes, name, address, date of birth, and sex to ascertain whether or not the individual's record is in the system.

#### RECORD ACCESS PROCEDURE:

Same as notification procedures. Requestors should also reasonably specify the record contents being sought. (These access procedures are in accordance with the Department Regulation 45 CFR 5b.5(a)(2).)

#### CONTESTING RECORD PROCEDURES:

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 identifying information contained in these records is obtained from demonstration enrollees, and from the group health plans operating the demonstration and their participating providers. These data will be linked with HCFA administrative data, such as claims and enrollment data.

#### SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 98-19376 Filed 7-20-98; 8:45 am]

BILLING CODE 4120-03-P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Substance Abuse and Mental Health Services Administration (SAMHSA)

#### Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the following meeting of the SAMHSA Special Emphasis Panel II in July 1998.

A summary of the meeting may be obtained from: Ms. Dee Herman, Committee Management Liaison, SAMHSA, Office of Program Planning and Coordination (OPPC), Division of Extramural Activities, Policy, and Review, 5600 Fishers Lane, Room 17-89, Rockville, Maryland 20857. Telephone: (301)443-7390.

Substantive program information may be obtained from the individual named as Contact for the meeting listed below.

The meeting will include the review, discussion and evaluation of individual contract proposals. These discussions could reveal personal information concerning individuals associated with the proposals and confidential and financial information about an individual's proposal. Accordingly, the meeting is concerned with matters exempt from mandatory disclosure in Title 5 U.S.C. 552b(c)(3), (4), and (6) and 5 U.S.C. App. 2, § 10(d).

*Committee Name:* SAMHSA Special Emphasis Panel II.

*Meeting Date:* July 22, 1998.

*Place:* Parklawn Building, Room 12-94, 5600 Fishers Lane, Rockville, MD 20857.

*Closed:* July 22, 1998, 9:00 a.m.—adjournment.

*Contact:* Joan Harrison, Room 12C-05, Parklawn Building, Telephone: (301)594-2811 and FAX: (301)443-3437.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Dated: July 15, 1998.

**Jeri Lipov,**

*Committee Management Officer, Substance Abuse and Mental Health Services Administration.*

[FR Doc. 98-19377 Filed 7-20-98; 8:45 am]

BILLING CODE 4162-20-P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Substance Abuse and Mental Health Services Administration (SAMHSA)

#### Notice of Meetings

Pursuant to Public Law 92-463, notice is hereby given of the following meetings of the SAMHSA Special Emphasis Panels I and II and the Center for Substance Abuse Treatment National Advisory Council in August 1998.

The Special Emphasis Panel I will meet and the meeting will include the review, discussion and evaluation of individual grant applications. These discussions could reveal personal information concerning individuals associated with the applications. Accordingly, the meeting is concerned with matters exempt from mandatory disclosure in Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App. 2, § 10(d).

A summary of the meeting may be obtained from: Ms. Dee Herman, Committee Management Liaison, SAMHSA, Office of Program Planning and Coordination (OPPC), Division of Extramural Activities, Policy, and Review, 5600 Fishers Lane, Room 17-89, Rockville, Maryland 20857. Telephone: (301) 443-7390.

Substantive program information may be obtained from the individual named as Contact for the meeting listed below.

*Committee Name:* SAMHSA Special Emphasis Panel I.

*Meeting Date:* August 3-6, 1998.

*Place:* Hyatt Regency at Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202.

*Closed:* August 3, 1998, 9:00 a.m.—5:00 p.m.; August 6, 1998, 9:00 a.m.—adjournment.

*Contact:* Peggy Thompson, Room 17-75, Parklawn Building, Telephone: (301) 443-5062 and FAX: (301) 443-3437.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

The Special Emphasis Panel I will have another meeting and the meeting will include the review, discussion and evaluation of individual grant applications. These discussions could reveal personal information concerning individuals associated with the applications. Accordingly, the meeting is concerned with matters exempt from mandatory disclosure in Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App. 2, § 10(d).

A summary of the meeting may be obtained from: Ms. Dee Herman, Committee Management Liaison, SAMHSA, Office of Program Planning and Coordination (OPPC), Division of Extramural Activities, Policy, and Review, 5600 Fishers Lane, Room 17-89, Rockville, Maryland 20857. Telephone: (301) 443-7390.