Description: Would amend the current Single Parent Employment Demonstration (SPED), requiring preschool children to be immunized and other children to attend school; considering as a single filing unit each family with a child in common, including all children in the household related to either parent; permitting parents removed from the grant due to non-cooperation or fraud to remain eligible for JOBS services, including support services; and allowing a ''best estimate'' of earnings in lieu of actual earnings so long as estimate is within $100 of actual earnings. These amendments would initially be limited to the Kearns office and later expanded to other SPED sites.

Date Received: 2/7/96.

Type: AFDC.

Current Status: Pending.

Contact Person: Bill Biggs, (801) 538–4337.

III. Listing of Approved Proposals Since March 1, 1995

Project Title: North Carolina—Cabarrus County Work Over Welfare Demonstration Project.

Contact Person: Kevin Fitzgerald, (919) 733–3055.

Project Title: Ohio—Ohio First.

Contact Person: Joel Rabb, (614) 466–3196.

Project Title: Oregon—Oregon Option.*

Contact Person: Jim Neely, (503) 945–5607.

* The provisions of two previously pending proposals, the Expansion of the Transitional Child Care Program and the Increased AFDC Motor Vehicle Limit, were consolidated into the approval of Oregon Option.

Project Title: Texas—Achieving Change for Texans.

Contact Person: Kent Gummerman, (512) 438–3743.

IV. Requests for Copies of a Proposal

Requests for copies of an AFDC or combined AFDC/Medicaid proposal should be directed to the Administration for Children and Families (ACF) at the address listed above. Questions concerning the content of a proposal should be directed to the State contact listed for the proposal.

(Catalog of Federal Domestic Assistance Program, No. 93562; Assistance Payments—Research)

Dated: April 1, 1996.

Karl Koerper,

Director, Division of Economic Independence, Office of Planning, Research and Evaluation.

[FR Doc. 96–8554 Filed 4–5–96; 8:45 am]

BILLING CODE 4184–01–P

Health Care Financing Administration

[BPO–136–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances and Coverage Decisions; Third 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 July, August, and September 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 timeframe. We are also providing the content of revisions to the Medicare Coverage Issues Manual published during the period July 1 through September 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 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).

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 that 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 list in this notice Medicaid issuances and Medicaid substantive and interpretive regulations published during July 1 through September 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 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 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 September 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) that have changed (if applicable), the agency file code number, 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 the initial list of all of the Food and Drug Administration-approved investigational device exemption numbers organized by 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 include the additions and deletions to this initial list of devices with a Food and Drug Administration-approved investigational device exemption.

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, PO 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.

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, 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 ''Electronic Data Interchange Enrollment Form,'' use the Superintendent of Documents No. HE 22.8/7 and the HCFA transmittal number 1519.

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 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: March 29, 1996.

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 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)

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 JULY THROUGH SEPTEMBER 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)
1655	• Electronic Data Interchange Enrollment Form HCFA–486.
1656	• Medical Update and Patient Information.
1657	• Medicare Part A Standard Paper Remittance Advice.
1658	• Reporting Outpatient Surgery and Other Services.
1659	• Claims Processing Terminology. Handling Incomplete or Invalid Claims. Data Element Requirements Matrix. Addendum L, Data Element Requirements Matrix.
1660	• Provider Electronic Billing File and Record Formats. Alphabetic Listing of Data Elements. Patient Information Data Definitions and Codes. Forms HCFA–700/701, Outpatient Rehabilitative Services Forms. Electronic Formats for Medical Review Attachment Information.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JULY THROUGH SEPTEMBER 1995—Continued

Trans. No.	Manual/subject/publication No.
	Electronic Media Claims Flat File Record for Outpatient Rehabilitation Services—Record Type 77. Flat File Requirements for Record Type 77, Outpatient Rehabilitation Services. Requirements by Record Type and Field (Data Element) for Outpatient Rehabilitative Services. Definition of Narrative Type Indicators. Validating Information and Returning Submissions Independent of Claim.
1661	• HCPCS for Hospital Outpatient Radiology Services and Other Diagnostic Procedures. Radiology HCPCS Codes Subject to the Payment Limit. Other Diagnostic Services HCPCS Codes Subject to the Payment Limit.
	Carriers Manual—Part 3, Claims Process (HCFA-Pub. 14–3) (Superintendent of Documents No. HE 22.8/7)
1519	• Electronic Data Interchange Enrollment Form.
1520	• Nurse Practitioner Services, Clinical Nurse Specialist Services.
1521	• Part B Provider Access to Limited Eligibility Data. Eligibility Data Available. Contractor Implementation. HCFA Standard Part B Eligibility Inquiry Flat File Specifications. HCFA Standard Part B Eligibility Response Flat File Specifications.
1522	• Nonparticipating Physicians to Provide Notices For Elective Surgery.
1523	• Services Received by Medicare Beneficiaries Outside the United States.
1524	• Drugs and Biologicals.
1525	• Local MR Policy. Internal MR Guidelines. The Carrier Advisory Committee. Data Analysis to Identify Aberrancies. Medical Review Prepayment Screens. Categories of MR Screens. HCFA Mandated and HCFA Optional MN Screens. Assessing an Overpayment When the CMR Was Based on a SVRS. The Carrier Medical Director and Carrier Coordination. Carrier Coordination With Peer Review Organization. Medicare FMR Status Report. Medical Review. Coordination With Carrier Medicare Fraud Unit. National Coverage Policy. Local MR Policy. Internal MR Guidelines. Utilization Guidelines and Parameters. The Carrier Advisory Committee. Data Analysis. Data Analysis to Identify Aberrancies. Aberrancies. Taking Corrective Actions on Identified Aberrancies. Conducting Evaluation of Effectiveness of Corrective Action. Standard Postpayment Data Reports. Evaluation of MR Prepayment Screens. MR Screen Parameters. HCFA Mandated and HCFA Optional MN Screens. Postpayment MR. Postpayment Review Personnel. CMR Corrective Actions. Assessing an Overpayment or Potential Overpayment When the CMR Was Based on a Limited Sample/Subsample. MN Denials. Carrier Coordination with Fiscal Intermediary.
1526	• Claims Processing Terminology. Handling Incomplete or Invalid Claims. Data Element Requirements Matrix. Conditional Data Element Requirements. Data Element Requirements Matrix.
	Program Memorandum, Intermediaries (HCFA-Pub. 60A) (Superintendent of Documents No. HE 22.8/7)
A–95–9	• Star Alert.
	Program Memorandum, Carriers (HCFA-Pub. 60B) (Superintendent of Documents No. HE 22.8/6–5)
B–95–5	• Implementation of Limitation on Information Provided by Suppliers on Certificates of Medical Necessity (§1834 of the Act, as amended by §131 of the Social Security Act Amendments of 1994).

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JULY THROUGH SEPTEMBER 1995—Continued

Trans. No.	Manual/subject/publication No.
	Program Memorandum, Intermediaries/Carriers (HCFA-Pub. 60AB) (Superintendent of Documents No. HE 22.8/6–5)
AB–95–7	• Current Status of Medicare Program Memorandums and Letters Issued Before Calendar Year (CY) 1995.
AB–95–8	• New Interest Rate Payable on Clean Claims Not Paid Timely.
AB–95–9	• Changes in MSP Demand Process.
AB–95–10	• Changes in MSP Demand Process (This PM was reissued to correct a typographical error.)
	Program Memorandum, Medicaid State Agencies (HCFA-Pub. 17) (Superintendent of Documents No. HE 22.8/6–5)
95–5	• Current Status of Medicaid PMs and Action Transmittals Issued Before Calendar Year (CY) 1995.
95–6	• Application of the Nursing Home Enforcement Regulations to Life Safety Code Surveys.
	Hospital Manual (HCFA-Pub 10) (Superintendent of Documents No. HE 22.8/2)
683	• Reporting Outpatient Surgery and Other Services.
684	• HCPCS for Hospital Outpatient Radiology and Other Diagnostic Procedures. Radiology HCPCS Codes Subject to the Payment Limit. Other Diagnostic Services HCPCS Codes Subject to the Payment Limit.
	Home Health Agency Manual (HCFA-Pub. 11) (Superintendent of Documents No. HE 22.8/5)
276	• HCFA–486—Medical Update and Patient Information.
	Skilled Nursing Facility Manual (HCFA-Pub. 12) (Superintendent of Documents No. HE 22.8/3)
339	• Special Billing Instructions for Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines.
	Health Maintenance Organization/Competitive Medical Plan Manual (HCFA-Pub. 75) (Superintendent of Documents No. HE 22/8/21:989)
15	• Risk Payment. Annual Reconciliation. Benefit Stabilization Fund Withholds/Withdrawals. Electronic Transfer of Funds. Plan Payment Report. Monthly Payment Letter. Adjustments to County Level. Conversion of County Per Capita Costs Into Rates Example of AAPCC Methodology. Definitions. Form of Additional Benefits. Report on Value of Additional and Supplemental Benefits.
	Coverage Issues Manual (HCFA-Pub. 6) (Superintendent of Documents No. HE 22.8/14)
78	• Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy. Transcutaneous Electrical Nerve Stimulation for Acute Post-Operative Pain. Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation and Neuromuscular Electrical Stimulation. Electrical Nerve Stipulators.
79	• Transcendental Meditation.
	Regional Office Manual Standards and Certification (HCFA-Pub. 23–4) (Superintendent of Documents No. HE 22.8/8–3)
60	• Request for Survey of Sections 489.20 and 489.24 Essentials of Provider Agreement: Responsibilities of Medicare Participating Hospitals in Emergency Cases. 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.
61	• Special Procedures for End Stage Renal Disease Facilities. Special Procedures for Laboratories. Program Background and Responsibilities. Validation and Complaint Surveys of CLIA-Exempt Laboratories. Adverse Actions. Appeals of Adverse Actions. Special Procedures for Accredited Laboratories. CLIA Fee Collection Procedures.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JULY THROUGH SEPTEMBER 1995—Continued

Trans. No.	Manual/subject/publication No.
	Federal Surveys.
	Budget and Administration, State Operations Manual, Provider Certification (HCFA-Pub. 7) (Superintendent of Documents No. HE 22.8/12)
275	• Approval Process. Resident Assessment Instrument for Long Term Care Facilities.
276	• Requirements for Specialty Hospitals. Interpretive Guidelines—Psychiatric Hospitals. Medicare/Medicaid Psychiatric Hospital Survey Data (HCFA–724). Surveyor Worksheet for Psychiatric Hospital Review (HCFA–725). HCFA Death Record Review Data Sheet (HCFA–726). HCFA Nursing Complement Data (HCFA–727). HCFA Total Nursing Staff Data (HCFA–728). Data Collection Medical Staff Coverage (HCFA–729).
	Peer Review Organization Manual (HCFA-Pub. 19) (Superintendent of Documents No. HE 8/8–15)
52	• Commonly Used Acronyms. Background and Authority. Hospital Requirements. Hospital Penalties for Noncompliance. RO Responsibilities. State Agency Surveys. PRO Review Responsibilities. Physician Review Outline. 60–Day PRO Review: Opportunity for Discussion.
53	• Glossary.
	Provider Reimbursement Manual, Part 1 (HCFA-Pub. 15–1), (Superintendent of Documents No. HE 22.8/4)
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.
	Provider Reimbursement Manual, Part II—Provider Cost Reporting Forms and Instructions—Chapter 28 (HCFA-Pub. 15–IIAB) (Superintendent of Documents No. HE 22.8/4)
7	• Electronic Reporting Specifications for Form-2552–92.
	Provider Reimbursement Manual, Part II—Provider Cost Reporting Forms and Instructions—Chapter 31 (HCFA-Pub. 15–IIAE) (Superintendent of Documents No. HE 22.8/4)
3	• This transmittal makes corrections to Chapter 31.
	Provider Reimbursement Manual, Part II—Provider Cost Reporting Forms and Instructions—Chapter 34—(HCFA-Pub. 15–IIAH) (Superintendent of Documents No. HE 22.8/4)
3	• Worksheet S–1—Independent Renal Dialysis Facility Statistical Data. Worksheet A—Reclassification and Adjustment of Trial Balance of Expenses. Worksheet A–2—Adjustment of Expenses.
	End Stage Renal Disease Network, Organizations Manual (HCFA-Pub. 81) (Superintendent of Documents No. 22.8.9/4)
4	• Introduction. Objectives. Network Role. Community Outreach Plan. Clearinghouse Activities. Patient Grievances. Origin of Patient Grievances. Scope of Grievances. Role of Network in Resolution of Patient Grievances. Determining Grievances for Network Involvement. Patient Awareness of Process. Use of Facility Grievance Process.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JULY THROUGH SEPTEMBER 1995—Continued

Trans. No.	Manual/subject/publication No.
	Determination of Network Involvement. Life-threatening Situations. Patient Representative. Requirement of Grievance in Writing. Timing of Network Activity. Written Acknowledgment of Grievance. Conclusion of Investigation. Exception. Nature of Response and Potential Outcomes. Contents of Report to Patient. Use of ROs. Potential Outcomes of Patient Grievance Process. Improvement Plans. Content of Improvement Plans. Time period for Review, Acceptance/Rejection of Improvement Plans. Information that May be Disclosed. Identity of Patient. Facility Identity. Conflict of Interest. States in Each Region.
	State Medicaid Manual, Part 4—Services (HCFA-Pub. 45–4) (Superintendent of Documents No. 22.8/10)
68	• Nurse Practitioner Services.
	Medicare/Medicaid, Sanction—Reinstatement Report
95–8	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—May 1995.
95–9	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—June 1995.
95–10	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—July 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. 78; sections 35–46 (Cont.)—35–48; sections 45–16–45–25; sections 60–19—60–20; sections 65–7—65–9

CHANGED IMPLEMENTING INSTRUCTIONS—EFFECTIVE DATE: For Services Furnished On or After 08/07/95.

Section 35–46, Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy, Section 45–19, Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain, Section 45–25, Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES), and Section 65–8, Electrical Nerve Stimulators, are revised to reflect that TENS are no longer covered under the prosthetic device benefit. HCFA has determined that they meet the definition of the durable medical equipment benefit rather than the prosthetic device benefit.

NEW IMPLEMENTING INSTRUCTIONS—EFFECTIVE DATE: For Services Furnished On or After 08/07/95.

Section 60–20, Transcutaneous electrical Nerve Stimulators (TENS), indicates that TENS are covered under the durable medical equipment benefit. HCFA has determined that TENS meets the definition of the durable medical equipment benefit rather than the prosthetic device benefit. These coverage guidelines had appeared in § 65–8 when TENS were covered under the prosthetic device benefit.

DISCLAIMER

The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

35–46 ASSESSING PATIENT'S SUITABILITY FOR ELECTRICAL NERVE STIMULATION THERAPY

Electrical nerve stimulation is an accepted modality for assessing a patient's suitability for ongoing treatment with a transcutaneous or an implanted nerve stimulator. Accordingly, program payment may be made for the following techniques when used to determine the potential therapeutic usefulness of an electrical nerve stimulator:

A. *Transcutaneous Electrical Nerve Stimulation (TENS).*—This technique involves attachment of a transcutaneous nerve stimulator to the surface of the skin over the peripheral nerve to be stimulated. It is used by the patient on a trial basis and its effectiveness in modulating pain is monitored by the physician or physical therapist. Generally, the physician or physical therapist is able to determine whether the patient is likely to derive a significant therapeutic benefit from continuous use of a transcutaneous stimulator within a trial period of 1 month; in a few cases this determination may take longer to make. Document the medical necessity for such services which are furnished beyond the first month. (See § 45–25 for an explanation of coverage of medically necessary supplies for the effective use of TENS.)

If TENS significantly alleviates pain, it may be considered as primary treatment; if it produces no relief or greater discomfort than the original

pain, electrical nerve stimulation therapy is ruled out. However, where TENS produces incomplete relief, further evaluation with percutaneous electrical nerve stimulation may be considered to determine whether an implanted peripheral nerve stimulator would provide significant relief from pain. (See § 35–46B.)

Usually, the physician or physical therapist providing the services will furnish the equipment necessary for assessment. Where the physician or physical therapist advises the patient to rent the TENS from a supplier during the trial period rather than supplying it himself, program payment may be made for rental of the TENS as well as for the services of the physician or physical therapist who is evaluating its use. However, the combined program payment which is made for the physician's or physical therapist's services and the rental of the stimulator from a supplier should not exceed the amount which would be payable for the total service, including the stimulator, furnished by the physician or physical therapist alone.

B. *Percutaneous Electrical Nerve Stimulation (PENS).*—This diagnostic procedure which involves stimulation of peripheral nerves by a needle electrode inserted through the skin is performed only in a physician's office, clinic, or hospital outpatient department. Therefore, it is covered only when performed by a physician or incident to physician's service. If pain is effectively controlled by percutaneous stimulation, implantation of electrodes is warranted.

As in the case of TENS (described in subsection A), generally the physician should be able to determine whether the patient is likely to derive a significant therapeutic benefit from continuing use of an implanted nerve stimulator within a trial period of 1 month. In a few cases, this determination may take longer to make. The medical necessity for such diagnostic services which are furnished beyond the first month must be documented.

Note: Electrical nerve stimulators do not prevent pain but only alleviate pain as it occurs. A patient can be taught how to employ the stimulator, and once this is done, can use it safely and effectively without direct physician supervision. Consequently, it is inappropriate for a patient to visit his physician, physical therapist or an outpatient clinic on a continuing basis for treatment of pain with electrical nerve stimulation. Once it is determined that electrical nerve stimulation should be continued as therapy and the patient has been trained to use the stimulator, it is expected that a stimulator will be implanted or the patient will employ the TENS on a continual basis in his home. Electrical nerve stimulation treatments furnished by a physician in his office, by a physical therapist or outpatient clinic are excluded from coverage by section 1862(a)(1) of the law. (See secton 65–8 for an explanation of coverage of the therapeutic use of *implanted peripheral nerve stimulators under the prosthetic devices benefit. See § 60–20 for an explanation of coverage of the therapeutic use of TENS under the durable medical equipment benefit.*)

45–19 TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) FOR ACUTE POST-OPERATIVE PAIN

The use of transcutaneous electrical nerve stimulation (TENS) for the relief of acute post-operative pain is covered under Medicare. TENS may be covered whether used as an adjunct to the use of drugs, or as an alternative to drugs, in the treatment of acute pain resulting from surgery.

TENS devices, whether durable or disposable, may be used in furnishing this service. When used for the purpose of treating acute post-operative pain, TENS devices are considered supplies. As such they may be hospital supplies furnished inpatients covered under Part A, or supplies incident to a physician's service when furnished in connection with surgery done on an outpatient basis, and covered under Part B.

It is expected that TENS, when used for acute post-operative pain, will be necessary for relatively short periods of time, usually 30 days or less. In cases when TENS is used for longer periods, contractors should attempt to ascertain whether TENS is no longer being used for acute pain but rather for *chronic pain, in which case the TENS device may be covered as durable medical equipment as described in § 60–20.*

Cross-refer: HCFA Pub. 13–3, §§ 65–8, 3101.4, 3112.4, 3113; HCFA Pub. 14–3, §§ 65–8, 2050.1, 2100; HCFA Pub. 10, §§ 65–8, 210.4, 230, 235.

45–25 SUPPLIES USED IN THE DELIVERY OF TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) AND NEUROMUSCULAR ELECTRICAL STIMULATION (NMES)—(Effective for services rendered (i.e., items rented or purchased) on or after July 14, 1988.)

Transcutaneous Electrical Nerve Stimulation (TENS) and/or Neuromuscular Electrical Stimulation (NMES) can ordinarily be delivered to patients through the use of conventional electrodes, adhesive tapes and lead wires. There may be times, however, where it might be medically necessary for certain patients receiving TENS or NMES treatment to use, as an alternative to conventional electrodes, adhesive tapes and lead wires, a form-fitting conductive garment (i.e., a garment with conductive fibers which are separated from the patients' skin by layers of fabric).

A form-fitting conductive garment (and medically necessary related supplies) may be covered under the program *only* when:

1. It has received permission or approval for marketing by the Food and Drug Administration;

2. It has been prescribed by a physician for use in delivering covered TENS or NMES treatment; and

3. *One* of the medical indications outlined below is met:

- The patient cannot manage without the conductive garment because there is such a large area or so many sites to be stimulated *and* the stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes and lead wires;
- The patient cannot manage without the conductive garment for the treatment of chronic intractable pain because the areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes and lead wires;
- The patient has a documented medical condition such as skin problems that preclude the application of conventional electrodes, adhesive tapes and lead wires;
- The patient requires electrical stimulation beneath a cast either to treat disuse atrophy, where the nerve supply to the muscle is intact, or to treat chronic intractable pain; or
- The patient has a medical need for rehabilitation strengthening (pursuant to a written plan of rehabilitation) following an injury where the nerve supply to the muscle is intact.

A conductive garment is not covered for use with a TENS device *during* the trial period specified in § 35–46 *unless*:

4. The patient has a documented skin problem prior to the start of the trial period; and

5. The carrier's medical consultants are satisfied that use of such an item is medically necessary for the patient.

(See conditions for coverage of the use of TENS in the diagnosis and treatment *of chronic intractable pain in §§ 35- 46 and 60–20 and the use of NMES in the treatment of disuse atrophy in § 35–77.)*

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.)

65–8 ELECTRICAL NERVE STIMULATORS

Two general classifications of electrical nerve stimulators are employed to treat chronic intractable pain: peripheral nerve stimulators and central nervous system stimulators.

A. Implanted Peripheral Nerve Stimulators.—Payment may be made under the prosthetic device benefit for implanted peripheral nerve stimulators. Use of this stimulator involves implantation of electrodes around a selected peripheral nerve. The stimulating electrode is connected by an insulated lead to a receiver unit which is implanted under the skin at a depth not greater than ½ inch. Stimulation is induced by a generator connected to an antenna unit which is attached to the skin surface over the receiver unit. Implantation of electrodes requires surgery and usually necessitates an operating room.

Note: Peripheral nerve stimulators may also be employed to assess a patient's suitability for continued treatment with an electric nerve stimulator. As explained in § 35–46, such use of the stimulator is covered as part of the total diagnostic service furnished to the beneficiary rather than as a prosthesis.

B. *Central Nervous System Stimulators (Dorsal Column and Depth Brain Stimulators).*—The implantation of central nervous system stimulators may be covered as therapies for the relief of chronic intractable pain, subject to the following conditions:

1. *Types of Implantations.*—There are two types of implantations covered by this instruction:

a. *Dorsal Column (Spinal Cord) Neurostimulation.*—The surgical implantation of neurostimulator electrodes within the dura mater (endodural) or the percutaneous insertion of electrodes in the epidural space is covered.

b. *Depth Brain Neurostimulation.*—The stereotactic implantation of electrodes in the deep brain (e.g., thalamus and periaqueductal gray matter) is covered.

2. *Conditions for Coverage.*—No payment may be made for the implantation of dorsal column or depth brain stimulators or services and supplies related to such implantation, unless *all* of the conditions listed below have been met:

a. The implantation of the stimulator is used only as a late resort (if not a last resort) for patients with chronic intractable pain;

b. With respect to item a, other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given patient;

c. Patients have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation);

d. All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and followup of the patient (including that required to satisfy item c) must be available; and

e. Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.

Contractors may find it helpful to work with PROs to obtain the information needed to apply these conditions to claims. See Intermediary Manual, § 3110.4 and §§ 35–20 and 35–27. Transmittal No. 79; sections 35–89–35–92 NEW IMPLEMENTING INSTRUCTIONS—EFFECTIVE DATE: For services performed on or after October 11, 1995.

Section 35–92, Transcendental Meditation.—This section has been added to reflect noncoverage of Transcendental meditation (TM) and the cost of training patients to practice TM when it is prescribed as a treatment of mild hypertension, as adjunctive therapy in the treatment of essential hypertension, or as the sole or adjunctive treatment of anxiety and other psychological stress-related disorders.

These instructions are to be implemented within your current operating budget.

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

35–92 TRANSCENDENTAL MEDITATION—NOT COVERED

Transcendental Meditation (TM) is a skill that is claimed to produce a state of rest and relaxation when practiced effectively. Typically, patients are taught TM techniques over the course of several sessions by persons trained in TM. The patient then uses the TM technique on his or her own to induce the relaxed state. Proponents of TM have urged that Medicare cover the training of patients to practice TM when it is medically prescribed as treatment for mild hypertension, as adjunctive therapy in the treatment of essential hypertension, or as the sole or adjunctive treatment of anxiety and other psychological stress-related disorders.

After review of this issue, we have concluded that the evidence concerning the medical efficacy of TM is incomplete at best and does not demonstrate effectiveness, and that a professional level of skill is not required for the training of patients to engage in TM.

Although many articles have been written about application of TM for patients with certain forms of hypertension and anxiety, there are no rigorous scientific studies that demonstrate the effectiveness of TM for use as an adjunct medical therapy for such conditions. Accordingly, neither TM nor the training of patients for its use are covered under the Medicare program.

ADDENDUM V.—REGULATION DOCUMENT PUBLISHED IN THE FEDERAL REGISTER

Publication date	FR vol. 60 page	CFR part	File code*	Regulation title	End of comment period	Effective date
07/05/95	34885–34888	417	OMC–022–F	Full Reporting by Health Maintenance Organizations (HMOs) and Competitive Medical Plans (CMPs) Paid on a Cost Basis.	.....	08/04/95.
07/10/95	35492–35498	414	BPD–494–F	Medicare Program; Payment for Durable Medical Equipment and Orthotic and Prosthetic Devices.	.....	08/09/95.

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

Publication date	FR vol. 60 page	CFR part	File code *	Regulation title	End of comment period	Effective date
07/10/95	34598–35503	433	MB–39–F	Medicaid Program; Third Party Liability (TPL) Cost-Effectiveness Waivers.	.....	09/08/95.
07/10/95	35544–35548	405	BP0–121–P	Medicare Program; Telephone and Electronic Requests for Review of Part B Initial Claim Determinations.	09/08/95	07/10/95.
07/18/95	36733–36736	410 414	BPD–789–CN ...	Medicare Program; Refinements to Geographic Adjustment Factor Values, Revisions to Payment Policies, Adjustments to the Relative Value Units (RVUs) Under the Physician Fee Schedule for Calendar Year 1995, and the 5-Year Refinement of RVUs; Correction.	.....	01/01/95.
07/21/95	37590–37596	413	BPD–409–F	Medicare Program; Optional Payment System for Low Medicare Volume Skilled Nursing Facilities.	.....	08/21/95.
07/21/95	37657–37660	.....	HSQ–229–N	CLIA Program; Approval of the American Osteopathic Association as an Accrediting Organization.	.....	07/21/95 through 07/21/97.
07/21/95	37660–37662	.....	HSQ–228–N	CLIA Program; Approval of the American Association of Blood Banks.	.....	07/21/95 through 07/21/97.
07/26/95	38266–38272	424	BPD–709–FC ...	Medicare Program; Allowing Certifications and Recertification by Nurse Practitioners and Clinical Nurse Specialists for Certain Services.	09/25/95	08/25/95.
07/26/95	38400–38433	400 413 405 414 410 415 411 417 412 489	BPD–827–P	Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 1996.	09/25/95	
07/26/95	38344–38352	.....	BPO–131–N	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances and Coverage Decisions—First Quarter 1995.	.....	
08/01/95	39122–39123	409 484	BPD–469–CN ...	Medicare Program; Medicare Coverage of Home Health Services, Medicare Conditions of Participation, and Home Health Aide Supervision; Correction.	.....	02/21/95.
08/02/95	39304–39306	412 485 413 489 424	BPD–825–CN ...	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1996 Rates; Correction.	08/01/95	
08/09/95	40594–40597	.....	ORD–077–N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: May 1995.	.....	
08/14/95	41914–41982	411	BPD–674–FC ...	Medicare Program; Physician Financial Relationships With, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services; Financial Relationship Reporting Requirements.	10/13/95	09/13/95.
08/14/95	41893–41894	.....	OPL–006–N	Medicare Program; September 11, 1995 Meeting of the Practicing Physicians Advisory Council.	.....	
08/28/95	44503–44507	.....	HSQ–230–N	Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Exemption of Permit- Holding Laboratories in the State of New York.	.....	08/28/95 to 06/30/2001.
08/30/95	45085–45086	442 486 493	BPD–840–CN ...	Medicare and Medicaid Programs; Technical Amendatory Language Changes; Correction.	.....	02/08/95, 04/24/95, and 07/01/95.
08/31/95	45344–45372	400 411	BPD–482–FC ...	Medicare Program; Medicare Secondary Payer for Individuals Entitled to Medicare and Also Covered Under Group Health Plans.	10/30/95	10/02/95.
08/31/95	45372	.....	OMC–022–F	Full Reporting by Health Maintenance Organizations (HMOs) and Competitive Medical Plans (CMPs) Paid on a Cost Basis.	.....	08/04/95.
09/01/95	45673–45682	417	OMC–011–FC ..	Medicare Program; Contracts With Health Maintenance Organizations (HMOS) and Competitive Medical Plans (CMPs).	10/31/95	10/01/95.

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

Publication date	FR vol. 60 page	CFR part	File code*	Regulation title	End of comment period	Effective date
09/01/95	45778–45946	412 485 413 489 424	BPD–825–FC ...	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1996 Rates.	10/31/95	10/01/95; except § 412.46 which is effective 09/01/95.
09/06/95	46228–46234	417	OMC–014–FC ..	Medicare Program; Payments to HMOs and CMPs and Appeals; Technical Amendments.	10/06/95	10/01/95.
09/06/95	46288–46296	.....	BPO–133–PN ...	Medicare Program; Data, Standards, and Methodology Used to Establish Fiscal Year 1996 Budgets for Fiscal Intermediaries and Carriers.	11/06/95	
09/08/95	46838–46841	.....	MB–094–N	Medicaid Program; Limitations on Aggregate Payments to Disproportionate Share Hospitals: Federal Fiscal Year 1995.	09/30/95.	
09/13/95	47534–47543	493	HSQ–225–P	Public Health Service; CLIA Program; Categorization of Waived Tests.	11/13/95	
09/15/95	47982–47998	493	HSQ–222–P	CLIA Program; Categorization and Certification Requirements for a New Subcategory of Moderate Complexity Testing.	11/14/95	
09/18/95	48039–48044	405	BPD–766–F	Medicare Program; Standards for Quality of Water Used in Dialysis and Revised Guidelines on Reuse of Hemodialysis Filters for End-Stage Renal Disease (ESRD) Patients.	.....	10/18/95.
09/19/95	48417–48425	405 411	BPD–841–FC ...	Medicare Program; Criteria and Procedures for Extending Coverage to Certain Devices and Related Services.	11/20/95	11/01/95.
09/19/95	48442–48490	441 447	MB–046–P	Medicaid Program; Payment for Covered Outpatient Drugs Under Drug Rebate Agreements With Manufacturers.	11/20/95	
09/20/95	48749	400 411	BPD–482–FC ...	Medicare Program; Medicare Secondary Payer for Individuals Entitled to Medicare and Also Covered Under Group Health Plans; Correction.	.....	09/29/95.
09/26/95	49619–49622	.....	BPD–824–N	Medicare Program; Update of Ambulatory Surgical Center (ASC) Payment Rates Effective for Services On or After October 1, 1995.	.....	10/01/95.
09/28/95	50115–50120	431 488 440 489 442 498	HSQ–156–CN ..	Medicare and Medicaid Programs; Survey, Certification and Enforcement of Skilled Nursing Facilities and Nursing Facilities; Correction.	.....	07/01/95.
09/29/95	50439–50443	401 473 403 476 409 482 413 483 420 484 421 488 424 489 462 498 466	BPD–830–FC ...	Medicare Program; Authority Citations: Technical Amendments.	11/28/95	09/29/95.
09/29/95	50443–50446	400	OFH–018–F	Medicare and Medicaid Programs; Approved Information Collection Requirements.	.....	09/29/95.
09/29/95	50446–50448	485 486	BPD–836–FC ...	Medicare Program; Providers and Suppliers of Specialized Services: Technical Amendments.	11/28/95	09/29/95.

*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.

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 device (Category A) 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.

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

(1) Class III devices of a type for which no marketing application has been approved through the premarket approval (PMA) process for any indication for use. (For pre-amendments [1] Class III devices, refer to the criteria under Category B).

(2) Class III devices that would otherwise be in Category B but have undergone significant modification for a new indication for use.

The following information presents the device number, category (in this case, A), and criterion code for FDA approved IDE devices.

L002702 A 1, L014521 A 1, G840208 A 1, G870031 A 1, G870181 A 2, G880028 A 1, G880063 A 1, G880151 A 1, G880210 A 2, G890047 A 1, G890103 A 1, G890144 A 2, G890148 A 1, G890189 A 1, G890201 A 2, G890210 A 2, G900100 A 2, G900142 A 2, G900143 A 2, G900155 A 1, G900205 A 1, G900214 A 1, G900217 A 1, G900246 A 2, G900259 A 2, G910034 A 1, G910064 A 2, G910078 A 2, G910083 A 1, G910121 A 1, G910130 A 1, G910166 A 2, G910170 A 2, G910175 A 2, G910197 A 2, G910202 A 2, G920003 A 1, G920021 A 1, G920035 A 1, G920045 A 2, G920046 A 1, G920052 A 2, G920084 A 2, G920101 A 1, G920111 A 1, G920211 A 1, G930054 A 2, G930063 A 1, G930092 A 1, G930115 A 2, G930136 A 1, G930140 A 1, G930155 A 1, G930190 A 2, G930192 A 2, G940001 A 1, G940024 A 1, G940084 A 2, G940088 A 2, G940111 A 2, G940119 A 2, G940150 A 1, G940151 A 2, G940191 A 1, G940192 A 1, G950058 A 2, G950062 A 1, G950083 A 2, G950093 A 1, G950096 A 1

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.

L010038 B 1, L010109 B 2, L010119 B 2, L010598 B 2, L010913 B 2, L011828 B 2, L013468 B 2, L013469 B 2, L016548 B 1, L017238 B 3, G780049 B 2, G780054 B 2, G790001 B 2, G790011 B 6, G790012 B 2, G790016 B 1, G790018 B 2, G790022 B 2, G790023 B 2, G790030 B 2, G790033 B 1, G800001 B 2, G800002 B 2, G800004 B 2, G800007 B 1, G800017 B 5, G800020 B 1, G800022 B 2, G800024 B 2, G800035 B 3, G800046 B 1, G800049 B 2, G800055 B 2, G800074 B 2, G800075 B 1, G800077 B 2, G800083 B 4, G800124 B 2, G800129 B 3, G800138 B 2, G800143 B 4, G810003 B 2, G810022 B 2, G810028 B 2, G810065 B 2, G810067 B 4, G810068 B 2, G810076 B 2, G810080 B 1, G810081 B 1, G810083 B 2, G810086 B 1, G810089 B 2, G810102 B 1, G810109 B 2, G810113 B 1, G810115 B 3, G810122 B 2, G810123 B 2, G810127 B 2, G810128 B 2, G810129 B 1, G810134 B 1, G810138 B 2, G810139 B 1, G810149 B 2, G810161 B 2, G810168 B 1, G810171 B 2, G810172 B 2, G810173 B 2, G810178 B 2, G810192 B 2, G810203 B 2, G810216 B 2, G810218 B 2, G820012 B 2, G820019 B 2, G820033 B 1, G820036 B 2, G820046 B 2, G820050 B 2, G820054 B 2, G820057 B 2, G820061 B 3, G820073 B 1, G820076 B 2, G820080 B 1, G820082 B 2, G820094 B 4, G820096 B 2, G820098 B 2, G820115 B 2, G820138 B 2, G820149 B 2, G820157 B 2, G820165 B 2, G820903 B 1, G820904 B 1, G830017 B 4, G830027 B 2, G830044 B 2, G830048 B 2, G830073 B 4, G830092 B 4, G830120 B 2, G830127 B 2, G830134 B 1, G830145 B 2, G830153 B 1, G830154 B 4, G830167 B 2, G830174 B 2, G830187 B 2, G830901 B 1, G830903 B 1, G830907 B 2, G840008 B 1, G840018 B 1, G840028 B 3, G840032 B 1, G840036 B 2, G840069 B 1, G840080 B 2, G840098 B 2, G840099 B 1, G840129 B 1, G840135 B 2, G840137 B 6, G840140 B 2, G840150 B 1, G840174 B 2, G840189 B 2, G840196 B 2, G840201 B 2, G850010 B 2, G850012 B 1, G850017 B 1, G850030 B 2, G850040 B 2, G850045 B 1, G850049 B 2, G850071 B 2, G850072 B 1, G850097 B 2, G850098 B 2, G850101 B 3, G850103 B 4, G850117 B 3, G850120 B 2, G850121 B 2, G850134 B 2, G850139 B 2, G850142 B 1, G850158 B 4, G850162 B 2, G850174 B 2, G850187 B 2, G850188 B 3, G850202 B 2, G850206 B 2, G850217 B 2, G850231 B 2, G850233 B 4, G850239 B 2, G860001 B 1, G860010 B 2, G860019 B 4, G860021 B 1, G860026 B 2, G860030 B 4, G860044 B 2, G860055 B 2, G860060 B 2, G860065 B 3, G860066 B 2, G860067 B 2, G860070 B 3, G860075 B 2, G860077 B 2, G860084 B 1, G860086 B 2, G860102 B 1, G860114 B 2, G860116 B 1, G860117 B 2, G860118 B 1, G860132 B 2, G860138 B 2, G860140 B 4, G860141 B 4, G860147 B 4, G860156 B 2, G860157 B 1, G860165 B 4, G860168 B 2, G860169 B 2, G860170 B 2, G860172 B 2, G860176 B 1, G860182 B 2, G860184 B 4, G860186 B 2, G860189 B 1, G860194 B 2, G860199 B 2, G860200 B 2, G860201 B 1, G860210 B 1, G860225 B 2, G860230 B 4, G870010 B 4, G870013 B 1,

[1] Pre-amendments devices are devices that were marketed before the enactment of the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act; that is, in commercial distribution before May 28, 1976.

G870017 B 1, G870019 B 3, G870030 B 2, G870035 B 2, G870036 B 2, G870037 B 2, G870038 B 6, G870040 B 3, G870046 B 2, G870048 B 4, G870049 B 1, G870052 B 1, G870053 B 2, G870055 B 6, G870056 B 6, G870058 B 1, G870060 B 1, G870061 B 6, G870067 B 2, G870069 B 4, G870080 B 2, G870082 B 2, G870091 B 1, G870101 B 4, G870104 B 2, G870109 B 2, G870112 B 1, G870114 B 2, G870120 B 2, G870122 B 6, G870123 B 2, G870129 B 2, G870134 B 6, G870136 B 2, G870142 B 4, G870144 B 4, G870158 B 6, G870161 B 2, G870163 B 2, G870167 B 1, G870174 B 2, G870195 B 2, G870200 B 2, G870213 B 2, G870224 B 2, G880001 B 1, G880007 B 3, G880008 B 4, G880018 B 4, G880021 B 2, G880022 B 3, G880026 B 1, G880032 B 3, G880040 B 2, G880042 B 1, G880044 B 2, G880045 B 1, G880050 B 6, G880051 B 2, G880068 B 2, G880069 B 3, G880076 B 1, G880080 B 2, G880084 B 2, G880100 B 2, G880102 B 1, G880103 B 1, G880104 B 1, G880112 B 3, G880118 B 4, G880122 B 2, G880123 B 6, G880129 B 2, G880131 B 2, G880136 B 6, G880149 B 4, G880150 B 2, 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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. 96–8623 Filed 4–5–96; 8:45 am]

BILLING CODE 4120–03–P

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

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 following meetings:

Name of SEP: National Institute on Aging Special Emphasis Panel.

Date: April 15–16, 1996.

Time: 7:00 p.m. on April 15 to adjournment on April 16, 1996.

Place: Radisson Plaza Hotel Lexington, 369 West Vine Street, Lexington, Kentucky 40507–1636.

Contact Person: Dr. Maria Mannarino, Scientific Review Administrator, Gateway Building, Room 2C212, National Institutes of Health, Bethesda, Maryland 20892–9205, (301) 496–9666.

Purpose/Agenda: To evaluate and review (grant applications, cooperative agreement applications, or contract proposals).

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

Name of SEP: National Institute on Aging Special Emphasis Panel.

Date: April 23, 1996.

Time: 1:30 p.m. EDT to adjournment.

Place: Teleconference Call Gateway Building, Room 2C212.

Contact Person: Dr. Paul Lenz, Scientific Review Administrator, Gateway Building, Room 2C212, National Institutes of Health, Bethesda, Maryland 20892–9205, (301) 496–9666.

Purpose/Agenda: To evaluate and review (grant applications, cooperative agreement applications, or contract proposals).

Name of SEP: National Institute on Aging Special Emphasis Panel.

Date: April 30—May 1, 1996.

Time: 7:00 p.m. on April 30 to adjournment on May 1, 1996.

Place: Holiday Inn—Georgetown, 2101 Wisconsin Ave., NW, Washington, D.C. 20007.

Contact Person: Dr. Maria Mannarino, Scientific Review Administrator, Gateway Building, Room 2C212, National Institutes of Health, Bethesda, Maryland 20892–9205, (301) 496–9666.

Purpose/Agenda: To evaluate and review (grant applications, cooperative agreement applications, or contract proposals).

The meetings will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.866, Aging Research, National Institutes of Health)