Board of Governors of the Federal Reserve System, June 20, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–16264 Filed 6–25–96; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The National Center for Infectious Diseases (NCID), of the Centers for Disease Control and Prevention (CDC) Announces the Following Meeting

Name: Pre-Application Workshop for Program Announcement Number 620: Prevention of the Complications of Hemophilia through Hemophilia Treatment Centers (HTCs).

Time and Date: 11 a.m.–5 p.m., July 2, 1996.

Place: CDC, Building 16, Room 1107A 1600 Clifton Road, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 35 people.

Purpose: The purpose of this meeting is to provide an opportunity for programmatic and business management technical assistance regarding the cooperative agreement, ''Prevention of the Complications of Hemophilia through HTCs.'' An important component of the workshop will be a question and answer session. A summary of the answers will be made available to all eligible applicants upon request.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sarah Wiley, Project Officer, Hematologic Diseases Branch, Division of AIDS, STD, and TB Laboratory Research, NCID, CDC, 1600 Clifton Road, M/S E64, Atlanta, Georgia 30333, telephone 404/639–4026.

Dated: June 20, 1996.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–16288 Filed 6–25–96; 8:45 am]

BILLING CODE 4163–18–M

Agency for Toxic Substances and Disease Registry; Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy Sites: Hanford Health Effects Subcommittee Meeting: Date Change

Federal Register Citation of Previous Announcement: 61 FR 17304—dated April 19, 1996.

SUMMARY: Notice is given that one of the meeting dates for the Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy Sites: Hanford Health Effects Subcommittee, of the Agency for Toxic Substances and Disease Registry (ATSDR), has changed. The meeting place, time, status, purpose, and matters to be discussed, announced in the original notice remain unchanged.

ORIGINAL DATES: September 19–20, 1996.

NEW DATES: September 12–13, 1996.

CONTACT PERSON FOR MORE INFORMATION: Linda A. Carnes, Health Council Advisor, ATSDR, M/S E–28, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639–0730, FAX 404/639–0759.

Dated: June 20, 1996.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–16287 Filed 6–25–96; 8:45 am]

BILLING CODE 4163–70–M

Health Care Financing Administration

[BPO–137–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances and Coverage Decisions—Fourth Quarter 1995

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice lists HCFA manual instructions, substantive and interpretive regulations and other Federal Register notices, and statements of policy that were published during October, November, and December of 1995 that relate to the Medicare and Medicaid programs. It also identifies certain devices with investigational device exemption numbers approved by the Food and Drug Administration that may be potentially covered under Medicare.

Section 1871(c) of the Social Security Act requires that we publish a list of Medicare issuances in the Federal Register at least every 3 months. Although we are not mandated to do so by statute, for the sake of completeness of the listing, we are including all Medicaid issuances and Medicare and Medicaid substantive and interpretive regulations (proposed and final) published during this time frame. We are also providing the content of revisions to the Medicare Coverage Issues Manual published during the period October 1 through December 31, 1995. On August 21, 1989, we published the content of the Manual (54 FR 34555) and indicated that we will publish quarterly any updates. Adding to this listing the complete text of the changes to the Medicare Coverage Issues Manual fulfills this requirement in a manner that facilitates identification of coverage and other changes in our manuals.

FOR FURTHER INFORMATION CONTACT:

Margaret Cotton, (410) 786–5255 (For Medicare instruction information).

Pat Prete, (410) 786–3246 (For Medicaid instruction information).

Sharon Hippler, (410) 786–4633 (For Food and Drug Administration-approved investigational device exemption information).

Cathy Johnson, (410) 786–5241 (For all other information).

SUPPLEMENTARY INFORMATION:

I. Program Issuances

The Health Care Financing Administration (HCFA) is responsible for administering the Medicare and Medicaid programs, which pay for health care and related services for 38 million Medicare beneficiaries and 36 million Medicaid recipients. Administration of these programs involves (1) providing information to Medicare beneficiaries and Medicaid recipients, health care providers, and the public, and (2) effective communications with regional offices, State governments, State Medicaid Agencies, State Survey Agencies, various providers of health care, fiscal intermediaries and carriers that process claims and pay bills, and others. To implement the various statutes on which the programs are based, we issue regulations under the authority granted the Secretary under sections 1102, 1871, and 1902 and related provisions of the Social Security Act (the Act) and also issue various manuals, memoranda, and statements necessary to administer the programs efficiently.

Section 1871(c)(1) of the Act requires that we publish in the Federal Register at least every 3 months a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations. We published our first notice June 9, 1988 (53 FR 21730). Although we are not mandated to do so by statute, for the sake of completeness of the listing of operational and policy statements, we are continuing our practice of including Medicare substantive and interpretive regulations (proposed and final) published during the 3-month time frame. Since the publication of our quarterly listing on June 12, 1992 (57 FR 24797), we decided to add Medicaid issuances to our quarterly listings. Accordingly, we list in this notice Medicaid issuances and Medicaid

substantive and interpretive regulations published during October through December 1995.

II. Medicare Coverage Issues

We receive numerous inquiries from the general public about whether specific items or services are covered under Medicare. Providers, carriers, and intermediaries have copies of the Medicare Coverage Issues Manual, which identifies those medical items, services, technologies, or treatment procedures that can be paid for under Medicare. On August 21, 1989, we published a notice in the Federal Register (54 FR 34555) that contained all the Medicare coverage decisions issued in that manual.

In that notice, we indicated that revisions to the Coverage Issues Manual will be published at least quarterly in the Federal Register. We also sometimes issue proposed or final national coverage decision changes in separate Federal Register notices. Readers should find this an easy way to identify both issuance changes to all our manuals and the text of changes to the Coverage Issues Manual.

Revisions to the Coverage Issues Manual are not published on a regular basis but on an as-needed basis. We publish revisions as a result of technological changes, medical practice changes, responses to inquiries we receive seeking clarifications, or the resolution of coverage issues under Medicare. If no Coverage Issues Manual revisions were published during a particular quarter, our listing will reflect that fact.

Not all revisions to the Coverage Issues Manual contain major changes. As with any instruction, sometimes minor clarifications or revisions are made within the text. This notice contains, as Addendum IV, reprinted manual revisions as transmitted to manual holders. The new text is shown in italics. We have not reprinted the table of contents, since the table of contents serves primarily as a finding aid for the user of the manual and does not identify items as covered or not.

III. How to Use the Addenda

This notice is organized so that a reader may review the subjects of all manual issuances, memoranda, substantive and interpretive regulations, coverage decisions, or Food and Drug Administration-approved investigational device exemptions published during the time frame to determine whether any are of particular interest. We expect it to be used in concert with previously published notices. Most notably, those unfamiliar with a description of our Medicare manuals may wish to review Table I of our first three notices (53 FR 21730, 53 FR 36891, and 53 FR 50577) and the notice published March 31, 1993 (58 FR 16837), and those desiring information on the Medicare Coverage Issues Manual may wish to review the August 21, 1989 publication (54 FR 34555).

To aid the reader, we have organized and divided this current listing into six addenda. Addendum I identifies updates that changed the Coverage Issues Manual. We published notices in the Federal Register that included the text of changes to the Coverage Issues Manual. These updates, when added to material from the manual published on August 21, 1989 constitute a complete manual as of the end of the quarter covered by this notice. Parties interested in obtaining a copy of the manual and revisions should follow the instructions in section IV of this notice.

Addendum II identifies previous Federal Register documents that contain a description of all previously published HCFA Medicare and Medicaid manuals and memoranda.

Addendum III of this notice lists, for each of our manuals or Program Memoranda, a HCFA transmittal number unique to that instruction and its subject matter. A transmittal may consist of a single instruction or many. Often it is necessary to use information in a transmittal in conjunction with information currently in the manuals.

Addendum IV sets forth the revisions to the Medicare Coverage Issues Manual that were published during the quarter covered by this notice. For the revisions, we give a brief synopsis of the revisions as they appear on the transmittal sheet, the manual section number, and the title of the section. We present a complete copy of the revised material, no matter how minor the revision, and identify the revisions by printing in italics the text that was changed. If the transmittal includes material unrelated to the revised section, for example, when the addition of revised material causes other sections to be repaginated, we do not reprint the unrelated material.

Addendum V lists all substantive and interpretive Medicare and Medicaid regulations and general notices published in the Federal Register during the quarter covered by this notice. For each item, we list the date published, the Federal Register citation, the parts of the Code of Federal Regulations (CFR) that have changed (if applicable), the agency file code number, the title of the regulation, the ending date of the comment period (if applicable), and the effective date (if applicable).

On September 19, 1995, we published a final rule (60 FR 48417) establishing in regulations that certain devices with an investigational device exemption approved by the Food and Drug Administration and certain services related to those devices may be covered under Medicare. That final rule states that we will announce in this quarterly notice all investigational device exemption categorizations, using the investigational device exemption numbers the Food and Drug Administration assigns. Addendum VI includes listings of the Food and Drug Administration-approved investigational device exemption numbers that have been approved during the quarter covered by this notice. The listings are organized according to the categories to which the device numbers are assigned (that is, Category A or Category B, and identified by the investigational device exemption number). Future notices will announce investigational device exemption categorizations and the numbers assigned by the Food and Drug Administration for the quarter for which the notices cover.

IV. How to Obtain Listed Material

A. Manuals

An individual or organization interested in routinely receiving any manual and revisions to it may purchase a subscription to that manual. Those wishing to subscribe should contact either the Government Printing Office (GPO) or the National Technical Information Service (NTIS) at the following addresses:

Superintendent of Documents, Government Printing Office, ATTN: New Order, P.O. Box 371954, Pittsburgh, PA 15250–7954, Telephone (202) 512–1800, Fax number (202) 512–2250 (for credit card orders); or

National Technical Information Service, Department of Commerce, 5825 Port Royal Road, Springfield, VA 22161, Telephone (703) 487–4630.

In addition, individual manual transmittals and Program Memoranda listed in this notice can be purchased from NTIS. Interested parties should identify the transmittal(s) they want. GPO or NTIS can give complete details on how to obtain the publications they sell.

B. Regulations and Notices

Regulations and notices are published in the daily Federal Register. Interested individuals may purchase individual copies or subscribe to the Federal Register by contacting the GPO at the

address given above. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The Federal Register is also available on 24x microfiche and as an online database through GPO Access. The online database is updated by 6 a.m. each day the Federal Register is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) forward. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using (1) the World Wide Web—the Superintendent of Documents home page address is http://www.access.gpo.gov/su__docs/; (2) local WAIS client software, or (3) telnet—swais.access.gpo.gov, then login as guest (no password required). Dial-in users should use communications software and modem to call (202) 512–1661; type swais, then login as guest (no password required). For general information about GPO Access, contact the GPO Access User Support Team by sending Internet e-mail to help@eids05.eids gpo.gov; by faxing to (202) 512–1262; or by calling (202) 512–1530 between 7 a.m. and 5 p.m. Eastern time, Monday–Friday, except for Federal holidays.

C. Rulings

We publish Rulings on an infrequent basis. Interested individuals can obtain copies from the nearest HCFA Regional Office or review them at the nearest regional depository library. We also sometimes publish Rulings in the Federal Register.

D. HCFA's Compact Disk-Read Only Memory (CD–ROM)

Our laws, regulations, and manuals are also available on CD–ROM, which may be purchased from GPO or NTIS on a subscription or single copy basis. The Superintendent of Documents list ID is HCLRM, and the stock number is 717–139–00000–3. The following material is on the CD–ROM disk:

- Titles XI, XVIII, and XIX of the Act.
- HCFA-related regulations.
- HCFA manuals and monthly revisions.
- HCFA program memoranda.

The titles of the Compilation of the Social Security Laws are current as of January 1, 1995. The remaining portions of CD–ROM are updated on a monthly basis.

Because of complaints about the unreadability of the Appendices (Interpretive Guidelines) in the State Operations Manual (SOM), as of March 1995, we deleted these appendices from CD–ROM. We intend to re-visit this issue in the near future, and with the aid of newer technology, we may again be able to include the appendices on CD–ROM.

Any cost report forms incorporated in the manuals are included on the CD–ROM disk as LOTUS files. LOTUS software is needed to view the reports once the files have been copied to a personal computer disk.

V. How to Review Listed Material

Transmittals or Program Memoranda can be reviewed at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1400 designated libraries throughout the United States. Interested parties may examine the documents at any one of the FDLs. Some may have arrangements to transfer material to a local library not designated as an FDL. To locate the nearest FDL, contact any library.

In addition, individuals may contact regional depository libraries, which receive and retain at least one copy of most Federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. Superintendent of Documents numbers for each HCFA publication are shown in Addendum III, along with the HCFA publication and transmittal numbers. To help FDLs locate the instruction, use the Superintendent of Documents number, plus the HCFA transmittal number. For example, to find the Carriers Manual, Part 3—Claims Process (HCFA-Pub. 14–3) transmittal entitled ''Self-Administered Drugs and Biologicals,'' use the Superintendent of Documents No. HE 22.8/7 and the HCFA transmittal number 1528.

VI. General Information

It is possible that an interested party may have a specific information need and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing information contact persons to answer general questions concerning these items. Copies are not available through the contact persons. Copies can be purchased or reviewed as noted above.

Questions concerning Medicare items in Addenda III may be addressed to Margaret Cotton, Bureau of Program Operations, Issuances Staff, Health Care Financing Administration, S3–01–27, 7500 Security Blvd., Baltimore, MD 21244–1850, Telephone (410) 786–5255.

Questions concerning Medicaid items in Addenda III may be addressed to Pat Prete, Medicaid Bureau, Office of Medicaid Policy, Health Care Financing Administration, C4–25–02, 7500 Security Boulevard, Baltimore, MD 21244–1850, Telephone (410) 786–3246.

Questions concerning Food and Drug Administration- approved investigational device exemptions may be addressed to Sharon Hippler, Bureau of Policy Development, Office of Chronic Care and Insurance Policy, Health Care Financing Administration, C4–11–04, 7500 Security Blvd., Baltimore, MD 21244–1850, Telephone (410) 786–4633.

Questions concerning all other information may be addressed to Cathy Johnson, Bureau of Policy Development, Office of Regulations, Health Care Financing Administration, C5–09–05, 7500 Security Blvd., Baltimore, MD 21244–1850, Telephone (410) 786–5241.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance, Program No. 93.774, Medicare—Supplementary Medical Insurance Program, and Program No. 93.714, Medical Assistance Program)

Dated: June 6, 1996.

Carol Walton,

Director, Bureau of Program Operations.

Addendum I

This addendum lists the publication dates of the most recent quarterly listing of program issuances and coverage decision updates to the Coverage Issues Manual. For a complete listing of the quarterly updates to the Coverage Issues Manual published during March 20, 1990 through November 14, 1994, please refer to the January 3, 1995 update (60 FR 134).

January 3, 1995 (60 FR 132)
April 6, 1995 (60 FR 17538)
July 26, 1995 (60 FR 38344)
November 15, 1995 (60 FR 57435)
April 8, 1996 (61 FR 15491)

Addendum II—Description of Manuals, Memoranda, and HCFA Rulings

An extensive descriptive listing of Medicare manuals and memoranda was published on June 9, 1988, at 53 FR 21730 and supplemented on September 22, 1988, at 53 FR 36891 and December 16, 1988, at 53 FR 50577. Also, a complete description of the Medicare Coverage Issues Manual was published on August 21, 1989, at 54 FR 34555. A brief description of the various Medicaid manuals and memoranda that we maintain was published on October 16, 1992, at 57 FR 47468.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS

[October through December 1995]

Trans. No.		Manual/Subject/Publication No.
		Intermediary Manual Part 3—Claims Process (HCFA—Pub. 13–3) (Superintendent of Documents No. HE 22.8/6–1)
1662	•	Rural Health Clinics—General
1663	•	Medicare Fraud and Abuse
1664	•	Accessibility Criteria Designated Intermediaries Designated Carriers
1665	•	Review of Form HCFA–1450 for Inpatient and Outpatient Bills Bill Review for Partial Hospitalization Services Provided In Community Mental Health Centers Hospital Outpatient Partial Hospitalization Services
1666	•	Requirements by Record Type and Field (Data Element) for Outpatient Rehabilitative Services
1667	•	Diagnostic Services and Radiological Therapy Application of Fee Schedule
1668	•	HCPCS for Hospital Outpatient Radiology Services and Other Diagnostic Procedures PPS Pricer Program Provider-Specific Data Record Layout and Description
1669	•	Provider Electronic Billing File and Record Formats
1670	•	Mammography Screening
		Carriers Manual—Part 3 Claims Process (HCFA—Pub. 14–3) (Superintendent of Documents No. HE 22.8/7)
1527	•	Payment for Outpatient Clinical Diagnostic Laboratory Tests Using Fee Schedules and for Specimen Collection
1528	•	Self-Administered Drugs and Biologicals
1529	•	Quarterly Supplements to Carrier Performance Report Forms HCFA–1565A, HCFA–1565B, HCFA–1565C, HCFA–1565D, and HCFA–1565E)—General Checking Form A Prior to Submittal to HCFA Completing Health Professional Shortage Area Quarterly Report, Form HCFA–1565E—General
1530	•	Payment for Outpatient Clinical Diagnostic Laboratory Tests Using Fee Schedules and For Specimen Collection Review of Laboratory Results by Physicians Payment for Outpatient Clinical Diagnostic Laboratory Tests Using Fee Schedules and For Specimen Collection Laboratory Claims Documentation for Nonphysician Claims
1531	•	Report on Number of Participating Physician and Suppliers
1532	•	Medicare Fraud and Abuse
		Program Memorandum Intermediaries (HCFA—Pub. 60A) (Superintendent of Documents No. HE 22.8/6–5)
A–95–11	•	Hospital Waivers for Organ Procurement Service Areas
A–95–12	•	FY 1996 Prospective Payment System and Other Bill Processing Changes
A–95–13	•	Recision of Requirement for Monthly Billing for Part A Home Health, Hospice, and Rural Health Clinic Providers
A–95–14	•	Extension of Due Date for Filing Provider Cost Reports
A–95–15	•	Hospital Outpatient Procedures: 1996 Update to List of Radiology Procedures and Other Diagnostic Services Subject to Payment Limitation and New Instructions on Grossing Up
		Program Memorandum Intermediaries/Carriers (HCFA—Pub. 60AB) (Superintendent of Documents No. HE 22.8/6–5)
AB–95–11	•	Standard Rates for Transmitting Claims Information Between Medicare Contractors and Complementary Insurers for FY 96
		Program Memorandum Medicaid State Agencies (HCFA—Pub. 17) (Superintendent of Documents No. HE 22.8/6–5)
95–7	•	Title XIX, Social Security Act, Tuberculosis—Infected Individuals

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October through December 1995]

Trans. No.		Manual/Subject/Publication No.
		Skilled Nursing Facility Manual (HCFA—Pub. 12) (Superintendent of Documents No. HE 22.8/3)
340	•	Other Services
341	•	Skilled Nursing Facility Defined
		Transfer Agreements
		Medical and Other Health Services Furnished to Patients of Participating SNFs
		Diagnostic X-ray and Clinical Laboratory Tests
		Providing Services Under Arrangement
		Billing for Durable Medical Equipment, Orthotic/Prosthetic Devices and Surgical Dressings
		Billing for Laboratory Tests
342	•	Billing for Mammography Screening
		Coverage Issues Manual (HCFA—Pub. 6) (Superintendent of Documents No. HE 22.8/14)
80	•	Magnetic Resonance Angiography
81	•	Pneumatic Compression Devices (Used for Lymphedema)
82	•	Artificial Hearts And Related Devices
83	•	Lung Volume Reduction Surgery (Reduction Pneumoplasty, also called Lung Shaving, or Lung Contouring) Unilateral or Bilateral by Open or Thoracoscopic Approach for Treatment of Emphysema and Chronic Obstructive Pulmonary Disease-Not Covered
		Peer Review Organization (HCFA—Pub. 19) (Superintendent of Documents No. HE 22.8/8–15)
54	•	PRO Quality Improvement Activities
		Purpose of Data Exchange Reports
		Reporting Requirements
		PRO/Intermediary Data Exchange Reports
55	•	Conducting PDC
56	•	60-Day PRO Review: Opportunity for Discussion
57	•	Transfers
		Hospital-Requested Higher-Weighted DRG Adjustments
		Hospital Manual (HCFA—Pub. 10) (Superintendent of Documents No. HE 22.8/2)
685	•	Payment for Services Received in Nonparticipating Providers
		Designated Intermediaries
		Designated Carriers
686	•	Billing for Hospital Outpatient Partial Hospitalization Services
		Completion of Form HCFA–1450 for Inpatient and/or Outpatient Billing
687	•	Billing for Mammography Screening
		Provider Reimbursement Manual—Part 1 (HCFA—Pub. 15–1) (Superintendent of Documents No. HE 22.8/4)
384	•	Regional Medicare Swing-Bed SNF Rates
385	•	Reasonable Costs
		Factors To Be Considered in Determining Reasonable Cost of Purchased Management and Administrative Support Services
		Insurance Purchased From a Limited Purpose Insurance Company
		Legal Fees and Other Related Costs
386	•	Inpatient Routine Nursing Salary Cost Differential
		Requirements to Fund Plan
		Allowability of Payments
		Exception to 1-Year Time Limit
		Limitation on Federal Participation for Capital Expenditures
		Designated Planning Agencies
		Intermediary Responsibility
		Record of Capital Expenditures
		Appeals
387	•	Political and Lobbying Activities
		Provider Political Activities
		Provider Lobbying Activities

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October through December 1995]

Trans. No.		Manual/Subject/Publication No.
		Professional, Technical, or Business Related Organizations Civic Organizations Organization Dues Related to Lobbying and Political Activities
388	•	Reorganization Costs
		Provider Reimbursement Manual Part II—Provider Cost Reporting Forms and Instructions Chapter 11—Form HCFA–339 (HCFA—Pub. 15–IIK) (Superintendent of Documents No. HE 22.8/4)
4	•	Changes to Form HCFA–339
		State Medicaid Manual Part 15—Income and Eligibility Verification System (HCFA—Pub. 45–15) (Superintendent of Documents No. HE 22.8/6–5)
5	•	This transmittal deletes Chapters 1–5
		Medicare Outpatient Physical Therapy and Comprehensive Outpatient Rehabilitation Facility Manual (HCFA—Pub. 9) (Superintendent of Documents No. HE 22.8/9)
123	•	Completion of Form HCFA–1450 for Billing CORF, Outpatient Physical Therapy, Occupational Therapy or Speech Pathology Services Billing Instructions for Partial Hospitalization Services Provided in Community Mental Health Centers
		Rural Health Clinic and Federally Qualified Health Centers Manual (HCFA—Pub. 27) (Superintendent of Documents No. HE 222.8/19:985)
21	•	Billing for Mammography Screening by Rural Health Clinics and Federally Qualified Health Centers
		State Medicaid Manual Part 6—Payment for Services (HCFA—Pub. 45–6) (Superintendent of Documents No. HE 22.8/10)
29	•	Drug Ingredient Prices
		Medicare/Medicaid Sanction—Reinstatement Report (HCFA—Pub. 69)
95–11	•	Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—August 1995
95–12	•	Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—September 1995
95–13	•	Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—October 1995
95–14	•	Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—November 1995

Addendum IV—Medicare Coverage Issues Manual

(For the reader's convenience, new material and changes to previously published material are in italics. If any part of a sentence in the manual instruction has changed, the entire line is shown in italics. The transmittal includes material unrelated to revised sections. In this addendum we do not reprint the unrelated material.)

Transmittal No. 80; section 50–13.

50–13 Magnetic Resonance Imaging (Effective for services performed on or after 11–22–85.)

Magnetic resonance imaging (MRI), formerly called nuclear magnetic resonance (NMR), is covered under Medicare when furnished as described below for the types of covered conditions described in this instruction.

A. General

1. *Method of Operation.*—Magnetic resonance imaging is a noninvasive method of graphically representing the distribution of water and other hydrogen-rich molecules in the human body. In contrast to conventional radiographs or CT scans, in which the image is produced by X-ray beam attenuation by an object, MRI is capable of producing images by several techniques. In fact, various combinations of MR image production methods may be employed to emphasize particular characteristics of the tissue or body part being examined. The basic elements by which MRI produces an image are the density of hydrogen nuclei in the object being examined, their motion, and the relaxation times, the period of time required for the nuclei to return to their original states in the main, static magnetic field after being subjected to a brief additional magnetic field. These relaxation times reflect the physical-chemical properties of tissue and the molecular environment of its hydrogen nuclei. Only hydrogen atoms are present in human tissues in sufficient concentration for current use in clinical MRI.

2. *General Clinical Utility.*—Overall, MRI is a useful diagnostic imaging modality that is capable of demonstrating a wide variety of soft-

tissue lesions with contrast resolution equal or superior to CT scanning in various parts of the body. Among the advantages of MRI are the absence of ionizing radiation and the ability to achieve high levels of tissue contrast resolution without injected iodinated radiological contrast agents. Recent advances in technology have resulted in development and FDA approval of new paramagnetic contrast agents for MRI which allow even better visualization in some instances. Multislice imaging and the ability to image in multiple planes, especially sagittal and coronal, have provided a flexibility not easily available with other modalities. Because cortical (outer layer) bone and metallic prostheses do not cause distortion of MR images, it has been possible to visualize certain lesions and body regions with greater certainty than has been possible with CT. The use of MRI on certain soft tissue structures for the purpose of detecting disruptive, neoplastic, degenerative, or inflammatory lesions has now become established in medical practice.

B. Covered Clinical Applications—Although several uses of MRI are still considered investigational and some uses are clearly contraindicated (see subsection D), MRI is considered medically efficacious for a number of uses. Use the following descriptions as general guidelines or examples of what may be considered covered rather than as a restrictive list of specific coverages. Coverage is limited to MRI units which have received FDA premarket approval, and such units must be operated within the parameters specified by the approval. As with all items and services, the services must be reasonable and necessary for the diagnosis or treatment of the specific patient involved.

MRI is useful in examining the head, central nervous system, and spine. Multiple sclerosis can be diagnosed with MRI and the contents of the posterior fossa are visible. The inherent tissue contrast resolution of MRI makes it an appropriate standard diagnostic modality for general neuroradiology.

MRI can assist in the differential diagnosis of mediastinal and retroperitoneal masses, including abnormalities of the large vessels such as aneurysms and dissection. When a clinical need exists to visualize the parenchyma of solid organs to detect anatomic disruption or neoplasia, this can be accomplished in the liver, urogenital system, adrenals, and pelvic organs without the use of radiological contrast materials. When MRI is considered reasonable and necessary, the use of paramagnetic contrast materials may be covered as part of the study. MRI may also be used to detect and stage pelvic and retroperitoneal neoplasms and to evaluate disorders of cancellous bone and soft tissues. It may also be used in the detection of pericardial thickening.

Primary and secondary bone neoplasm and aseptic necrosis can be detected at an early stage and monitored with MRI. Patients with metallic prostheses, especially of the hip, can be imaged in order to detect the early stages of infection of the bone to which the prothesis is attached.

Effective for services provided on or after 03/22/94, MRI may also be covered to diagnose disc disease without regard to whether radiological imaging has been tried first to diagnose the problem.

C. Gating Devices and Surface Coils (Effective for Services On or After 3/04/91)—Gating devices which eliminate distorted images caused by cardiac and respiratory movement cycles are now considered state of the art techniques and may be covered. Surface and other specialty coils may also be covered, as they are used routinely for high resolution imaging where small limited regions of the body are studied. They produce high signal-to-noise ratios resulting in images of enhanced anatomic detail.

D. Contraindications and Noncovered Uses—1. *Contraindications.*—MRI is not covered when the following patient-specific contraindications are present. It is not covered for patients with cardiac pacemakers or with metallic clips on vascular aneurysms. MRI during a viable pregnancy is also contraindicated at this time. The danger inherent in bringing ferromagnetic materials within range of MRI units generally constrains the use of MRI on acutely ill patients requiring life support systems and monitoring devices which employ ferromagnetic materials. In addition, the long imaging time and the enclosed position of the patient may result in claustrophobia, making patients who have a history of claustrophobia unsuitable candidates for MRI procedures.

2. *Noncovered Uses.*—Several uses of MRI have been identified as investigational and are not covered. These include measurement of blood flow and spectroscopy. In addition, MRI is not suitable for the imaging of cortical bone and calcifications and for procedures involving spatial resolution of bone or calcifications.

Transmittal No. 80; section 50–14.

New Implementing Instructions—Effective Date: Services furnished on or after October 1, 1995.

Section 50–14, Magnetic Resonance Angiography, is added to provide limited coverage of magnetic resonance angiography (M.A.) procedures. Previously, coverage of the MRA was a matter of carrier discretion. MRA procedures are covered for the evaluation of carotid vessels found in the head and neck and when performed on beneficiaries: (1) with vascular conditions of the head and neck for which surgery is anticipated; and (2) for whom conventional catheter angiography is inappropriate because of contraindications to contrast media. All other applications of MRA performed on or after October 1, 1995 are to be considered noncovered.

50–14 Magnetic Resonance Angiography

Magnetic resonance angiography (MRA) is an application of magnetic resonance imaging that provides visualization of blood flow, as well as images of normal and diseased blood vessels. MRA techniques typically are noninvasive because they do not require the use of contrast media. (While contrast media may sometimes be used to enhance the images obtained in MRA, the use of these agents is not necessary.) As a result, MRA is an attractive imaging alternative for patients who cannot tolerate contrast media.

Although MRA may be performed on several different anatomical regions, presently available scientific data and studies reveal that the most clinically useful application of MRA is in the evaluation of blood flow and vessels in the head and neck. In addition, studies have proven that MRA is most effective when evaluating large vessels, such as the carotids, which are located in the area of the head and neck. Since the clinical value of MRA for anatomical regions other than the head and neck is not yet proven, Medicare will cover MRA only on a limited basis. Therefore, effective for services furnished on or after October 1, 1995, all of the following requirements must be fulfilled before Medicare coverage is available for MRA:

- *The MRA is for the evaluation of the carotid vessels in the head and neck;*
- *The MRA is performed on patients with vascular conditions of the head and neck, such as carotid stenosis, for which surgery is anticipated and may be found to be appropriate based on the MRA test results; and*
- *The MRA is performed when conventional catheter angiography is inappropriate because the patient has contraindications to contrast media.*

Readily acceptable scientific data are lacking for other applications of MRA. Therefore, effective for services

furnished on or after October 1, 1995, other applications are not covered.

This limited coverage policy will be assessed and reviewed as new information becomes available, in order to determine whether the limited coverage should be continued, expanded, or retracted.

Transmittal No. 81; section 60–20.

Changed Procedures—Effective Date: June 1, 1995.

This revision to the Coverage Issues Manual was originally issued as Transmittal #77. It is now being reissued to indicate an effective date of June 1, 1995. This policy may be applied to claims with a date of service on or after June 1, 1995. Do not reopen any claims. However, if claims come to your attention, process them applying the revised policy.

Section 60–16, Pneumatic Compression Devices (Used for Lymphedema), is revised to clarify (1) that the nonsegmented and segmented pump without manual control of pressure in each chamber is considered the least costly alternative that meets the clinical needs of the individual for this type of durable medical equipment (HCPCS codes E0650 and E0651), unless there is documentation that warrants payment of the more costly manual control pump (HCPCS code E0652); (2) the documentation needed for determination of the type of pump to be used for the treatment of lymphedema; and (3) which pneumatic compression pump is appropriate for chronic venous insufficiency.

60–20 Transcutaneous Electrical Nerve Stimulators (Tens)

TENS is a type of electrical nerve stimulator that is employed to treat chronic intractable pain. This stimulator is attached to the surface of the patient's skin over the peripheral nerve to be stimulated. It may be applied in a variety of settings (in the patient's home, a physician's office, or in an outpatient clinic). Payment for TENS may be made under the durable medical equipment benefit. (See § 45–25 for an explanation of coverage of medically necessary supplies for the effective use of TENS and § 45–19 for an explanation of coverage of TENS for acute post-operative pain.)

Transmittal No. 82; sections 65–14 and 65–15.

Changed Procedures—Effective Date: 01–22–96.

Section 65–15, Artificial Hearts And Related Devices, amends this section by removing the words ''not covered'' from the title. Also, it revises the statement of general noncoverage of these devices to allow exceptions for use of the BVS 5000 for temporary life support and the addition of coverage of the use of the HeartMate IP LVAS for use as a bridge to cardiac transplantation.

65–14 Cochlear Implantation

A cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture and amplify sound. Cochlear implant devices are available in single channel and multi-channel models. The purpose of implanting the device is to provide an awareness and identification of sounds and to facilitate communication for persons who are profoundly hearing impaired.

Medicare coverage is provided only for those patients who meet *all* of the following selection guidelines.

A. *Adults.*—

- Diagnosis of total sensorineural deafness that cannot be mitigated by use of a hearing aid in patients whose auditory cranial nerves are stimulable;
- Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
- Post-lingual deafness;
- Adulthood (at least 18 years of age);
- Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system; and
- No contraindications to surgery.

B. *Children (Effective for services performed on and after 12/31/92)*—.The FDA has approved marketing of a multi-channel cochlear implant device for use in prelingually and postlingually deafened children 2 through 17 years of age. (FDA-approved labeling limits use of the device in adults to those who are postlingually deafened.) Medicare coverage is provided for such a device for children who meet the following patient selection guidelines. *There are two exceptions to this general prohibition for two specific devices which have been approved by the Food and Drug Administration. These are described below.*

- No contraindications to the implant, including those described in the product's FDA-approved package insert;
- Diagnosis of bilateral profound sensorineural deafness with little or no benefit from a hearing (or vibrotactile) aid, as demonstrated by the inability to improve on age appropriate closed-set word identification tasks;
- Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system; and
- The device must be used in accordance with the FDA-approved labeling.

65–15 Artificial Hearts and Related Devices

There are several devices either in use or under development which replace all or part of the human heart or assist the heart in performing its pumping function. Artificial hearts are considered investigational and not covered under Medicare either when used as a permanent replacement for a human heart or when used as temporary life-support systems (i.e., until a human heart becomes available for transplant).

The FDA-approved ventricular assist device (known as the B.S. 5000) is covered when it is used in accordance with its FDA-approved labeled uses for postcardiotomy ventricular dysfunction. The device is intended for short term use and is not covered when used as a bridge to cardiac transplantation. *The FDA-approved HeartMate Implantable Pneumatic Left Ventricular Assist Systems (HeartMate IP LVAS) is covered:*

A. When it is used in accordance with its FDA-approved labeled uses as a temporary mechanical circulatory support for approved transplant candidates in nonreversible left ventricular failure as a bridge to cardiac transplantation; and

B. Only if all of the following conditions are met:

1. The patient is an approved heart transplant candidate, i.e., approved and listed as a candidate by a Medicare-approved heart transplant center;

2. The implantation of the system is done in a Medicare-approved heart transplant center, either on a patient listed by that center, or, if the patient is listed by another Medicare-approved center, with the written permission of the center listing the patient;

3. The patient is on inotropes;

4. The patient is on an intra-aortic balloon pump (if possible); and

5. The patient has left atrial pressure or pulmonary capillary wedge pressure > 20 mm Hg with either:

a. Systolic blood pressure < 80 mm Hg; or

b. Cardiac index of < 2.0 1/min/m².

Coverage of this device is limited to its FDA-approved use as a bridge to transplantation. Consequently, centers implanting such devices should make every reasonable effort to transplant patients on such devices as soon as practicable. Ideally, they should

determine patient-specific timetables for transplantation and should not maintain such patients on this device if suitable hearts become available for transplantation.

Other ventricular assist devices used as temporary life-support systems are still considered investigational and are not covered under the Medicare program.

Transmittal No. 83; section 35–93.

MANUALIZATION—EFFECTIVE DATE: NOT APPLICABLE.

Section 35–93, Lung Volume Reduction Surgery (Reduction Pneumoplasty, also called Lung Shaving, or Lung Contouring) Unilateral or Bilateral by Open or Thoracoscopic Approach for Treatment of Emphysema and Chronic Obstructive Pulmonary Disease-Not Covered.—This instruction explains Medicare's position of noncoverage for lung volume reduction. The lack of scientific evidence available at this time concerning the safety and effectiveness of lung volume reduction reveals that this procedure cannot be considered reasonable and necessary under § 1862(a)(1)(A) of the Social Security Act.

35–93 Lung Volume Reduction Surgery (Reduction Pneumoplasty, Also Called Lung Shaving or Lung Contouring) Unilateral or Bilateral by Open or Thoracoscopic Approach for Treatment of Emphysema and Chronic Obstructive Pulmonary Disease-Not Covered

Lung volume reduction surgery or reduction pneumoplasty, also referred to as lung shaving or lung contouring, is performed on patients with emphysema and chronic obstructive pulmonary disease (OPD) in order to allow the underlying compressed lung to expand, and thus, establish improved respiratory function. The goal of this procedure is to offer a better quality of life for patients with emphysema and OPD. In addition, lung volume reduction may be offered as a ''bridge to transplant'' for patients who otherwise may not have been considered candidates for lung transplantation.

Unilateral or bilateral lung volume reduction surgery by open or thoracoscopic approach is not covered because there is little medical evidence available to base a determination that this procedure is safe and effective. Therefore, lung volume reduction surgery cannot be considered reasonable and necessary under § 1862(a)(1)(A) of the law. When more scientific evidence becomes available, this policy will be reevaluated.

ADDENDUM V.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER

Publication date	FR Vol. 60 page	CFR part	File code [1]	Regulation title	End of comment period	Effective date
10/02/95	51483–51487		ORD–079–N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: June 1995.		10/02/95
10/06/95	52396–52403		BPD–797–PN	Medicare Program: Limitations on Medicare Coverage of Cataract Surgery.	12/05/95	
10/10/95	52684–52688		ORD–080–N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: July 1995.		10/10/95
10/10/95	52731	489, 498	HSQ–156–CN	Medicare and Medicaid Programs; Survey, Certification and Enforcement of Skilled Nursing Facilities and Nursing Facilities; Correction.		07/01/95
10/13/95	53456	489	HSQ–156–CN	Medicare and Medicaid Programs; Survey, Certification and Enforcement of Skilled Nursing Facilities and Nursing Facilities; Correction.		07/01/95
10/16/95	53625–53626		OACT–049–N	Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 1996.		01/01/96
10/16/95	53626–53631		OACT–050–N	Medicare Program; Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Rate Beginning January 1, 1996.		01/01/96
10/16/95	53631–53632		OACT–051–N	Medicare Program; Part A Premium for 1996 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement.		01/01/96
10/18/95	53876–53877	411	BPD–482–CN	Medicare Program; Medicare Secondary Payer for Individuals Entitled to Medicare and Also Covered Under Group Health Plans; Correction.		09/29/95
10/18/95	53877	414	BPD–830–F	Medicare Program; Authority Citations; Technical Amendments.		09/29/95
10/18/95	53877	486	BPD–836–F	Medicare Program; Suppliers of Specialized Services; Technical Amendment.		09/29/95
11/15/95	57435–57448		BPO–132–N	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances and Coverage Decisions—Second Quarter 1995.		11/15/95
11/28/95	58631–58632		OPL–007–N	Medicare Program; December 11, 1995 Meeting of the Practicing Physicians Advisory Council.		11/28/95

ADDENDUM V.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER—Continued

Publication date	FR Vol. 60 page	CFR part	File code [1]	Regulation title	End of comment period	Effective date
11/29/95	61264–61265		BPD–820–N	Medicare Program; Notice Containing the Statement Drafted by the Committee Established to Negotiate the Wage Index To Be Used to Adjust Hospice Payment Rates Under Medicare.		11/29/95
11/30/95	61483–61487		MB–085–F	Medicare Program; Nurse-Midwife Services		01/02/96
12/01/95	61704–61705		OPL–008–N	Medicare Program; Request for Nominations for Members for the Practicing Physicians Advisory Council.		12/01/95
12/05/95	62237–62241	413	BPD–788–P	Medicare Program; Uniform Electronic Cost Reporting for Skilled Nursing Facilities and Home Health Agencies.	02/05/96	
12/08/95	63124–63357	400, 405, 410, 411, 412, 413, 414, 415, 417, 489.	BPD–827–FC	Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1996.	02/06/96	[2] 01/01/96
12/08/95	63358–63366		BPD–828–FN	Medicare Program; Physician Fee Schedule Update for Calendar Year 1996 and Physician Volume Performance Standard Rates of Increase for Federal Fiscal Year 1996.		[3] 10/01/95
12/11/95	63438–63440	411	BPD–850–F	Medicare Program; Physician Self-Referral Regulations: Change in Date for Submission of Group Attestation Statement.		12/11/95
12/11/95	63440–63444	424	BPD–838–FC	Medicare Program; Additional Supplier Standards.	02/09/96	01/01/96
12/11/95	63532–63536		ORD–081–N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: August and September 1995.		12/11/95
12/15/95	64440–64444		ORD–082–N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: October 1995.		12/15/95

[1] GN—General Notice; PN—Proposed Notice, FN—Final Notice; P—Notice of Proposed Rulemaking (NPRM); F—Final Rule; FC—Final Rule with Comment Period; CN—Correction Notice; SN—Suspension Notice; WN—Withdrawal Notice; NR—Notice of HCFA Ruling.
[2] Except CFR Part 415, 07/01/96.
[3] For Volume Performance Standard Rates of Increase; 01/01/96 for Medicare Physician Fee Schedule Update.

Addendum VI—Categorization of Food and Drug Administration-Approved Investigational Device Exemptions

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c), devices fall into one of three classes:

Class I—Devices for which the general controls of the Food, Drug, and Cosmetic Act, such as adherence to good manufacturing practice regulations, are sufficient to provide a reasonable assurance of safety and effectiveness.

Class II—Devices that, in addition to general controls, require special controls, such as performance standards or postmarket surveillance, to provide a reasonable assurance of safety and effectiveness.

Class III—Devices that cannot be classified into Class I or Class II because insufficient information exists to determine that either special or general controls would provide reasonable assurance of safety and effectiveness. Class III devices require premarket approval.

Under the new categorization process to assist HCFA, the Food and Drug Administration assigns each device with a Food and Drug Administration-approved investigational device exemption to one of two categories: Experimental/Investigational (Category A) Devices, or Non-Experimental/Investigational (Category B) Devices. Under this categorization process, an experimental/investigational (Category A) device is an innovative device in Class III for which ''absolute risk'' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the Food and Drug Administration is unsure whether the device type can be safe and effective). A non-experimental/investigational (Category B) device is a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained Food and Drug Administration approval for that device type.

There were no new FDA-approved IDE device numbers in Category A to report for this quarter.

The criteria the Food and Drug Administration uses to categorize an investigational device under Category B include the following:

(1) Devices, regardless of the classification, under investigation to establish substantial equivalence to a predicate device, that is, to establish substantial equivalence to a previously/currently legally marketed device.

(2) Class III devices whose technological characteristics and indication for use are comparable to a PMA-approved device.

(3) Class III devices with technological advances compared to a PMA-approved device, that is, a device with technological changes that represent advances to a device that has

already received PMA-approval (generational changes).

(4) Class III devices that are comparable to a PMA-approved device but are under investigation for a new indication for use. For purposes of studying the new indication, no significant modification to the device were required.

(5) Pre-amendments Class III devices that become the subject of an investigational device exemption after the Food and Drug Administration requires premarket approval, that is, no PMA application was submitted or the PMA application was denied.

(6) Nonsignificant risk device investigations for which the Food and Drug Administration required the submission of an investigational device exemption.

The following information presents the device number, category (in this case, B), and criterion code.

G950165 B3
G950167 B2
G950169 B3
G950170 B4
G950172 B3
G950173 B1
G950174 B4
G950179 B1
G950180 B1
G950181 B1
G950183 B3
G950184 B1
G950187 B2
G950188 B1
G950189 B1
G950190 B4
G950191 B4
G950192 B6
G950193 B4
G950195 B1
G950196 B4
G950197 B3
G950198 B1
G950201 B1
G950202 B4
G950206 B1
G950208 B3
G950209 B4

Note: Some investigational devices may exhibit unique characteristics or raise safety concerns that make additional consideration necessary. For these devices, HCFA and the Food and Drug Administration will agree on the additional criteria to be used. The Food and Drug Administration will use these criteria to assign the device(s) to a category. As experience is gained in the categorization process, this addendum may be modified.

[FR Doc. 96–16217 Filed 6–25–96; 8:45 am]

BILLING CODE 4120–01–P

[BPD–873–N]

Medicare Program; Announcement of Collaborative Effort With the National Institutes of Health to Study the Effectiveness of Lung Volume Reduction Surgery

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

We are announcing our participation in a collaborative effort with the National Heart, Lung and Blood Institute of the National Institutes of Health to study the effectiveness of lung volume reduction surgery. The purpose of this multi-centered randomized study, which will include a prospective registry examining the role of lung volume reduction surgery, is to evaluate the long-term outcome of the procedure on function, morbidity, and mortality as well as to define appropriate patient selection criteria. We are issuing this announcement so that interested facilities and providers who monitor the Federal Register are aware of this collaborative effort. The National Heart, Lung and Blood Institute announced in the May 9 and 10, 1996 issues of the *Commerce Business Daily* the qualifications and experience required for the clinical centers and the clinical coordinating center to participate in the program. It also described the patient population who will be included in the study and how the study will be conducted.

On June 3, 1996, the National Heart, Lung and Blood Institute made available a formal request for proposals for clinical centers and a clinical coordinating center interested in participating in the study through the National Institutes of Health (NIH) Request for Proposals (RFP) Gopher. Users have access via the NIH Home Page (World Wide Web) at http://www.nih.gov. Once users are at the NIH Home Page, they should select ''Grants & Contracts,'' then select ''R&D Requests for Proposals (RFP).'' Offerors that have access to the NIH Gopher Server but not the Internet can access the RFP by pointing their gopher clients to GOPHER.NIH.GOVPORT70. They should select ''Grant and Research Information,'' then select ''R&D Requests for Proposals (RFP).''

FOR FURTHER INFORMATION CONTACT: Karen McVearry, (410) 786–4643.

Authority: Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh)

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 9, 1996.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 96–16216 Filed 6–25–96; 8:45 am]

BILLING CODE 4120–01–P

National Institutes of Health

National Cancer Institute; Notice of Meeting of the National Cancer Advisory Board

Pursuant to Section 10(d) of the Federal Advisory Committee act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the National Cancer Advisory Board, National Cancer Institute on July 18, 1996. The meeting will be open to the public and attendance by the public will be limited to space available.

The Committee Management Office, National Cancer Institute, National Institutes of Health, Executive Plaza North, Room 630E, 9000 Rockville Pike, Bethesda, Maryland 20892 (301/496–5708), will provide summaries of the meetings and rosters of the Board members, upon request.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Carole Frank, Committee Management Specialist, at 301/496–5708 in advance of the meeting.

Name of Committee: National Cancer Advisory Board.

Contact Person: Dr. Marvin R. Kalt, Executive Secretary, National Cancer Institute, NIH, Executive Plaza North, Room 600A, 6130 Executive Blvd., Bethesda, MD 20892–7405; (301) 496–5147.

Date of Meeting: July 18, 1996.

Place of Meeting: National Cancer Institute via telephone conference, National Institutes of Health, Room 640, 6130 Executive Blvd., Rockville, MD 20852.

Open: 1 pm to approximately 2 pm.

Agenda: To discuss the NCAB resolution for the 25th Anniversity of the National Cancer Act.

Dated: June 21, 1996.

Susan K. Feldman,

Committtee Management Officer, NIH.

[FR Doc.96–16323 Filed 6–25–96; 8:45 am]

BILLING CODE 4140–01–M

Office of Extramural Research; Notice of Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice