

imported into the United States under 21 U.S.C. 42.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Open board discussion. The board will discuss and select tea standards.

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.

The Commissioner approves the scheduling of meetings at locations outside of the Washington, DC, area on the basis of the criteria of 21 CFR 14.22 of FDA's regulations relating to public advisory committees.

Dated: January 13, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 95-1552 Filed 1-19-95; 8:45 am]

BILLING CODE 4160-01-F

Health Care Financing Administration

Privacy Act of 1974; System of Records

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

ACTION: Notice to propose a name change, purpose change, and the addition of new routine uses for an existing system of records.

SUMMARY: HCFA is proposing to amend the system notice for the "Supplemental Medical Insurance" (SMI) Accounting Collection and Enrollment System (SPACE)," System No. 09-70-0505, by revising the system name, revising the purpose, and by adding new routine uses. Also, sections of this notice have been updated to reference current

addresses and appropriate HCFA components.

HCFA is proposing to change the system name to better reflect the current function of the SPACE system, which now processes Medicare premium billing information for both Part B, SMI, and Part A, HI. The proposed new name is "Supplementary Medical Insurance (SMI) and Hospital Insurance (HI) Premium Accounting, Collection and Enrollment System (SPACE)." Despite the amendment to the system name, the acronym SPACE, which refers to this system, will not be changed.

The purpose of this system of records is being updated to include beneficiaries whose HI benefit premiums are paid by a State Medicaid agency, the U.S. Office of Personnel Management (OPM), or a formal third party group (the latter defined in 42 CFR section 408.80 through section 408.92). The purpose originally only references those beneficiaries whose SMI was paid by these named parties.

HCFA is also proposing to add routine uses, which permit the disclosure of data without the prior written consent of an individual, when the use of a record is for a purpose which is compatible with the purpose for which the record was collected. The proposed new routine uses would permit the disclosure of information to the following parties: OPM, formal third party groups, contractors in connection with the maintenance of automated data processing (ADP) software, and an individual or organization for research. (SEE SUPPLEMENTARY INFORMATION)

EFFECTIVE DATES: HCFA filed an altered system report with the Chair of the House Committee on Government Operations, 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 January 13, 1995. To ensure that all parties have adequate time in which to comment, the revised system of records, including routine uses, will become effective 40 days from the publication of this notice or from the date it is submitted to OMB and the Congress, whichever is later, unless HCFA receives comments which require alterations to this notice.

ADDRESSES: Please address comments to Richard A. DeMeo, HCFA Privacy Act Officer, Office of Customer Relations and Communications, Office of Beneficiary Services, Health Care Financing Administration, Room 2-H-4 East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207-

5187. Comments received will be available at this location.

FOR FURTHER INFORMATION CONTACT: Mr. Samuel N. Guida, Bureau of Program Operations, Office of Contracting and Financial Management, Division of Accounts Management and Collection, Health Care Financing Administration, Room 1-E-5, Meadows East Building, 6325 Security Boulevard, Baltimore, Maryland 21207-5187. His telephone number is (410) 966-7495.

SUPPLEMENTARY INFORMATION: HCFA is proposing to amend the system notice for the "Supplemental Medical Insurance (SMI) Accounting Collection and Enrollment System (SPACE)," System No. 09-70-0505, by revising the system name, revising the purpose, and by adding new routine uses.

HCFA is proposing to change the system name to better reflect the current function of the SPACE system, which now processes Medicare premium billing information for both Part B, SMI, and Part A, HI. The proposed new name is "Supplementary Medical Insurance (SMI) and Hospital Insurance (HI) Premium Accounting, Collection and Enrollment System (SPACE)." Despite the amendment to the system name, the acronym SPACE, which refers to this system, will not be changed.

The SPACE system contains information on Medicare beneficiaries whose HI benefit and/or SMI benefit premiums are paid by a State Medicaid agency, OPM, or formal third party groups. The purpose of this system of records is being updated to include beneficiaries whose HI benefit premiums are paid by a State Medicaid agency, the U.S. Office of Personnel Management (OPM), or a formal third party group (the latter defined in 42 CFR 408.80 through 408.92). The purpose originally only references those beneficiaries whose SMI was paid by a State Medicaid agency.

Also, HCFA is proposing to add routine uses which would permit the disclosure of information to OPM and formal third party groups when necessary to perform monthly premium billing functions, to identify annuitants for whom premium collections must be initiated and to periodically reconcile third party master records. Formal third party groups are defined in 42 CFR 408.80 through 408.92, which discusses the formal group billing arrangement. OPM and formal third party groups are mandated by law to conduct these activities as detailed in both the Social Security Act and the CFR.

Sections 1818 and 1818A of the Act (42 U.S.C. sections 1395i-2 and 1395i-2a) provide for the payment premiums

for HI. Section 1840 of the Act (42 U.S.C. section 1395s) establishes the bases for the payment of premiums for SMI. Also, sections 1818(g) and 1843 of the Act (42 U.S.C. sections 1395i-2(g) and 1395v) provide that a State may enter into a buy-in agreement to secure HI and SMI coverage for certain individuals by paying the premiums on their behalf. These statutory provisions are implemented in HCFA regulations 42 CFR part 406, subpart C; part 408; and part 407, subpart C.

The first proposed new routine use would permit the release of data to OPM when necessary to perform monthly premium billing functions, to identify annuitants for whom premium collections must be initiated and to periodically reconcile third party master records. The second routine use would permit disclosure to formal third party groups for the purpose of paying Medicare premiums on behalf of their members. A third routine use would permit the disclosure of information to a contractor in connection with the maintenance of ADP software. A fourth routine use would permit the disclosure of information to an individual or organization for research. The latter two routine uses are established in all HCFA systems of records and have inadvertently been omitted from the SPACE system. Therefore, we are proposing that they be added to the system at this time.

The proposed new routine uses will be numbered (4), (5), (6) and (7) and will read as follows:

(4) To the Office of Personnel Management in order to perform monthly premium billing functions, to identify annuitants for whom premium collections must be initiated, and to periodically reconcile third party master records.

(5) To formal third party groups pursuant to agreements with the Health Care Financing Administration to pay the Medicare premiums on behalf of their members.

(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 ADP or telecommunications systems containing or supporting records in the system.

(7) To an individual or organization for a research, evaluation, or epidemiologic 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 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 objectives 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 an individual.

b. For use in another research project, under these same conditions, and written authorization of HCFA.

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 the provisions.

Data maintained in the SPACE system are collected for the following purpose: "To process changes to HI/SMI premium payments by third parties (such as State agencies, private groups, Office of Personnel Management) on behalf of Medicare beneficiaries; for billing third parties; and for enrolling individuals for HI/SMI coverage under State buy-in agreements." The proposed new routine uses for the SPACE system are compatible with this purpose and are therefore consistent with the Privacy Act, 5 U.S.C. 552a.

In accordance with OMB Guidelines (Circular A-130, 58 Fed. Reg. 36077 July

2, 1993), this proposed name change, purpose change, and addition of routine uses constitutes a significant change in the system of records. Accordingly, we have prepared a report of an altered system of records under 5 U.S.C. 552a(r). In addition, for the convenience of the reader, we are publishing the notice in its entirety below.

Dated: January 10, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

09-70-0505

SYSTEM NAME:

Supplementary Medical Insurance (SMI) and Hospital Insurance (HI) Premium Accounting, Collection and Enrollment System. HHS/HCFA/BPO

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Health Care Financing Administration, Bureau of Data Management and Strategy, HCFA Data Center, 7131 Rutherford Road, Baltimore, MD 21244.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Health insurance beneficiaries whose supplementary medical insurance (SMI) benefit and/or hospital insurance (HI) benefit premiums are paid by a State Medicaid agency, the U.S. Office of Personnel Management (OPM), or a formal third party group (the latter defined in 42 CFR 408.80 through 408.92).

CATEGORIES OF RECORDS IN THE SYSTEM:

Beneficiary's name, health insurance claim number, date of birth, sex, amount of premium liability, date agency first became liable for HI benefit or SMI benefit premiums, last month of agency premium liability, agency identification numbers, U.S. Office of Personnel Management annuity number.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Sections 1818(e) and (g), 1840(d) and (e), and 1843 of Title XVIII of the Social Security Act (42 U.S.C. 1395i-2(e) and (g), 1395s(d) and (e), and 1395v).

PURPOSES:

To process changes to HI/SMI premium payments by third parties (such as State agencies, OPM, formal third party groups) on behalf of Medicare beneficiaries; for billing third parties; and for enrolling individuals for HI or SMI coverage under State buy-in agreements.

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

Disclosure may be made:

- (1) To State Medicaid agencies pursuant to agreements with the Department of Health and Human Services for enrollment of Medicaid recipients for medical insurance under section 1843 of the Social Security Act.
- (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 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;
 - (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 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.

(4) To the Office of Personnel Management in order to perform monthly premium billing functions, to identify annuitants for whom premium collections must be initiated, and to periodically reconcile third party master records.

(5) To formal third party groups pursuant to agreements with the Health Care Financing Administration to pay the Medicare premiums on behalf of their members.

(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 ADP or telecommunications systems containing or supporting records in the system.

(7) To an individual or organization for a research, evaluation, or epidemiologic 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 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 an individual;
 - b. For use in another research project, under these same conditions, and with written authorization of HCFA;
 - 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 the provisions.

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

STORAGE:

Magnetic media, microfilm.

RETRIEVABILITY:

The system is indexed by health insurance claim number.

SAFEGUARDS:

Only authorized personnel have direct access to information in the

Third-Party Master Record and all personnel are advised that this information is confidential. 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 unauthorized personnel. Systems 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 for Systems Security Policies.

RETENTION AND DISPOSAL:

Tape records are retained for 90 days. Monthly microfilm records are destroyed after 3 years.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Bureau of Program Operations, Health Care Financing Administration, 6325 Security Boulevard, Baltimore, MD 21207.

NOTIFICATION PROCEDURE:

Inquiries and requests for system records should be addressed to the system manager named above and directed to the attention of the Office of Program Operations Procedures, Division of Appeals and Communications. The individual should furnish his or her health insurance claim number and name as shown as Medicare records.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. (The access procedures are in accordance with Department of Health and Human Services (DHHS) Regulations (45 CFR 5b.5(a)(2))).

CONTESTING RECORD PROCEDURES:

Contact the official at the address specified under notification procedures 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 DHHS Regulations (45 CFR 5b.7.))

RECORD SOURCE CATEGORIES:

The identifying information contained in these records is obtained from third-party agencies, the Social Security Administration's Master Beneficiary Record, and the Medicare Enrollment Database.

SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 95-1465 Filed 1-19-95; 8:45 am]

BILLING CODE 4120-03-M

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of February 1995:

Name: National Advisory Council on Migrant Health.
Date and Time: February 24-26, 1994—8:30 a.m.

Place: Radisson Barcelo Hotel, 2121 P Street, N.W., Washington, DC 20037, 202/293-3100.

The meeting is open to the public. Purpose: The Council is charged with advising, consulting with, and making recommendations to the Secretary and the Administrator, Health Resources and Services Administration, concerning the organization, operation, selection, and funding of Migrant Health Centers and other entities under grants and contracts under section 329 of the Public Health Service Act.

Agenda: The agenda includes an overview of Council general business activities and priorities. In addition, to a review and discussion of 1995 National Advisory Council on Migrant Health Recommendations.

The Council meeting is being held in conjunction with the National Association of Community Health Centers, Policy and Issues Forum, February 27-March 1, 1995.

Anyone requiring information regarding the subject Council should contact Susan Hagler, Migrant Health Program, Staff Support to the National Advisory Council on Migrant Health, Bureau of Primary Care, Health Resources and Services Administration, 4350 East West Highway, Room 7A6-1, Rockville, Maryland 20857, Telephone (301) 594-4302.

Agenda Items are subject to change as priorities dictate.

Dated: January 17, 1995.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 95-1437 Filed 1-19-95; 8:45 am]

BILLING CODE 4160-15-P

Office of Inspector General

Program Exclusions: December 1994

AGENCY: Office of Inspector General, HHS

ACTION: Notice of program exclusions.

During the month of December 1994, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, Maternal and Child Health Services Block Grant and Block Grants to States for Social Services programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all other Federal non-procurement programs.

Subject, city, state	Effective date
Program-Related Convictions	
Akpaeti, Imo John, Miami Beach, FL	01/03/95
Ali, Mohamed F., Johnson City, TN	01/03/95
Burlingame, Connie M., Newport Beach, CA	01/04/95
Domotor, Tibor, Akron, OH	01/04/95
Ingram, Donna Elliott, Gulfport, MS	01/03/95
Key Management, Inc., Gulfport, MS	01/03/95
Liverman, Carla D., Murfreesboro, NC	01/03/95
McDaniel, Angela R., Jacksonville, FL	01/03/95
Otiti, Abayomi, Stone Mountain, GA	01/03/95
Piacentile, Joseph, Yardley, PA ..	01/04/95
Pizzi, Wilson B., Waynesburg, PA	01/04/95
Ripps, Daniel N., New York, NY	01/04/95
Rogan, Edward, East Setauket, NY	01/04/95
Runyon, Michael Blake, Calabasas, CA	01/04/95
Teel, Robert Waldo Jr., Gulfport, MS	01/03/95
Tino, Page K., Greeneville, TN ..	01/03/95
Vogel song, James D., McDermott, OH	01/04/95
Walling, Sheryl A., Phoenix, AZ ..	01/04/95
Wilding, Karen Locke, Boulder, CO	01/04/95
Wingate, Spencer A., Decatur, GA	01/03/95

Patient Abuse/Neglect Convictions

Clarke, Correl E., Palm Bay, FL ..	01/04/95
Grewal, Jasbir S., El Cajon, CA ..	01/04/95