ADDRESSES: The public workshops will be held at the following locations:

1. Baltimore Marriott Inner Harbor, 110 South Eutaw St., Baltimore, MD.

2. Crown Plaza Boston/Woburn, 2 Forbes Rd., Woburn, MA.

FOR FURTHER INFORMATION CONTACT:

Regarding registration for the Baltimore public workshop: Jo Ann Maquire, Regional Training Specialist, Mid-Atlantic Region, Food and Drug Administration, 900 U.S. Customhouse, 2d & Chestnut Sts., Philadelphia, PA 19106, 215–597–4390, ext. 4004, or FAX 215–597–5798.

Regarding registration for the Woburn public workshop: Ellen Madigan, Blood Bank Monitor, Northeast Region, Food and Drug Administration, One Montvale Ave., Stoneham, MA 02180, 617–279–1675, ext. 157 or FAX 617–279–1742.

Those persons interested in attending a workshop should register by FAXing their name(s), firm name/affiliation, address, telephone and FAX numbers, and any specific questions they want addressed at the workshop to the information contact person listed above for each workshop. There is no registration fee for these workshops, but advance registration is required. Interested parties are encouraged to register early because space is limited.

SUPPLEMENTARY INFORMATION: The purpose of these workshops is to further assist small companies that are developing and producing biopharmaceutical and biologic therapeutic products in better understanding: Current regulatory policy; licensing requirements for products and establishments and cooperative manufacturing arrangements; multiproduct facilities design and operation; clinical trial design and monitoring; points to consider during processing, cell culture, fermentation, harvest, recovery, purification, and ascites production; current good manufacturing practice requirements in the production of clinical material; and recordkeeping, processing changes, and environmental monitoring.

Dated: November 8, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–28148 Filed 11–9–95; 9:54 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

Public Information Collection Requirements Submitted for Public Comment and Recommendations

AGENCY: Health Care Financing Administration, DHHS.

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

1. *Type of Information Collection Request:* Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Income, and Eligibility Verification System (IEVS) Information Collection Requirements in 42 CFR 435.940–435.965; *Form No.:* HCFA–R–74; *Use:* Section 1137 of the Social Security Act requires Medicaid State agencies and other federally-funded welfare agencies to request income and resource data from certain federal agencies, State wage information collection agencies, and State unemployment compensation agencies through an IEVS. The purpose of the IEVS is to ensure that only eligible individuals receive benefits. Our regulations implementing these requirements are found at 42 CFR 435.940–435.965; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 54; *Total Annual Responses:* 54; *Total Annual Hours Requested:* 131,390.

To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collection should be sent within 60 days of this notice direct to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: Linda Mansfield, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: November 6, 1995.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 95–28114 Filed 11–14–95; 8:45 am]

BILLING CODE 4120–03–P

[BPO–132–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances and Coverage Decisions—Second 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 April, May, and June of 1995 that relate to the Medicare and Medicaid programs. 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 timeframe. We are also providing the content of revisions to the Medicare Coverage Issues Manual published between April 1 and June 30, 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 allows us to fulfill 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).

Nancy Ranels, (410) 786–8928 (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 who process claims and pay bills, and others. To implement the various statutes on which the programs are based, we issue regulations under 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 timeframe. 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 are listing in this notice Medicaid issuances and Medicaid substantive and interpretive regulations published from April 1 through June 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. We have reprinted manual revisions as transmitted to manual holders. The new text is shown in italics. We will not reprint 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, or coverage decisions published during the timeframe 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 five 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 June 30, 1995. 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 title of the regulation, the parts of the Code of Federal Regulations (CFR) which have changed (if applicable), the agency file code number, the ending date of the comment period (if applicable), and the effective date (if applicable).

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

C. Rulings

Rulings are published on an infrequent basis by HCFA. 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)

HCFA's laws, regulations, and manuals are now 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 contained 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, 1993. The remaining portions of CD–ROM are updated on a monthly basis.

The CD–ROM disk does not contain Appendix M (Interpretative Guidelines for Hospices). Copies of this appendix may be reviewed at a Federal Depository Library (FDL).

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 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, individuals should 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 2—Program Administration (HCFA-Pub. 14–2) transmittal entitled ''Beneficiary Services,'' use the Superintendent of Documents No. HE 22.8/7–3 and the HCFA transmittal number 132.

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 all other information may be addressed to Nancy Ranels, Bureau of Policy Development, Office of Regulations, Health Care Financing Administration, C5–09–05, 7500 Security Blvd., Baltimore, MD 21244–1850, Telephone (410) 786–8928.

(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: November 3, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

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 between 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)

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

[April through June 1995]

Trans. No.		Manual/Subject/Publication No.
		Intermediary Manual Part 2—Audits, Reimbursement Program Administration (HCFA-Pub. 13–2) (Superintendent of Documents No. HE 22.8/6–1)
405	•	Beneficiary Services
		Intermediary Manual Part 3—Claims Process (HCFA-Pub. 13–3) (Superintendent of Documents No. HE 22.8/6)
1647	•	On-Site CMRs Review Options
1648	•	Table of Contents Updates (Chapters I through X)
1649	•	Under Arrangements Skilled Nursing Facility Defined Utilization Review Plan Physician Members of UR Committee Reporting Outpatient Surgery and Other Services Ambulatory Surgical Center PRICER Program PRO Reporting on Medical Review
1650	•	Provider Information Notification Rural Health Clinics—General
1651	•	Review of Form HCFA–1450 for Inpatient and Outpatient Bills
1652	•	Pneumococcal Pneumonia Vaccinations Influenza Virus Vaccine
1653	•	Special Billing Instructions for Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines
1654	•	Outpatient Services Treated as Inpatient Services Requirements for Submission of EMC Data File Specifications, Records Specifications, and Data Element Specifications for EMC Bills National Standard Electronic Remittance Advice Medicare Standard Electronic PC-Print Software
		Carriers Manual—Part 2 Program Administration (HCFA-Pub. 14–2) (Superintendent of Documents No. HE 22.8/7–3)
132	•	Beneficiary Services
		Carriers Manual—Part 3 Claims Process (HCFA-Pub. 14–3) (Superintendent of Documents No. HE 22.8/7)
1513	•	Claims for Outpatient Services Furnished by Physical or Occupational Therapist in Independent Practice
1514	•	Sample Notification Letter
1515	•	List of Covered Surgical Procedures ASC Payment Group Rates
1516	•	Pneumococcal Pneumonia Vaccinations Influenza Virus Vaccine
1517	•	Type of Service
1518	•	Data Sets and Formats for Electronic Media Claims and Electronic Remittance Advice Personal Computer Software Medicare Standard PC-Print-B Software
		Program Memorandum Intermediaries (HCFA-Pub. 60A) (Superintendent of Documents No. HE 22.8/7)
A–95–4	•	Requirement for Line Item Dates of Service on All Claims Containing Clinical Diagnostic Laboratory Services Subject to the Laboratory Fee Schedule Spanning 2 or More Dates
A–95–5	•	Submission of Form HCFA–265–94 (Independent Renal Dialysis Facility Cost Report)
A–95–6	•	Submission of Form HCFA–2552–92 (Hospital and Hospital Health Care Complex Cost Report) Print Image Encryption
A–95–7	•	Extension of Due Date for Filing Cost Reports on Form HCFA–2540–92, Revised January 1995
A–95–8	•	Medicare's Partial Hospitalization Benefit-Eligibility and Scope of Services
		Program Memorandum Carriers (HCFA-Pub. 60B) (Superintendent of Documents No. HE 22.8/6–5)
B–95–2	•	Coverage of Epoetin Alfa for HIV/AIDS and Cancer Patients Undergoing Chemotherapy

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April through June 1995]

Trans. No.		Manual/Subject/Publication No.
B–95–3	•	Statistical Software Tools to Assist in Random Sampling and Overpayment Projection
B–95–4	•	Temporary HCPCS Codes for Certain Drugs and Radionuclides
		Program Memorandum Intermediaries/Carriers (HCFA-Pub. 60 A/B) (Superintendent of Documents No. HE 22/8–5)
AB–95	•	Preparing and Transmitting Provider Data for the Medicare Transaction System Medicare Provider Database Preparation Project
		Program Memorandum Medicaid State Agencies (HCFA-Pub. 17) (Superintendent of Documents No. HE 22.8/6–5)
95–2	•	Title XIX, Social Security Act, Persons with Drug Addiction or Alcoholism
95–3	•	Title XIX, Social Security Act, Medicaid Eligibility and Coverage
95–4	•	Title XIX, Social Security Act—Survey, Certification, and Enforcement Regulation for Nursing Facilities
		Hospital Manual (HCFA-Pub. 10) (Superintendent of Documents No. HE 22.8/2)
679	•	Table of Contents Updates (Chapters 1 through IV)
680	•	Reporting Outpatient Surgery and Other Services
681	•	Need to Reprocess Inpatient Claims in Sequence
682	•	Outpatient Services Treated as Inpatient Services
		Home Health Agency Manual (HCFA-Pub. 11) (Superintendent of Documents No. HE 22.8/5)
275	•	Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines
		Skilled Nursing Facility Manual (HCFA-Pub. 12) (Superintendent of Documents No. HE 22.8/3)
337	•	Skilled Nursing Facility Defined Utilization Review Plan Physician Members of UR Committee Limitations on Payment for Inpatient Services Following Adverse Finding by URC Availability and Appropriateness of Other Facilities and Services Failure to Make Timely Review of Cases
338	•	Need to Reprocess Inpatient Claims in Sequence
		Health Maintenance Organization/Competitive Medical Plan Manual (HCFA-Pub. 75) (Superintendent of Documents No. HE 22/8/21:989)
14	•	General Reasonable Cost Payment Direct Payment by HMO/CMP to Hospital and Skilled Nursing Facilities Services Furnished Directly or Through Arrangement Interim Payment for Cost Reimbursed Plans Plan Payment Report Interim Cost and Enrollment Reports Interim Cost Report for Experienced HMO/CMPs Adjustment of Payments Final Settlement Process—Cost Basis HMO/CMPs Interest Charges for Medicare Overpayments/Underpayments Prudent Buyer Principle Costs in Excess of Adjusted Average Per Capita Costs Medicare as Secondary Payer Payment Procedures for Provider Services Paid for Directly by HMO/CMP Filing Requirements for Providers Using Form HCFA–2552 Providers Receiving Payment Under Prospective Payment System New Limitations Imposed by OBRA 1989 Enrollment and Marketing Costs Determining Deductibles and Coinsurance Medicare Secondary Payer Policies Benefit Coordination LGHP Alternative Method for Cost Report Treatment of Employer Health Plans Determining Total Costs for Comparison With AAPCC Limits Taxes

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April through June 1995]

Trans. No.		Manual/Subject/Publication No.
		Rural Health Clinic and Federally Qualified Health Centers Manual (HCFA-Pub. 27) (Superintendent of Documents No. HE 22.8/19:985)
20	•	Billing of Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines by Rural Health Clinics and Federally Qualified Health Centers
		Hospice Manual (HCFA-Pub. 21) (Superintendent of Documents No. HE 22.18)
46	•	Credit Balance Reporting Requirements Payment of Amounts Owed Medicare Medicare Credit Balance Report Certification Medicare Credit Balance Report (HCFA–838)
		Coverage Issues Manual (HCFA-Pub. 6) (Superintendent of Documents No. HE 22.8/14)
75	•	Home Blood Glucose Monitors
76	•	Positron Emission Tomography (PET or PETT) Scans
77	•	Pneumatic Compression Devices (Used for Lymphedema)
		Regional Office Manual Medicare (HCFA-Pub. 23–2) (Superintendent of Documents No. HE 22.8/8)
328	•	Contractor Performance Evaluation
		Regional Office Manual Standards and Certification (HCFA-Pub. 23–4) (Superintendent of Documents No. HE 22.8/8–3)
58	•	Approval of Facilities Furnishing Renal Services Health and Safety Conditions to be Surveyed by the State Agency Participation of Veterans Administration Hospitals in the Program Use of Provider Tie-In Notice, HCFA–2007, for Suppliers of ESRD Program Services Network Activities Continuous Ambulatory Peritoneal Dialysis Coverage Notice of Initial Approval of ESRD Facility Notice—Recertification of ESRD Facility Notice of Approval of CAPD Services
59	•	Citations Processing Allegations of Noncompliance Termination Procedures for Violations of 42 CFR 489.20 and 42 CFR 489.24 Procedures for Coordinating Statutorily Mandated Peer Review Organization Review of Confirmed Dumping Cases Request for Survey of 42 CFR 489.20 and 42 CFR 489.24, Essentials of Provider Agreements: Responsibilities of Medicare Participating Hospitals in Emergency Cases, Form HCFA–1541A Model Letter Acknowledging Complaint Alleging Noncompliance with 42 CFR 489.24 and/or the Related Requirements of 42 CFR 489.20: Investigation Not Warranted Model Letter Acknowledging Complaint Alleging Noncompliance with 42 CFR 489.24 and/or the Related Requirements of 42 CFR 489.20: Investigation Warranted Responsibilities of Medicare Participating Hospitals in Emergency Cases Investigation Report, Form HCFA–1541B Model Letter Requesting Physician Review of A Possible Violation of 42 CFR 489.24 Physician Review Outline for Emergency Care Obligations of Medicare Participating Hospitals Model Letter Following Investigation Into Alleged Violation of 42 CFR 489.24 and/or the Related Requirements of 42 CFR 489.20: Facility in Compliance Model Letter for a Violation of 42 CFR 489.24: Preliminary Determination Letter (Immediate and Serious Threat) Model Letter for a Violation of 42 CFR 489.24 and/or the Related Requirements of 42 CFR 489.20: Preliminary Determination Letter (90 Day Termination Track) Model Letter to Complainant Following Investigation of Alleged Violation of 42 CFR 489.24 and/or the Related Requirements of 42 CFR 489.20: Complaint Not Substantiated Model Letter to Complainant Following Investigation of Alleged Violation of 42 CFR 489.24 and/or the Related Requirements of 42 CFR 489.20: Complaint Substantiated Model Letter for Referring a Violation of 42 CFR 489.24 to the Office of the Inspector General Model Letter for Referring a Violation of 42 CFR 489.24 to the Regional Office for Civil Rights Model Letter for a Past Violation of 42 CFR 489.24 and/or the Related Requirements of 42 CFR 489.20: No Termination Model Letter for a Violation of 42 CFR 489.24 and/or the Related Requirements of 42 CFR 489.20: Notice of Termination Model Letter Requesting PRO Review of a Confirmed Violation of 42 CFR 489.24 for Purposes of Assessing Civil Monetary Penalties or Excluding Physicians

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April through June 1995]

Trans. No.		Manual/Subject/Publication No.
		Peer Review Organization Manual (HCFA-Pub. 19) (Superintendent of Documents No. HE 22.8/15)
49	•	Citations and Authority
		Issuance of Hospital Notices of Noncoverage
		Content of Hospital-Issued Notice of Noncoverage
		Monitoring Hospital-Issued Notices of Noncoverage
		Background
		Monitoring Procedures
50	•	Consumer Representative
51	•	Sections 2100–2150 are Deleted
		Sections 4700–4735 are Deleted
		Exhibit 4–2 is Deleted
		Sections 12200–12210 are Deleted
		State Operations Manual Provider Certification (HCFA-Pub. 7) (Superintendent of Documents No. HE 22.8/12)
270	•	Certification Functions of the State Agency
		Types of ESRD Facility
		ESRD Application Requirement
		State Agency Control of HCFA–3427
		ESRD Survey Procedures
		End-Stage Renal Disease Survey Report—Crucial Data Extract
		Model Letter to Previously-Approved Facility Requesting Approval to Expand or Add a New ESRD Service
		Model Letter to Facility Returning Application Not Accompanied by Required Certificate of Need (Where Applicable)
		ESRD Application and Survey and Certification Report, HCFA–3427
		Survey Procedures and Interpretive Guidelines for ESRD Facilities
271	•	Basis for Accredited Hospital Complaint Investigation
		RO Direction of Accredited Hospital Complaint Investigation
		Conducting an Accredited Hospital Complaint Investigation
		Background
		Basis for Investigation
		RO Direction of Investigation
		Conducting an Investigation
		Forwarding Report of Investigation to the RO
		RO Review of Investigation
		Termination Procedures for Violations of Section 489.24 and/or the Related Requirements of Section 489.20
		Request for Survey of Section 489.20 and Section 489.24, Essentials of Provider Agreements: Responsibilities of Medicare Participating Hospitals in Emergency Cases, Form HCFA–1541A
		Responsibilities of Medicare Participating Hospitals in Emergency Cases Investigation Report, Form HCFA–1541B
		Physician Review Outline for Emergency Care Obligations of Medicare Hospitals
		Investigation Procedures and Interpretive Guidelines-Special Responsibilities of Medicare Hospitals in Emergency Cases
272	•	Specification of RAIs for Use in Long Term Care Facilities
		Definitions
		Minimum Data Set and RAI Designated by HCFA
		Specification of a State RAI
		Variations in Formatting the State Specified RAI
		Approval Process
		Resident Assessment Instrument for Long Term Care Facilities
273	•	Introduction
		Definitions and Acronyms
		Change in Certification Status for Medicaid NFs
		SNFs—Citations and Description
		NFs—Citations and Description
		Types of Facilities That May Qualify as SNFs and NFs
		SNFs Providing Outpatient Physical Therapy, Speech Pathology or Occupational Services
		Special Waivers Applicable to SNFs and NFs
		Emphasis, Components and Applicability
		Survey Team Size and Composition—Length of Survey
		Conflicts of Interest for Federal and State Employees
		Survey Protocol
		Survey Frequency
		Unannounced Surveys
		Substandard Quality of Care and Extended and Partial Extended Surveys
		Informal Dispute Resolution
		Certification of Compliance and Noncompliance for SNFs and NFs
		Action When Facility Is Not in Substantial Compliance

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April through June 1995]

Trans. No.	Manual/Subject/Publication No.
	Appeal of Certification of Noncompliance
	Certification-Related Terms
	Notice Requirements
	Timing of CMPs
	Immediate Jeopardy Exists
	Enforcement Action When Immediate Jeopardy Exists
	Key Dates When Immediate Jeopardy Exists
	Immediate Jeopardy Does Not Exist
	Enforcement Action When Immediate Jeopardy Does Not Exist
	Considerations Affecting Enforcement Recommendation to Impose Remedies When Immediate Jeopardy Does Not Exist
	Procedures for Recommending Enforcement Remedies When Immediate Jeopardy Does Not Exist
	Special Procedures for Recommending and Imposing Category 1 Remedies
	Disagreements About Remedies When Immediate Jeopardy Does Not Exist
	Key Dates When Immediate Jeopardy Does Not Exist
	Response to Allegation of Compliance
	New Deficiencies Identified
	Procedures for Certifying Compliance
	Action When There is Substandard Quality of Care
	Enforcement Remedies for SNFs and NFs
	Directed Plan of Correction
	Directed In-Service Training
	State Monitoring
	Denial of Payment For All New Admissions for SNFs and NFs
	Secretarial Authority to Deny All Payment
	Basis for Imposing CMPs
	Compliance With Section 1128A of the Act
	Special Procedures Regarding Compliance Decision and Overlap of Remedies
	Determining Amount of CMP
	Effective Date of CMP
	Notice of Imposition of CMP
	Duration of CMP
	Settlement of CMP
	Appeal of Noncompliance Which Led to Imposition of CMP
	When Penalty Is Due and Payable
	Notice of Amount Due and Collectible
	Disposition of Collected CMP
	Loss of NATCEP or CEP as a Result of CMP
	Temporary Management
	Transfer of Residents and Transfer of Residents with Closure of Facility
	Termination Procedures for SNFs and NFs When Facility is Not in Substantial Compliance with Program Participation Requirements
	Continuation of Payment During Remediation
	Investigation of Complaints of Violations and Monitoring of Compliance
	Action on Complaints of Resident Neglect and Abuse and Misappropriation of Resident Property
	Consistency of Survey Results
	Sanctions for Inadequate State Survey Performance
	Educational Programs
	Criteria for Reviewing State Plan Amendments for Specified and Alternative Enforcement Remedies
	State/Federal Disagreements Over Timing and Choice of Remedies
	NATCEP and CEP Disapprovals
	Information Disclosed to Public
	Requesting Public Information
	Charges for Information
	Time Periods for Disclosing SNF/NF Information
	Information Furnished to State's Long Term Care Ombudsman
	Information Furnished to Attending Physician and State Board
	Access to Information by State Medicaid Fraud Control Unit
	Model Letter to Provider (Immediate Jeopardy Does Not Exist)
	Model Letter Notifying Provider of Acceptance of Allegation of Compliance
	Model Letter Notifying Provider of Results of Revisit
	Model Letter to Provider (Imposition of Remedies) (Immediate Jeopardy Does Not Exist)
	Model Letter to Provider (Imposition of Remedies) (Immediate Jeopardy Exists)
	Notice of Imposition of a Civil Money Penalty
	Notification of Change in the Amount of the Civil Money Penalty
	Notice of Receipt of the Written Request of Waiver of Right to a Hearing
	Notice of Payment Amount Due and Payable
	Notification of Deduction of Civil Money Penalty From Money Owing to the Provider

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April through June 1995]

Trans. No.	Manual/Subject/Publication No.
	Medicare Provider Reimbursement Manual (Part 1) (HCFA-Pub. 15–1) (Superintendent of Documents No. HE 22.8/4)
383	• Regional Medicare Swing-Bed SNF Rates
	Provider Reimbursement Manual Part II—Provider Cost Reporting Forms and Instructions—Chapter 16 (HCFA-Pub. 15–IIP) (Superintendent of Documents No. HE 22.8/4)
4	• Return on Equity Capital Reimbursement in the SNF Cost Report for Community Mental Health Centers
	Provider Reimbursement Manual Part II—Provider Cost Reporting Forms and Instructions—Chapter 24 (HCFA-Pub. 15–IIX) (Superintendent of Documents No. HE 22.8/4)
7	• Allocation of the Operating Cost Reduction Due to Change in Payment for Ambulatory Surgery and Radiology for Cost Reporting Periods Ending January 31, 1991, through September 29, 1991
	Provider Reimbursement Manual Part II— Provider Cost Reporting Forms and Instructions—Chapter 28 (HCFA-Pub. 15–II–AB) (Superintendent of Documents No. HE 22.8/4)
6	• Regulatory Changes for the Wage Index Electronic Reporting Specifications for Form-2552–92
	Provider Reimbursement Manual Part II—Provider Cost Reporting Forms and Instructions—Chapter 22 (HCFA-Pub. 15–II–AG) (Superintendent of Documents No. HE 22.8/4)
1	• Organ Procurement Organization and Tissue Typing Laboratory (Histocompatibility Laboratory) Cost Report, Form HCFA–216–94
	End Stage Renal Disease Network Organizations Manual (HCFA-Pub. 81) (Superintendent of Documents No. HE 22.8.9/4)
3	• Background/Authority Objectives System Capacity Software Requirements Hardware Requirements Communications Data Security Confidentiality of Data Data Management ESRD Data Responsibility HCFA ESRD Forms Review of ESRD Medical Evidence Report—Medicare Entitlement and/or Patient Registration Form Collection, Completion, and Validation of ESRD Forms Tracking System for ESRD Forms ESRD Forms Submission Compliance Rates HCFA ESRD Forms Facsimiles and Data Corrections Resolving Discrepant Records—Forms Facsimiles Disposition Code Correcting Facsimile Error Code Determining Correct Medicare Health Insurance Claim Number Other Incorrect Data Elements Maintenance of Hardcopy Forms Facility Roster Update of Network Database National Surveillance of Dialysis-Associated Disease Form Special Studies/Surveys

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April through June 1995]

Trans. No.		Manual/Subject/Publication No.
		Department of Veterans Affairs
		Renal Transplant Data
		Obtaining and Processing Renal Transplant Data
		Inquiries from HMOs/CMPs
		Network Required to Provide Information to HMOs/CMPs
		Network Not Required to Furnish Information to HMOs/CMPs
		Data—Core Indicators
		Authority
		Objectives
		Health Care Quality Improvement Program
		Quality of Care Assessment
		Core Indicators
		Core Indicators—Network National Sample
		Core Indicators—Sampling Method
		Core Indicators—Data Collection
		Core Indicators—Data Validation
		Core Indicators—Data Reporting
		Pattern Analysis
		Pattern Analysis Reporting
		Preparation of Reports
		National Cooperative Projects
		National Cooperative Process
		Quality of Care Evaluation and Improvement
		Feedback Reports
		Network Intervention and Follow-up
		Improvement Plan
		Special Projects
		Special Projects Protocol
		Special Projects—Delivery Requirements
		Quality Assessment and Improvement Reports Authority
		Network Role Prior to Initiating a Sanction Recommendation
		Documentation Requirements for Sanction Recommendation
		Forwarding the Sanction Recommendation to the Appropriate Regional Office
		Project Officer Role in Sanction Procedures
		RO Role in Sanction Procedures
		RO Role in Notice and Appeal Rights
		Duration and Removal of Alternative Sanction
		State Medicaid Manual Part 3—Eligibility (HCFA-Pub. 45–3) (Superintendent of Documents No. HE 22.8/10)
66	•	American Indian Born in Canada—Types of Documentation
		Illegal Aliens Eligible for Emergency Services
		State Medicaid Manual Part 4—Services (HCFA-Pub. 45–4) (Superintendent of Documents No. HE 22.8/10)
67	•	Personal Care Services
		State Medicaid Manual Part 5—Early and Periodic Screening, Diagnosis, and Treatment (HCFA-Pub. 45–5) (Superintendent of Documents No. HE 22.8/10)
9	•	Screening Service Content
10	•	Periodicity Schedule
		Transportation and Scheduling Assistance (Support Services)
		Program Monitoring, Planning, and Evaluation
		Reimbursement
		State Medicaid Manual Part 6—Payment for Services (HCFA-Pub. 45–6) (Superintendent of Documents No. HE 22.8/10)
28	•	Updates the Drug Ingredient Prices Used to Establish Upper Limits for Prescription Drugs
		Medicare/Medicaid
		Sanction/Reinstatement Report
95–4	•	Report of Physician/Practitioners, Providers and/or Other Health Care Suppliers—February 1995

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April through June 1995]

Trans. No.	Manual/Subject/Publication No.
95–5	• Cumulative Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Sanctioned/Reinstated
95–6	• Report of Physician/Practitioners, Providers and/or Other Health Care Suppliers—March 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. We are not reprinting the unrelated material.)

Transmittal No. 75; sections 60–11 - 60–11 (Cont.) Home Blood Glucose Monitors CHANGED IMPLEMENTING INSTRUCTIONS—EFFECTIVE DATE: For Services Furnished On or After 04/27/95.

Section 60–11, Home Blood Glucose Monitors.—This section is revised to eliminate the requirement that the patient must be subject to poor diabetic control. Medical evidence indicates that blood glucose monitors are medically appropriate for individuals who do not have poor diabetic control. In addition, the policy is revised to allow any responsible individual, not only a family member, to be trained to use the equipment and monitor the patient when the patient is not capable of doing so.

60–11 Home Blood Glucose Monitors

There are several different types of blood glucose monitors which use reflectance meters to determine blood glucose levels. Medicare coverage of these devices varies, both with respect to the type of device and the medical condition of the patient for whom the device is prescribed.

Reflectance colorimeter devices used for measuring blood glucose levels in clinical settings are not covered as durable medical equipment for use in the home because their need for frequent professional recalibration makes them unsuitable for home use. However, some types of blood glucose monitors which use a reflectance meter specifically designed for home use by diabetic patients may be covered as durable medical equipment, subject to the conditions and limitations described below.

Blood glucose monitors are meter devices which read color changes produced on specially treated reagent strips by glucose concentrations in the patient's blood. The patient, using a disposable sterile lancet, draws a drop of blood, places it on a reagent strip and, following instructions which may vary with the device used, inserts it into the device to obtain a reading. Lancets, reagent strips, and other supplies necessary for the proper functioning of the device are also covered for patients for whom the device is indicated. Home blood glucose monitors enable certain patients to better control their blood glucose levels by frequently checking and appropriately contacting their attending physician for advice and treatment. Studies indicate that the patient's ability to carefully follow proper procedures is critical to obtaining satisfactory results with these devices. In addition, the cost of the devices, with their supplies, limits economical use to patients who must make frequent checks of their blood glucose levels. Accordingly, coverage of home blood glucose monitors is limited to patients meeting the following conditions:

- The patient must be an insulin-treated diabetic;
- The patient's physician states that the patient is capable of being trained to use the particular device prescribed in an appropriate manner. In some cases, the patient may not be able to perform this function, but a *responsible individual can be trained to use the equipment and monitor* the patient to assure that the intended effect is achieved. This is permissible if the record is properly documented by the patient's physician; and
- The device is designed for home rather than clinical use.

There is also a blood glucose monitoring system designed especially for use by those with visual impairments. The monitors used in such systems are identical in terms of reliability and sensitivity to the standard blood glucose monitors described above. They differ by having such features as voice synthesizers, automatic timers, and specially designed arrangements of supplies and materials to enable the visually impaired to use the equipment without assistance.

These special blood glucose monitoring systems are covered under Medicare if the following conditions are met:

- The patient and device meet the four conditions listed above for coverage of standard home blood glucose monitors; and
- The patient's physician certifies that he or she has a visual impairment severe enough to require use of this special monitoring system.

The additional features and equipment of these special systems justify a higher reimbursement amount than allowed for standard blood glucose monitors. Separately identify claims for such devices and establish a separate reimbursement amount for them. For those carriers using HCPCS, the procedure code and definition is: EO609—Blood Glucose Monitor—with special features (e.g., voice synthesizers, automatic timer).

Transmittal No. 76; sections 50–36—50–39.1 Positron Emission Tomography (PET or PETT) Scans—New Implementing Instructions—Effective Date: Services furnished on or after March 14, 1995.

Section 50–36, Positron Emission Tomography (PET or PETT) Scans.—This section is revised to provide limited coverage of positron emission tomography scans. Previously, PET scans were considered experimental by HCFA. PET scans are covered for use in noninvasive imaging of the perfusion of the heart for diagnosis and management of patients with known or suspected coronary artery disease. Coverage is limited to scans which employ Rubidium-82, done on equipment approved by the Food and Drug Administration, and when done in place of, but not in addition to a single photon emission computed tomography (SPECT) scan. PET centers must file claims for Medicare beneficiaries using specific G codes, and provide information regarding the results of previous tests. PET centers are also expected to maintain patient records for each Medicare patient with sufficient information to substantiate the need for the scan.

50–36 Positron Emission Tomography (Pet or Pett) Scans (Effective for Services Performed on or After March 14, 1995)

Positron emission tomography (PET), also known as positron emission transverse tomography (PETT), is a noninvasive imaging procedure that assesses perfusion and the level of metabolic activity in various organ systems of the human body. A positron camera (tomograph) is used to produce cross-sectional tomographic images by detecting radioactivity from a radioactive tracer substance (radiopharmaceutical) that is injected into the patient.

Until recently Medicare considered PET scans experimental and, therefore, not covered. HCFA has now concluded that one use of PET scans, imaging of the perfusion of the heart using Rubidium 82 (Rb 82), is no longer experimental, and may be covered, provided that several conditions, outlined below, are met. This conditional coverage is dictated by two significant factors that apply to PET scans.

First, although PET is no longer considered experimental for this single use, it duplicates other covered forms of diagnostic testing, and the degree to which PET scans may substitute as primary tests for such uses, as compared to a confirming or medically necessary additional test, is not as clear as is preferable. For example, in the case of imaging perfusion of the heart, body size and type may result in a technically uninterpretable single photon emission computed tomography (SPECT) test in some cases, necessitating a PET scan in order to produce clearer images and allow diagnosis and treatment of the patient.

Second, the Food and Drug Administration (FDA) has approved only Rubidium 82 for general PET scan use. The FDA considers radiopharmaceuticals drugs, subject to all of the requirements for manufacture, testing and approval (including approval for certain specific uses) that the FDA applies to all drugs. Thus some uses of PET cannot be considered for coverage due to the lack of approval of the radiopharmaceuticals involved in those uses.

Although the FDA has approved another radiopharmaceutical (deoxy-2–Fluoro-D-glucose (FDG)), that approval is very limited and is restricted to a single PET site at this time. The FDA currently requires each site to submit its version of FDG for testing and approval as a new drug. In view of these restrictions, coverage of PET with FDG is not being considered at this time. HCFA will continue to monitor the use of PET with FDG, with a view toward considering coverage of such uses when they appear appropriate.

The following coverage requirements must be met to assure that PET scans (1) are medically necessary, (2) do not unnecessarily duplicate other covered diagnostic tests, and (3) do not involve investigational drugs or procedures using investigational drugs.

A. Approved Sites.—PET scans may be covered only at PET imaging centers with PET scanners that have been approved by the FDA. Medicare contractors must determine, prior to making payment for any PET scans, whether the center applying for payment has an FDA-approved scanner.

B. Use of Rubidium 82 (Rb 82) and Related Tests.—Coverage of PET scans under Medicare is currently limited to rest alone or rest with pharmacologic stress PET scans used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using the FDA-approved radiopharmaceutical Rubidium 82 (Rb 82). Coverage is further limited to scans that meet either one of the following conditions:

- *The PET scan, whether rest alone or rest with stress, is used in place of, but not in addition to, a single photon emission computed tomography (SPECT); or*
- *The PET scan, whether rest alone or rest with stress, is used following a SPECT that was found inconclusive. In these cases, the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the patient. (For purposes of this requirement, an inconclusive test is a test(s) whose results are equivocal, technically uninterpretable, or discordant with a patient's other clinical data.)*

Note: PET scans using Rubidium 82, whether rest or stress are not covered by Medicare for routine screening of asymptomatic patients, regardless of the level of risk factors applicable to such patients.

C. Submission of Claims Data.—Claims for PET scans must include the following information. Failure to submit this information may result in denial of a claim.

The PET center must, for any PET scan for which payment is claimed, complete all required information on the claim form (including proper codes and modifiers) to indicate the results of the PET scan, as well as information as to whether the PET scan was done after an inconclusive noninvasive cardiac test. The information submitted with respect to the previous cardiac test must specify the type of test done prior to the PET scan and whether it was inconclusive or unsatisfactory. These explanations are in the form of special G codes used for billing PET scans.

D. Maintenance of Patient Record Data Onsite.—In view of these limitations on coverage, HCFA may decide to conduct some post-payment reviews to determine that the use of PET scans is consistent with this instruction. PET centers must keep patient record information on file for each Medicare patient for whom a PET scan claim is made. These medical records will be used in any post-payment reviews and must include the information necessary to substantiate the need for the PET scan. The records must include standard information (e.g., age, sex, and height) along with any annotations regarding body size or type which indicated a need for a PET scan to determine that patient's condition (i.e., any reason the nature of the patient's body size or type mandated the use of a PET scan in order to continue treatment).

Transmittal No. 77; sections 60–16—60–19 (Cont.) Pneumatic Compression Devices (Used for Lymphedema) CLARIFICATION—Effective Date: Not Applicable.

Section 60–16, Pneumatic Compression Devices (Used for Lymphedema).—This section is revised to clairfy (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. 60–16 Pneumatic Compression Devices (used for Lymphedema)

Lymphedema is the swelling of subcutaneous tissues due to the accumulation of excessive lymph fluid. The accumulation of lymph fluid results from an impairment to the normal clearing function of the lymphatic system and/or from an excessive production of lymph. It is a relatively uncommon, chronic condition which may be due to many causes, e.g., surgical removal of lymph nodes, post radiation fibrosis, scarring of lymphatic

channel, onset of puberty (Milroy's Disease), and congenital anomalies. In the home setting, both the segmental and nonsegmental pneumatic compression devices are covered only for the treatment of generalized, refractory lymphedema.

Pneumatic compression devices are only covered as a treatment of last resort, i.e., other less intensive treatments must have been tried first and found inadequate. Such treatments would include leg or arm elevation and custom fabricated gradient pressure stockings or sleeves.

Pneumatic compression devices may be covered only when prescribed by a physician and when they are used with appropriate physician oversight, i.e., physician evaluation of the patient's condition to determine medical necessity of the device, suitable instruction in the operation of the machine, a treatment plan defining the pressure to be used and the frequency and duration of use, and ongoing monitoring of use and response to treatment.

The determination by the physician of the medical necessity of a pneumatic compression device must include (1) The patient's diagnosis and prognosis; (2) symptoms and objective findings, including measurements which establish the severity of the condition; (3) the reason the device is required, including the treatments which have been tried and failed; and (4) the clinical response to an initial treatment with the device. The clinical response includes the change in pre-treatment measurements, ability to tolerate the treatment session and parameters, and ability of the patient (or caregiver) to apply the device for continued use in the home.

In general, the nonsegmented (HCPCS code E0650) or segmented (HCPCS code E0651) compression device without manual control of pressure in each chamber is considered the least costly alternative that meets the clinical needs of the individual.

Therefore, when a claim for a segmented pneumatic compression device which allows for manual control in each chamber is received, payment must be made for the least expensive medically appropriate device. If the patient medically needs a segmented device but does not need manual controls, payment must be made for HCPCS code E0651. The segmented device with manual control (HCPCS code E0652) is covered only when there are unique characteristics that prevent the individual from receiving satisfactory pneumatic treatment using a less costly device, e.g., significant sensitive skin scars or the presence of contracture or pain caused by a clinical condition that requires the more costly manual control device.

The use of pneumatic compression devices may be medically appropriate only for those patients with generalized, refractory edema from venous insufficiency with lymphatic obstruction (i.e., recurrent cellulitis with secondary scarring of the lymphatic system) with significant ulceration of the lower extremity(ies) who have received repeated, standard treatment from a physician using such methods as a compression bandage system or its equivalent, but fail to heal after 6 months of continuous treatment. The exact nature of the medical problem must be clear from the medical evidence submitted. If, after obtaining this information, a question of medical necessity remains, the contractor's medical staff resolves the issue.

ADDENDUM V.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER

Publication date	FR Vol. 60 page	CFR part	File code	Regulation title	End of comment period	Effective date
04/06/95 ...	17538–17547	.....	BPO–130–N.	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances and Coverage Decisions—Fourth Quarter 1994.	.....	04/06/95
04/10/95 ...	18136–18137	.....	MB–084–N	Medicaid Program; Rescission of the Guidelines for Documenting Medicaid Recipient Access to Immunizations Under the Vaccines for Children (VFC) Program.	.....	.....
04/20/95 ...	19753	.....	OFHR–001–N.	New Address and Telephone Numbers of the Office of Acquisition and Grants, Office of Financial and Human Resources.	.....	05/22/95
04/21/95 ...	19856–19862	440, 441	MB–041–F	Medicaid Program; Required Coverage Of Nurse Practitioner Services.	.....	05/22/95
04/24/95 ...	20035–20051	493	HSQ–216–FC.	CLIA Program; Categorization of Tests and Personnel Modifications.	06/23/95	04/24/95
05/01/95 ...	21048	421	BPO–083–F.	Medicare Program; Revisions to Criteria and Standards for Evaluating Intermediaries and Carriers (Correction).	.....	05/01/95
05/03/95 ...	21824–21825	.....	HSQ–227–N.	Medicaid Program; Peer Review Organization Contracts: Solicitation of Statements of Interest From In-State Organizations-Alaska, Delaware, the District of Columbia, Idaho, Kentucky, Maine, Nebraska, Nevada, South Carolina, Vermont, and Wyoming.	.....	05/03/95
05/08/95 ...	22533–22535	406	BPD–738–F.	Medicare Program; Clarification of Resumption of Entitlement Rules for Medicare Patients With End-Stage Renal Disease (ESRD).	.....	06/07/95
05/25/95 ...	27736	.....	OPL–005–N.	Medicare Program; June 12, 1995 Meeting of the Practicing Physicians Advisory Council.	.....	05/25/95
06/02/95 ...	29202–29434	412, 485, 413, 489, 424	BPD–825–P.	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1996 Rates.	08/01/95	.....
06/12/95 ...	30877–30891	.....	BPD–832–N.	Medicaid Program; HHS' Approval of NAIC Statements Relating to Duplication of Medicare Benefits.	.....	08/11/95

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

Publication date	FR Vol. 60 page	CFR part	File code	Regulation title	End of comment period	Effective date
06/13/95 ...	31158–31161	.....	ORD–075–N.	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: February and March 1995.	.....	06/13/95
06/27/95 ...	31126–31137	.....	BPD–366–F.	Medicare Program; Clarification of Medicare's Accrual Basis of Accounting Policy.	.....	07/27/95
06/27/95 ...	33123–33126	413	BPD–689–F.	Medicare Program; Uniform Electronic Cost Reporting System for Hospitals.	.....	07/27/95
06/27/95 ...	33262–33298	417, 483, 430, 484, 431, 489, 434	BPD–718–F.	Medicare and Medicaid Programs; Advance Directives.	.....	07/27/95
06/27/95 ...	33137–33143	.....	BPD–794–F.	Medicare Program; Date for Filling Medicare Cost Reports.	.....	06/27/95
06/27/95 ...	33221–33224	.....	ORD–076–N.	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: April 1995.	.....	06/27/95

*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.

[FR Doc. 95–28172 Filed 11–14–95; 8:45 am]
BILLING CODE 4120–01–P

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has made final findings of scientific misconduct in the following case:

Weishu Y. Weiser, Ph.D., Harvard Medical School: On October 19, 1995, ORI found that Weishu Y. Weiser, Ph.D., formerly of the Harvard Medical School at Brigham and Women's Hospital, committed scientific misconduct by falsifying data in biomedical research supported by two Public Health Service (PHS) grants.

Dr. Weiser has entered into a Voluntary Exclusion Agreement with ORI in which she has accepted ORI's finding and has agreed to exclude herself voluntarily, for the three (3) year period beginning October 19, 1995, from:

(1) Participating in any Federal contracts or subcontracts and from eligibility for or involvement in Federal nonprocurement transactions (e.g., grants and cooperative agreements), as covered in 45 C.F.R. Part 76 and 48 C.F.R. Subparts 9.4 and 309.4 (Debarment Regulations); and

(2) Serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

She has agreed to submit a letter to the Journal of Immunology and to the Proceedings of the National Academy of Sciences to retract the articles entitled ''Human recombinant migration inhibitory factor activates human macrophages to kill Leishmania donovani'' (Journal of Immunology 147:2006–2011, 1991), ''Recombinant migration inhibitory factor induces nitric oxide synthase in murine macrophages'' (Journal of Immunology 150:1908–1912, 1993), and ''Recombinant human migration inhibitory factor has adjuvant activity'' (Proceedings of the National Academy of Sciences 89:8049–8052, 1992).

FOR FURTHER INFORMATION CONTACT: Director, Division of Research Investigations, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852.

Lyle W. Bivens,

Director, Office of Research Integrity.

[FR Doc. 95–28150 Filed 11–14–95; 8:45 am]
BILLING CODE 4160–17–P

Office of Inspector General

Program Exclusions: October 1995

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of October 1995, 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 Executive Branch procurement and non-procurement programs and activities.

Subject City, State	Effective Date
PROGRAM-RELATED CONVICTIONS	
CONNOLLY, JOHN L, CARLTON, MN	11/14/95
COOPER, JEAN, LONGMONT, CO	11/16/95
DERENZO, ADRIANNE, BERWYN, PA	11/16/95
DONOVAN, JAMES, BALTIMORE, MD	11/16/95
EARLEY, TERESITA E, NEW YORK, NY	11/16/95
ELITE AMBULANCE SERVICE, SUNBURY, PA	11/16/95
FARO, ANTHONY J, ANCHORAGE, AK	11/16/95
GONCHOROFF, MICHAEL C, WIXOM, MI	11/14/95
ISLAM, KAZI, BROOKLYN, NY	11/16/95
KAHN, WALAYAT A, YPSILANTI, MI	11/14/95
KARMO, ROOSEVELT Q, BALTIMORE, MD	11/16/95
KNIGHT, MARY ROSEANN, HOT SPRINGS, AR	11/16/95