investigational new drug applications and submissions to the National Institutes of Health's Recombinant DNA Advisory Committee as it relates to gene therapy. Representatives from FDA's Center for Biologics Evaluation and Research and the National Institutes of Health's Office of Recombinant DNA Activities will make presentations and answer questions concerning the application process.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the task force. Those desiring to make formal presentations should notify the contact person before September 6, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: July 19, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 95–18503 Filed 7–26–95; 8:45 am]

BILLING CODE 4160–01–F

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, ''Evaluation of, and External Quality Assurance for, the Community Nursing Organization (CNO) Demonstration,'' HHS/HCFA/ORD No. 360–94–30500, 30501. We have provided background information about the proposed 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 Operations 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 21, 1995. 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 this notice or from the date the report was submitted to OMB and the Congress, whichever is later, unless HCFA receives comments which require alterations to this notice.

ADDRESSES: The public should address comments to Richard DeMeo, HCFA Privacy Act Officer, Office of the Associate Administrator for External Affairs, HCFA, Room C2–01–11, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for inspection at this location.

FOR FURTHER INFORMATION CONTACT: Melissa McNiff, Project Officer for the evaluation of the Community Nursing Organization Demonstration and the External Quality Assurance Program, Office of Research and Demonstrations, HCFA, Room C3–21–06, 7500 Security Boulevard, Baltimore, Maryland 21244–1850, Telephone 410–786–8494.

SUPPLEMENTARY INFORMATION: HCFA proposes to initiate a new system of records, collecting data under the authority of section 4079 of Pub. L. 100–203, the Omnibus Budget Reconciliation Act of 1987. The purpose of this system is to provide data necessary to test the operational feasibility of the CNO and examine whether the combination of capitated payment and nurse-case management will promote timely and appropriate use of community nursing and ambulatory care services and reduce the use of costly acute care services. It will further determine the effect of membership in a CNO on a typical beneficiary's use of health services covered under the CNO package and on services such as physician and inpatient hospital care

which are covered by Medicare but which are not part of the CNO plan. This system of records will also provide data necessary to monitor the quality of home health care and selected ambulatory care services furnished by providers participating in the CNO Demonstration.

The external QA contractor will establish a system of records that includes information on the individual patients receiving Medicare coverage for this purpose. The system of records will contain information concerning a patient's name, Health Insurance Claim Number, demographic characteristics, medical diagnoses and conditions, plans of treatment, receipt of services, health and functional status, and utilization of home health services and certain ambulatory care services. HCFA and the QA contractor will collect only that information necessary to perform the system's function. The database will contain a record for each client enrolled in each CNO. Depending on the size of the CNO enrollment, information will be collected on approximately 7,500 Medicare enrollees.

In order to fulfill the objectives and complete the tasks of this contract, the contractor must have individually identifiable records. Since we are proposing to establish this system of records in accordance with the requirements and principles of the Privacy Act, it will not have an unfavorable effect on the privacy or other personal rights of individuals.

The Privacy Act permits us to disclose information without the consent of the individual for a ''routine use''—that is, disclosures which are compatible with the purpose for which we collected the information. The proposed routine uses in the new system meet the compatibility criteria since the information is collected for the purpose of administering the Community Nursing Organization demonstration for which we are responsible. The disclosures under the routine uses will not result in any unwarranted adverse effects on personal privacy.

Dated: July 12, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

09–70–0066

SYSTEM NAME:

Evaluation of, and External Quality Assurance for, the Community Nursing Organization Demonstration.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

The system will be maintained by the evaluation/quality assurance contractor selected by HCFA. Contact the System Manager for the location of the contractor. The system, or portions of the system, may also be maintained at the HCFA Data Center located at 7131 Rutherford Road, Baltimore, MD 21244.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Medicare beneficiaries who receive home health care and certain ambulatory care services from one of the four CNO project sites (Carle Clinic, Mahomet, IL; Carondelet Health Care, Tucson, AZ; Living at Home/Block Nurse Program, St. Paul, MN; Visiting Nurse Service of New York, New York, NY) chosen to participate in the demonstration.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system will contain information concerning a patient's name, Health Insurance Claim Number, demographic characteristics (e.g., sex, age), medical diagnoses and conditions, receipt of service, health and functional status, and utilization of home health services and certain ambulatory care services.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 4079(c)(6) of the Omnibus Reconciliation Act of 1987 (Pub. L. 100–203).

PURPOSE(S)

To provide data necessary to test the feasibility of a capitated nurse-case managed service delivery model and the effect it has on patient care. The system will also provide data necessary to assess and monitor the quality of home health care and selected ambulatory care services rendered by providers participating in the Community Nursing Organization Demonstration.

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

Disclosures may be made:

1. To the CNOs that provided the home health and selected ambulatory care services in order to verify service utilization rates, elicit feedback on evaluation findings, and investigate potential quality problems and notify the CNOs of any confirmed quality problems that are found.

2. 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.

3. To the Bureau of Census for use in processing research and statistical data directly related to the administration of programs under the Social Security Act.

4. 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 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, provided, however, that in each case HHS determines that such disclosure is compatible with the purpose for which the records were collected.

5. To an individual or organization for a research, evaluation, or epidemiological project related to the prevention of disease or disability, or the restoration or maintenance of health if HCFA:

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 a reasonable probability that the objective for the use would be accomplished.

(c) Requires the information recipient 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) In emergency circumstances affecting the health or safety of any individual, or

(b) For use in another research project, under these same conditions, and with written authorization of HCFA, or

(c) 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

(d) When required by law;

d. Secures a written statement attesting to the information recipient's understanding of and willingness to abide by these provisions.

6. 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 ADP software. Data would also be disclosed to contractors incidental to consultation, programming, operation, user assistance, or maintenance for an ADP or telecommunications system containing or supporting records in the system.

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

STORAGE:

Paper and magnetic media.

RETRIEVABILITY:

Records are retrieved by beneficiary name and health insurance claim number.

SAFEGUARDS:

The contractor will maintain all records in secure storage areas accessible only to authorized employees and will notify all employees having access to records of criminal sanctions for unauthorized disclosure of information. For computerized records, safeguards established in accordance with Departmental 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 DHHS Information Resources Manual, Circular #10, Automated Information Systems Security Program; and HCFA Automated Information Systems (AIS) Guide, Systems Security Policies.

RETENTION AND DISPOSAL:

Hardcopy data collection forms and magnetic media with identifiers will be retained in secure storage areas. These records will be retained for 1 year after the termination of the monitoring contract. Records are maintaned with identifiers as long as needed for program research analysis.

SYSTEM MANAGERS AND ADDRESS:

Director, Office of Research and Demonstrations, HCFA, Room C3–25–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

Inquiries and requests for system records should be addressed to the system manager at the address indicated above. The requestor must specify the name, address, and health insurance number.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requestors should also reasonably specify the record contents being sought. These access procedures are in accordance with 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 being sought and the reasons for the correction with supporting justification. These procedures are in accordance with Department Regulation (45 CFR 5b.7).

RECORDS SOURCE CATEGORIES:

Sources of information contained in this records system are expected to include: Data collected from the Medicare claims files; Medicare Statistical Systems; CNO plans of care and related patient records; supplemental patient intake forms prepared by the CNOs; and results of quality assessments conducted by the contractor.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 95–18487 Filed 7–26–95; 8:45 am]

BILLING CODE 4120–03–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–3849–N–03]

Office of the Assistant Secretary for Public and Indian Housing; Fund Availability (NOFA) for Fiscal Year 1995 for Rental Voucher Program and Rental Certificate Program; Correction

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice of Fund Availability (NOFA) for Fiscal Year (FY) 1994 for the Rental Voucher Program and Rental Certificate Program; Correction.

SUMMARY: The Department is publishing a correction to the Notice of Fund Availability (NOFA) published in the **Federal Register** on March 3, 1995 (60 FR 12036), for the Rental Voucher Program and Rental Certificate Program. The fair share allocation areas for the States of Maine, New Hampshire, and Vermont were erroneously combined into one Metropolitan allocation area and one Non-Metropolitan allocation area. Instead, using the principle that each allocation area is supposed to be the smallest possible area, the NOFA should have identified two allocation areas (Metropolitan and Non-Metropolitan) for each State.

DATES AND ADDRESSES: Applications have already been received for these revised allocation areas, in accordance with the original NOFA. Housing agencies do not need to submit any additional application materials.

FOR FURTHER INFORMATION CONTACT: Gerald J. Benoit, Director, Operations Branch, Rental Assistance Division, Office of Public and Indian Housing, Room 4220, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410–8000, telephone (202) 708–0477. Hearing- or speech-impaired individuals may call HUD's TDD number (202) 708-4594. (These telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: The Department discovered that when the original NOFA for the Rental Voucher Program and Rental Certificate Program was published, the allocation areas for the New Hampshire State Office had not been based on the principle of using the smallest possible area, which was used for determining the allocation areas for the other offices. Instead, the States of Maine, New Hampshire, and Vermont had been combined into one area. The total amount of funding for the program operation in those States remains the same, but this correction document