## Health Care Financing Administration

**[OPL–013–N]**

## Medicare Program; Request for Nominations for Members for the Practicing Physicians Advisory Council

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

**ACTION:** Notice.

**SUMMARY:** This notice requests nominations from medical organizations representing physicians for individuals to serve on the Practicing Physicians Advisory Council. There will be three vacancies on February 28, 1997.

**DATES:** Nominations from medical organizations representing physicians will be considered if we receive them at the appropriate address, provided below, no later than January 17, 1997.

**ADDRESSES:** Mail or deliver nominations for membership to the following address: Health Care Financing Administration, Office of the Associate Administrator for External Affairs, Attention: Samuel S. Shekar, M.D., Executive Director, Practicing Physicians Advisory Council, Room 425 H, Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Washington, DC 20201.

**FOR FURTHER INFORMATION CONTACT:** Samuel S. Shekar, M.D., Executive Director, Practicing Physicians Advisory Council, (202) 260–5463.

**SUPPLEMENTARY INFORMATION:** Section 4112 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101–508), enacted on November 5, 1990, added a new section 1868 to the Social Security Act (the Act), which established the Practicing Physicians Advisory Council (the Council). The Council advises the Secretary of the Department of Health and Human Services (the Secretary) on proposed regulations and manual issuances related to physicians' services. An advisory committee created by the Congress, such as this one, is subject to the provisions of the Federal Advisory Committee Act (5 U.S.C. App. 2).

Section 1868(a) of the Act requires that the Council consist of 15 physicians, each of whom must have submitted at least 250 claims for physicians' services under Medicare in the previous year. At least 11 Council members must be physicians as defined in section 1861(r)(1) of the Act; that is, State-licensed physicians of medicine or osteopathy. The other four Council members may include dentists, podiatrists, optometrists, and chiropractors. The Council must include both participating and nonparticipating physicians, as well as physicians practicing in rural and underserved urban areas. In addition, section 1868(a) of the Act provides that the Secretary's appointments for Council membership must be based on nominations made by medical organizations representing physicians.

This notice is an invitation to all organizations representing physicians to submit names of nominees for membership on the Council. Current members whose terms expire in 1997 will be considered for reappointment, if renominated. The Secretary will appoint new members to the Council from among those candidates determined to have the expertise required to meet specific agency needs and in a manner to ensure appropriate balance of membership.

Each nomination must state that the nominee has expressed a willingness to serve as a Council member and must be accompanied by a short resume or description of the nominee's experience. To permit evaluation of possible sources of conflict of interest, potential candidates will be asked to provide detailed information concerning financial holdings, consultant positions, research grants, and contracts.

Section 1868(b) of the Act provides that the Council meet once each calendar quarter, as requested by the Secretary, to discuss proposed changes in regulations and manual issuances that relate to physicians services. Council members are expected to participate in all meetings.

Section 1868(c) of the Act provides for payment of expenses and a per diem allowance for Council members at a rate equal to payment provided members of other advisory committees. In addition to making these payments, the Department of Health and Human Services provides management and support services to the Council.

(Section 1868 of the Social Security Act (42 U.S.C. 1395ee); 5 U.S.C. App. 2; and 45 CFR part 11)

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

Dated: December 9, 1996.

Bruce C. Vladeck,

*Administrator, Health Care Financing Administration.*

[FR Doc. 96–32093 Filed 12–17–96; 8:45 am]

**BILLING CODE 4120–01–P**

**[BPO–140–N]**

## Medicare and Medicaid Programs; Quarterly Listing of Program Issuances and Coverage Decisions—Second Quarter 1996

**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 1996 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 of April 1 through June 30, 1996. 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:**

Bridget Wilhite, (410) 786–5248 (For Medicare instruction information).

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

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

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

**SUPPLEMENTARY INFORMATION:**

I. Program Issuances

The Health Care Financing Administration (HCFA) is responsible for administering the Medicare and Medicaid programs, which pay for health care and related services for 38 million Medicare beneficiaries and 36 million Medicaid recipients. Administration of these programs

involves (1) providing information to Medicare beneficiaries and Medicaid recipients, health care providers, and the public, and (2) effective communications with regional offices, State governments, State Medicaid Agencies, State Survey Agencies, various providers of health care, fiscal intermediaries and carriers that process claims and pay bills, and others. To implement the various statutes on which the programs are based, we issue regulations under the authority granted the Secretary under sections 1102, 1871, and relevant provisions of the Social Security Act (the Act) and also issue various manuals, memoranda, and statements necessary to administer the programs efficiently.

Section 1871(c)(1) of the Act requires that we publish in the Federal Register at least every 3 months a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations. We published our first notice June 9, 1988 (53 FR 21730). Although we are not mandated to do so by statute, for the sake of completeness of the listing of operational and policy statements, we are continuing our practice of including Medicare substantive and interpretive regulations (proposed and final) published during the 3-month time frame. Since the publication of our quarterly listing on June 12, 1992 (57 FR 24797), we decided to add Medicaid issuances to our quarterly listings. Accordingly, we list in this notice Medicaid issuances and Medicaid substantive and interpretive regulations published during April through June 1996.

## 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 many of those medical items, services, technologies, or treatment procedures that can be paid for under Medicare. On August 21, 1989, we published a notice in the Federal Register (54 FR 34555) that contained all the Medicare coverage decisions issued in that manual.

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

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

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

## III. How To Use the Addenda

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

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

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

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

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

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

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

assigned by the Food and Drug Administration for the quarter for which the notices cover.

IV. How To Obtain Listed Material

*A. Manuals*

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

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

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

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

*B. Regulations and Notices*

Regulations and notices are published in the daily Federal Register. Interested individuals may purchase individual copies or subscribe to the Federal Register by contacting the GPO at the address given above. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The Federal Register is also available on 24x microfiche and as an online database through GPO Access. The online database is updated by 6 a.m. each day the Federal Register is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) forward. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using the World Wide Web; the Superintendent of Documents home page address is http://www.access.gpo.gov/su__docs/, by using local using localWAIS client software, or by telnet to swais.access.gpo.gov, then login as guest (no password required). Dial-in users should use communications software and modem to call (202) 512–1661; type swais, then login as guest (no password required).

*C. Rulings*

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

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

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

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

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

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

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

V. How to Review Listed Material

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

In addition, individuals may contact regional depository libraries, which receive and retain at least one copy of most Federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. Superintendent of Documents numbers for each HCFA publication are shown in Addendum III, along with the HCFA publication and transmittal numbers. To help FDLs locate the instruction, use the Superintendent of Documents number, plus the HCFA transmittal number. For example, to find the Intermediary Manual, Part 1—Fiscal Administration (HCFA–Pub. 13–1) transmittal entitled ''Electronic Funds Transfer,'' use the Superintendent of Documents No. HE 22.8/6–3 and the HCFA transmittal number 126.

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 Addendum III may be addressed to Bridget Wilhite, Bureau of Program Operations, Issuances Staff, Health Care Financing Administration, S3–01–27, 7500 Security Blvd., Baltimore, MD 21244–1850, Telephone (410) 786–5248.

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

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

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

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

Dated: December 3, 1996.

Gary Kavanagh,

*Acting Director, Bureau of Program Operations.*

Addendum I

This addendum lists the publication dates of the most recent quarterly listing of program issuances and coverage decision updates to the Coverage Issues Manual. In addition, for a complete listing of the prior quarterly updates to the Coverage Issues Manual please refer to the January 3, 1995 update (60 FR 132).

July 26, 1995 (60 FR 38344)
November 15, 1995 (60 FR 57435)
April 8, 1996 (61 FR 154)
June 26, 1996 (61 FR 33119)

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 1996]

| Trans. No. | | Manual/Subject/Publication No. |
|---|---|---|
| | | **Intermediary Manual<br>Part 1—Fiscal Administration (HCFA Pub. 13–1)<br>(Superintendent of Documents No. HE 22.8/6–3)** |
| 126 | • | Electronic Funds Transfer |
| | | **Intermediary Manual<br>Part 2—Audits, Reimbursement Program Administration (HCFA Pub. 13–2) (Superintendent of Documents No. HE 22.8/6–2)** |
| 406 | • | Maximum Payment For Rural Health Clinics<br>Maximum Payment Per Visit for Freestanding Federally Qualified Health Centers |
| 407 | • | Assessment of Benefit Savings Attributable to Medical Review Activities<br>Completion of the RBS |
| | | **Intermediary Manual<br>Part 3—Claims Process (HCFA Pub. 13–3)<br>(Superintendent of Documents No. HE 22.8/6–1)** |
| 1674 | • | Alphabetic Listing of Data Elements<br>Medical Review Attachment Data Definitions and Codes<br>Requirements by Record Type and Field (Data Element) for Outpatient Rehabilitative Services<br>Validating Information for Outpatient Rehabilitation Plan of Treatment Submissions |
| 1675 | • | HCPCS for Hospital Outpatient Radiology Services and Other Diagnostic Procedures |
| 1676 | • | Outpatient Observation Services |
| 1677 | • | Conditions To Be Met For Coverage of Home Health Services<br>Reasonable and Necessary Services<br>Impact of Other Available Care Givers and Other Available Coverage on Medicare Coverage of Home Health Services<br>Conditions Patient Must Meet To Qualify For Coverage of Home Health Services<br>Confined to the Home<br>Services are Provided Under a Plan of Care Established and Approved by a Physician<br>Under the Care of a Physician<br>Needs Skilled Nursing Care on an Intermittent Basis or Physical Therapy or Speech-Language Pathology Services or Has Continued Need for Occupational Therapy<br>Physician Certification<br>Coverage of Services Which Establish Home Health Eligibility<br>Skilled Nursing Care<br>Skilled Therapy Services<br>Skilled Nursing, Physical Therapy, Speech-Language Pathology Services, and Occupational Therapy<br>Home Health Aide Services<br>Medical Social Services<br>Medical Supplies (Except for Drugs and Biologicals) and the Use of Durable Medical Equipment<br>Services of Interns and Residents<br>Part-time or Intermittent Home Health Aide and Skilled Nursing Services<br>Non-eligibility Hospital Insurance<br>Number of Home Health Visits Under Hospital Insurance (Part A)<br>Number of Home Health Visits Under Supplementary Medical Insurance (Part B)<br>Visit Defined<br>Counting Visits<br>Specific Exclusions from Coverage as Home Health Services<br>Physician Certification for Medical and Other Health Services Furnished by Home Health Agency<br>Osteoporosis Injections as HHA Benefit |
| 1678 | • | Physician Acknowledgment<br>Processing No-Payment Bills<br>PRO Reporting on Medical Review |
| 1679 | • | Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines |
| 1680 | • | Claims Processing Timeliness |
| 1681 | • | HCPCS for Hospital Outpatient Radiology Services and Other Diagnostic Procedures |

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April through June 1996]

| Trans. No. | Manual/Subject/Publication No. |
|---|---|
| 1682 | • Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines |
| 1683 | • Stem Cell Transplantation<br>Allogeneic Stem Cell Transplantation<br>Autologous Stem Cell Transplantation<br>Billing for Stem Cell Transplantation |
| | **Carriers Manual<br>Part 1—Fiscal Administration (HCFA Pub. 14–1)<br>(Superintendent of Documents No. HE 22.8/7–2)** |
| 120 | • Electronic Funds Transfer |
| | **Carriers Manual<br>Part 2—Program Administration (HCFA Pub. 14–2)<br>(Superintendent of Documents No. HE 22.8/7–3)** |
| 133 | • Functional Standards for Claims Processing Operations |
| | **Carriers Manual<br>Part 3—Claims Process (HCFA Pub. 14–3)<br>(Superintendent of Documents No. HE 22.8/7)** |
| 1539 | • Local MR Policy<br>The Carrier Advisory Committee<br>Medical Review Prepayment Screens<br>CMR Case Selection<br>Carrier Coordination With Peer Review Organization<br>Data Analysis to Identify Aberrancies<br>Standard Postpayment Data Reports<br>Prepayment MR and Audit Trail<br>Categories of MR Screens<br>HCFA Mandated and HCFA Optional MN Screens Determination |
| 1540 | • Reasonableness and Necessity |
| 1541 | • Chemotherapy Administration Codes |
| 1542 | • Beneficiary Address Change |
| 1543 | • Claims for Outpatient Services Furnished by a Physical or Occupational Therapist in Independent Practice |
| 1544 | • Payable Physical Therapy |
| 1545 | • Definition of a Global Surgical Package<br>Billing Requirements for Global Surgeries<br>Claims Review for Global Surgeries<br>Adjudication of Claims for Global Surgeries<br>Postpayment Issues<br>Claims for Multiple Surgeries<br>Claims for Bilateral Surgeries<br>Claims for Co- and Team Surgeons<br>Claims for Anesthesia Services Performed on and After January 1, 1992<br>Billing for Portable X-ray Set-up Services |
| 1546 | • Telephone Services<br>Definition of Physician for Care Plan Oversight Services<br>Otologic Evaluations<br>Monthly Capitation Payment Method for Physician's Services Furnished to Patients on Maintenance Dialysis<br>Daily Visit Charges for Inpatient Hospital Visits<br>Correct Coding Policy |
| 1547 | • Chemotherapy Administration Codes<br>Billing Procedures for Maxillofacial Services<br>Claims for Transportation in Connection With Furnishing Diagnostic Tests<br>Payment for Certain Physician Services Performed in Facility Settings |
| | **Carriers Manual<br>Part 4—Professional Relations (HCFA Pub. 14–4)<br>(Superintendent of Documents No. HE 22.8/7–4)** |
| 12 | • Non-Certified Provider/Supplier Enrollment<br>Enrollment Instructions for New Medicare Providers/Suppliers<br>Enrollment Procedures for All Applicants<br>Provider/Supplier Specific Procedures<br>• Procedures for Denials and Appeals<br>• Request for Additional Information<br>• Provider/Supplier Education<br>• Data Collection/Maintenance Requirements<br>• Tracking Requirements |

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April through June 1996]

| Trans. No. | | Manual/Subject/Publication No. |
|---|---|---|
| | | **Program Memorandum<br>Intermediaries (HCFA Pub. 60A)<br>(Superintendent of Documents No. HE 22.8/6–5)** |
| A–96–1 | • | Billing of CPT–4 Code 83721, Direct Measurement Lipoprotein; Low Density Lipoprotein Cholesterol |
| | | **Program Memorandum<br>Intermediaries/Carriers (HCFA Pub. 60A/B)<br>(Superintendent of Documents No. HE 22.8/6–5)** |
| AB–96–3 | • | New Modifier for Laboratory Services |
| AB–96–4 | • | Requirement to Halt Payments for Non-Covered Items and Services or for Previous Erroneous Payments |
| AB–96–5 | • | New Waived Test |
| AB–96–6 | • | Establishment of the Medicare Fraud Information Specialist Position |
| | | **Program Memorandum<br>Regional Offices Standard and Certification (HCFA Pub. 54)<br>(Superintendent of Documents No. HE 22.28/5:90–1)** |
| 96–1 | • | Civil Money Penalty Collections Procedures |
| | | **Hospital Manual<br>(HCFA Pub. 10)<br>Superintendent of Documents No. HE 22.8/2)** |
| 688 | • | HCPCS for Hospital Outpatient Radiology and Other Diagnostic Procedures |
| 689 | • | Outpatient Observation Services |
| 690 | • | Physician Acknowledgment |
| 691 | • | Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines |
| 692 | • | Claims Processing Timeliness |
| 693 | • | HCPCS for Hospital Outpatient Radiology and Other Diagnostic Procedures |
| 694 | • | Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines |
| 695 | • | Stem Cell Transplantation<br>Allogeneic Stem Cell Transplantation<br>Autologous Stem Cell Transplantation<br>Billing for Stem Cell Transplantation |
| | | **Christian Science Sanatorium Hospital Manual Supplement<br>(HCFA Pub. 32)<br>(Superintendent of Documents No. HE 22.8/2–2)** |
| 35 | • | Claims Processing Timeliness |
| 36 | • | Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines |
| | | **Home Health Agency Manual<br>(HCFA Pub. 11)<br>(Superintendent of Documents No. HE 22.8/5)** |
| 277 | • | Home Health Agency<br>Rehabilitation Centers<br>Reasonable and Necessary Services<br>Impact of Other Available Care Givers and Other Available Coverage on Medicare Coverage of Home Health Services<br>Conditions the Patient Must Meet to Qualify for Coverage of Home Health Services<br>Confined to the Home<br>Services are Provided Under a Plan of Care Established and Approved by a Physician<br>Under the Care of a Physician<br>Needs Skilled Nursing Care on an Intermittent Basis, or Physical Therapy or Speech-Language Pathology Services or Has Continued Need for Occupational Therapy<br>Physician Certification<br>Coverage of Services Which Establish Home Health Eligibility<br>Skilled Nursing Care<br>Skilled Therapy Services<br>Skilled Nursing Care, Physical Therapy, Speech-Language Pathology Services, and Occupational Therapy<br>Home Health Aide Services<br>Medical Social Services<br>Medical Supplies (Except for Drugs and Biologicals) and the Use of Durable Medical Equipment<br>Services of Interns and Residents<br>Outpatient Services<br>Part-time or Intermittent Home Health Aide and Skilled Nursing Services<br>Non-eligible Under Hospital Insurance<br>Number of Home Health Visits Under Hospital Insurance (Part A) |

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April through June 1996]

| Trans. No. | | Manual/Subject/Publication No. |
|---|---|---|
| | | Number of Home Health Visits Under Supplementary Medical Insurance (Part B) |
| | | Visit Defined |
| | | Counting Visits |
| | | Specific Exclusions From Coverage as Home Health Services |
| | | Billing for Osteoporosis Injections |
| 278 | • | Claims Processing Timeliness |
| 279 | • | Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines |
| | | **Skilled Nursing Facility Manual (HCFA Pub. 12) (Superintendent of Documents No. HE 22.8/3)** |
| 343 | • | Claims Processing Timeliness |
| 344 | • | Special Billing Instructions for Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines |
| | | **Rural Health Clinic and Federally Qualified Health Centers Manual (HCFA Pub. 27) (Superintendent of Documents No. HE 22.8/19:985)** |
| 22 | • | Rural Health Clinics |
| | | Federally Qualified Health Centers |
| 23 | • | Claims Processing Timeliness |
| | | **Renal Dialysis Facility Manual (Non-Hospital Operated) (HCFA Pub. 29) (Superintendent of Documents No. HE 22.8/13)** |
| 72 | • | Pneumococcal Pneumonia and Influenza Virus Vaccines |
| 73 | • | Claims Processing Timeliness |
| 74 | • | Covered Home Dialysis Equipment |
| | | Non-covered Home Dialysis Equipment |
| | | **Hospice Manual (HCFA Pub. 21) (Superintendent of Documents No. HE 22.8/18)** |
| 48 | • | Claims Processing Timeliness |
| 49 | • | Billing Hospice Claims for Pneumococcal Pneumonia and Influenza Virus Vaccines |
| | | **Outpatient Physical Therapy and Comprehensive Outpatient Rehabilitation Facility Manual (HCFA Pub. 9) (Superintendent of Documents No. HE 22.8/9)** |
| 124 | • | Claims Processing Timeliness |
| 125 | • | Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccine |
| | | **Coverage Issues Manual (HCFA Pub. 6) Superintendent of Documents No. HE 22.8/14)** |
| 84 | • | Blood Platelet Transfusions |
| | | Stem Cell Transplantation |
| 85 | • | Osteogenic Stimulation |
| 86 | • | Infusion Pumps |
| 87 | • | Adult Liver Transplantation |
| | | **Provider Reimbursement Manual Part 1—(HCFA Pub. 15–1) (Superintendent of Documents No. HE 22.8/4)** |
| 393 | • | Changing Bases for Allocating Cost Centers or Order in Which Cost Centers Are Allocated |
| 394 | • | Provider Charge Structure as Basis for Apportionment |
| | | **Provider Reimbursement Manual Part II—(HCFA Pub. 15–11–A) (Superintendent of Documents No. HE 22.8/4)** |
| 18 | • | Cost Report Due Dates |
| | | Filing of Cost Reports by Providers of Chain Organization or Other Group of Providers |

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April through June 1996]

| Trans. No. | Manual/Subject/Publication No. |
|---|---|
| | **Provider Reimbursement Manual Part II—(HCFA Pub. 15–11–AB) (Superintendent of Documents No. HE 22.8/4)** |
| 8 | • Cost Reporting Forms |
| 9 | • Electronic Reporting Specifications for Form-2552–92 |
| | **Provider Reimbursement Manual Part II—(HCFA Pub. 15–11–AF) (Superintendent of Documents No. HE 22.8/4)** |
| 2 | • General<br>Worksheet A—Reclassification and Adjustment of Trial Balance of Expenses<br>Worksheet A–5—Adjustments to Expenses<br>Worksheet B—Cost Allocation—General Service Costs and Worksheet B–1 Cost Allocation—Statistical Basis |
| | **State Medicaid Manual—Part 2—State Organization and General Administration (HCFA Pub. 45–2) (Superintendent of Documents No. HE 22.8/10)** |
| 86 | • Early and Periodic Screening, Diagnostic and Treatment Report (Form HCFA–416) |
| | **State Medicaid Manual—Part 4—Services (HCFA Pub. 45–4) (Superintendent of Documents No. HE 22.8/10)** |
| 69 | • Institutions for Mental Diseases |
| | **State Medicaid Manual—Part 6—Payment for Services (HCFA Pub. 45–6) (Superintendent of Documents No. HE 22.8/10)** |
| 30 | • A Listing of Multiple Source Drugs |
| | **Medicare/Medicaid Sanction—Reinstatement Report (HCFA Pub. 69)** |
| 96–5 | • Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—May 1996 |
| 96–6 | • Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—June 1996 |

Addendum IV—Medicare Coverage Issues Manual April Through June 1996—

Transmittal No. 84; section 35–30, CHANGED PROCEDURES—EFFECTIVE DATE: For services performed on or after May 24, 1996.

Section 35–30, Blood Platelet Transfusions.—This section is reorganized to separate blood platelet transfusions from bone marrow transplants.

Section 35–30.1, Stem Cell Transplantation.—This section dedesignates and revises material previously contained in section 35–30.B and C. to clarify that the policy for bone marrow transplants, a type of stem cell transplantation, applies to all types of stem cell transplants. Multiple myeloma is added to the conditions for which stem cell transplantation is excluded from coverage.

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35–30 Blood Platelet Transfusions

Effective for services performed on or after August 1, 1978, blood platelet transplants are safe and effective for the correction of thrombocytopenia and other blood defects. It is covered under Medicare when treatment is reasonable and necessary for the individual patient.

35–30.1 Stem Cell Transplantation

Stem cell transplantation is a process in which stem cells are harvested from either a patient's or donor's bone marrow or peripheral blood for intravenous infusion. The transplant can be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy (HDCT) and/or radiotherapy used to treat various malignancies. Allogeneic stem cell transplant may also be used to restore function in recipients having an inherited or acquired deficiency or defect.

A. *Allogeneic Stem Cell Transplantation.*—Allogeneic stem cell transplantation (ICD–9–CM codes 41.02 and 41.03) is a procedure in which a portion of a healthy donor's stem cell or bone marrow is obtained and prepared for intravenous infusion.

1. *Covered Conditions.*—The following uses of allogeneic bone marrow transplantation are covered under Medicare:

• Effective for services performed on or after August 1, 1978, for the treatment of leukemia, leukemia in remission (ICD–9–CM codes 204.00 through 208.91), or aplastic anemia (ICD–9–CM codes 284.0 through 284.9) when it is reasonable and necessary; and

• Effective for services performed on or after June 3, 1985, for the treatment of severe combined immunodeficiency disease (SCID) (ICD–9–CM code 279.2), and for the treatment of Wiskott-Aldrich syndrome (ICD–9–CM 279.12).

2. *Noncovered Conditions.*—Effective May 24, 1996, allogeneic stem cell

transplantation is not covered as treatment for multiple myeloma (ICD–9–CM codes 203.0 and 238.6).

B. *Autologous Stem Cell Transplantation (Effective for Services Performed on or After 04/28/89).*—Autologous stem cell transplantation (ICD–9–CM procedure code 41.01 or 41.04) is a technique for restoring stem cells using the patient's own previously stored cells.

1. *Covered Conditions.*—Autologous stem cell transplantation (ICD–9–CM code 41.01, CPT–4 code 38241) is considered reasonable and necessary under § 1862(a)(1)(A) of the Act for the following conditions and is covered under Medicare for patients with:

- Acute leukemia in remission (ICD–9–CM codes 204.01, lymphoid; 205.01, myeloid; 206.01, monocytic; 207.01, acute erythremia and erythroleukemia; and 208.01, unspecified cell type) who have a high probability of relapse and who have no human leucocyte antigens (HLA)-matched;
- Resistant non-Hodgkin's lymphomas (ICD–9–CM codes 200.00–200.08, 200.10–200.18, 200.20–200.28, 200.80–200.88, 202.00–202.08, 202.80–202.88, and 202.90–202.98) or those presenting with poor prognostic features following an initial response;
- Recurrent or refractory neuroblastoma (see ICD–9–CM Neoplasm by site, malignant); or
- Advanced Hodgkin's disease (ICD–9–CM codes 201.00–201.98) who have failed conventional therapy and have no HLA-matched donor.

2. *Noncovered Conditions.*—Insufficient data exist to establish definite conclusions regarding the efficacy of autologous stem cell transplantation for the following conditions:

- Acute leukemia not in remission (ICD–9–CM codes 204.00, 205.00, 206.00, 207.00 and 208.00);
- Chronic granulocytic leukemia (ICD–9–CM codes 205.10 and 205.11);
- Solid tumors (other than neuroblastoma) (ICD–9–CM codes 140.0–199.1); or
- Effective May 24, 1996, multiple myeloma (ICD–9–CM code 203.0 and 238.6).

In these cases, autologous stem cell transplantation is not considered reasonable and necessary within the meaning of § 1862(a)(1)(A) of the Act and is not covered under Medicare.

Transmittal No. 85; section 35–48, CHANGED IMPLEMENTING INSTRUCTIONS—EFFECTIVE DATE: SERVICES PERFORMED ON OR AFTER 07/01/96.

SECTION 35–48, OSTEOGENIC STIMULATION, is revised to expand coverage of this procedure and provide additional clarification. The following changes have been made.

- Coverage of osteogenic stimulation, used noninvasively or invasively, is expanded to include its use as an adjunct to spinal fusion surgery for certain patients; and
- Clarification is provided when noninvasive osteogenic stimulation is indicated after failed fusion.

35–48 OSTEOGENIC STIMULATION (Effective for services performed on and after September 15, 1980.)

Electrical stimulation to augment bone repair can be attained either invasively or noninvasively. Invasive devices provide electrical stimulation directly at the fracture site either through percutaneously placed cathodes or by implantation of a coiled cathode wire into the fracture site. The power pack for the latter device is implanted into soft tissue near the fracture site and subcutaneously connected to the cathode, creating a self-contained system with no external components. The power supply for the former device is externally placed and the leads connected to the inserted cathodes. With the noninvasive device, opposing pads, wired to an external power supply, are placed over the cast. An electromagnetic field is created between the pads at the fracture site.

*Noninvasive Stimulator.*—The noninvasive stimulator device is covered only for the following indications:

- Nonunion of long bone fractures;
- Failed fusion, where a minimum of nine months has elapsed since the last surgery;
- Congenital pseudarthroses; and
- As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3–L5, L4–S1, etc).

*Invasive (Implantable) Stimulator.*—The invasive stimulator device is covered only for the following indications:

- Nonunion of long bone fractures;
- As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3–L5, L4–S1, etc).

Nonunion, for all types of devices, is considered to exist only after six or more months have elapsed without healing of the fracture.

Transmittal No. 86; section 60–14, NEW IMPLEMENTING INSTRUCTIONS—EFFECTIVE DATE: Services Beginning on or after September 1, 1996.

Section 60–14, Infusion Pumps, is revised to exclude coverage of vancomycin used with an external infusion pump. There is insufficient evidence to support the necessity of using an external infusion pump, instead of a disposable elastomeric pump or the gravity drip method, to administer vancomycin in a safe and appropriate manner.

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60–14 INFUSION PUMPS

THE FOLLOWING INDICATIONS FOR TREATMENT USING INFUSION PUMPS ARE COVERED UNDER MEDICARE:

A. *External Infusion Pumps.*—

1. *Iron Poisoning (Effective for Services Performed On or After 9/26/84).*—When used in the administration of deferoxamine for the treatment of acute iron poisoning and iron overload, only external infusion pumps are covered.

2. *Thromboembolic Disease (Effective for Services Performed On or After 9/26/84).*—When used in the administration of heparin for the treatment of thromboembolic disease and/or pulmonary embolism, only external infusion pumps used in an institutional setting are covered.

3. *Chemotherapy for Liver Cancer (Effective for Services Performed On or After 1/29/85).*—The external chemotherapy infusion pump is covered when used in the treatment of primary hepatocellular carcinoma or colorectal cancer where this disease is unresectable or where the patient refuses surgical excision of the tumor.

4. *Morphine for Intractable Cancer Pain (Effective for Services Performed On or After 4/22/85).*—Morphine infusion via an external infusion pump is covered when used in the treatment of intractable pain caused by cancer (in either an inpatient or outpatient setting, including a hospice). Other uses of external infusion pumps *are covered* if the contractor's medical staff verifies the appropriateness of the therapy and of the prescribed pump for the individual patient.

Note: Payment may also be made for drugs necessary for the effective use of an external infusion pump as long as the drug being used with the pump is itself reasonable and necessary for the patient's treatment.

B. *Implantable Infusion Pumps.*—

1. *Chemotherapy for Liver Cancer (Effective for Services Performed On or After 9/26/84).*—The implantable infusion pump is covered for intra-arterial infusion of 5–FUdR for the treatment of liver cancer for patients with primary hepatocellular carcinoma or Duke's Class D colorectal cancer, in whom the metastases are limited to the liver, and where (1) the disease is unresectable or (2) where the patient refuses surgical excision of the tumor.

2. *Anti-Spasmodic Drugs for Severe Spasticity.*—An implantable infusion pump is covered when used to administer anti-spasmodic drugs intrathecally (e.g., baclofen) to treat chronic intractable spasticity in patients who have proven unresponsive to less invasive medical therapy as determined by the following criteria:

- As indicated by at least a 6-week trial, the patient cannot be maintained on noninvasive methods of spasm control, such as oral anti-spasmodic drugs, either because these methods fail to control adequately the spasticity or produce intolerable side effects, and
- Prior to pump implantation, the patient must have responded favorably to a trial intrathecal dose of the anti-spasmodic drug.

3. *Opioid Drugs for Treatment of Chronic Intractable Pain.*—An implantable infusion pump is covered when used to administer opioid drugs (e.g., morphine) intrathecally or epidurally for treatment of severe chronic intractable pain of malignant or nonmalignant origin in patients who have a life expectancy of at least 3 months and who have proven unresponsive to less invasive medical therapy as determined by the following criteria:

- The patient's history must indicate that he/she would not respond adequately to non-invasive methods of pain control, such as systemic opioids (including attempts to eliminate physical and behavioral abnormalities which may cause an exaggerated reaction to pain); and
- A preliminary trial of intraspinal opioid drug administration must be undertaken with a temporary intrathecal/epidural catheter to substantiate adequately acceptable pain relief and degree of side effects (including effects on the activities of daily living) and patient acceptance.

4. *Coverage of Other Uses of Implanted Infusion Pumps.*—Determinations may be made on coverage of other uses of implanted infusion pumps if the contractor's medical staff verifies that:

- The drug is reasonable and necessary for the treatment of the individual patient;
- It is medically necessary that the drug be administered by an implanted infusion pump; and
- The FDA approved labeling for the pump must specify that the drug being administered and the purpose for which it is administered is an indicated use for the pump.

5. *Implantation of Infusion Pump Is Contraindicated.*—The implantation of an infusion pump is contraindicated in the following patients:

- Patients with a known allergy or hypersensitivity to the drug being used (e.g., oral baclofen, morphine, etc.);
- Patients who have an infection;
- Patients whose body size is insufficient to support the weight and bulk of the device; and
- Patients with other implanted programmable devices since crosstalk between devices may inadvertently change the prescription.

Note: Payment may also be made for drugs necessary for the effective use of an implantable infusion pump as long as the drug being used with the pump is itself reasonable and necessary for the patient's treatment.

THE FOLLOWING INDICATIONS FOR TREATMENT USING INFUSION PUMPS ARE *NOT* COVERED UNDER MEDICARE:

A. *External Infusion Pumps.*—

1. *Diabetes (Effective for Services Performed On or After 1/29/85).*—The use of an external infusion pump for the subcutaneous infusion of insulin in the treatment of diabetes is not covered.

2. *Vancomycin (Effective for Services Beginning On or After September 1, 1996).*—Medicare coverage of vancomycin as a durable medical equipment infusion pump benefit is not covered. There is insufficient evidence to support the necessity of using an external infusion pump, instead of a disposable elastomeric pump or the gravity drip method, to administer vancomycin in a safe and appropriate manner.

B. *Implantable Infusion Pump.*—

1. *Thromboembolic Disease (Effective for Services Performed On or After 9/26/84).*—According to the Public Health Service, there is insufficient published clinical data to support the safety and effectiveness of the heparin implantable pump. Therefore, the use of an implantable infusion pump for infusion of heparin in the treatment of recurrent thromboembolic disease is not covered.

Transmittal No. 87; Section 35–53, CHANGED POLICY INSTRUCTIONS—EFFECTIVE DATE: For services performed on or after July 15, 1996.

Section 35–53, Adult Liver Transplantation, has been revised to expand Medicare coverage of liver transplantation to include all end stage liver disease diagnoses expect for hepatitis B or malignancies.

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These instructions should be implemented within your current operating budget.

35–53 ADULT LIVER TRANSPLANTATION

A. *General.*—Effective July 15, 1996, adult liver transplantation when performed on beneficiaries with end stage liver disease other than hepatitis B or malignancies is covered under Medicare when performed in a facility which is approved by HCFA as meeting institutional coverage criteria.

Coverage of adult liver transplantation is effective as of the date of the facility's approval, but for applications received before July 13, 1991, can be effective as early as March 8, 1990. (See Federal Register 56 FR 15006 dated April 12, 1991.)

B. *Follow-up Care.*—Follow-up care or retransplantation (ICD–9–CM 996.82, Complications of Transplanted Organ, Liver) required as a result of a covered liver transplant is covered, provided such services are otherwise reasonable and necessary. Follow-up care is also covered for patients who have been discharged from a hospital after receiving a noncovered liver transplant. Coverage for follow-up care is for items and services that are reasonable and necessary as determined by Medicare guidelines. (See Intermediary Manual § 3101.14 and Carriers Manual § 2300.1.)

C. *Immunosuppressive Drugs.*—See Intermediary Manual § 3660.8 and Carriers Manual §§ 2050.5, 4471, and 5249.

ADDENDUM V.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER

| Publication date | FR Vol. 61 page | CFR Part | File code | Regulation title |
|---|---|---|---|---|
| 04/03/96 | 14640–14658 | 405, 491 | BPD–728–F | Medicare Program; Payment for Federally Qualified Health Center Services. |
| 04/05/96 | 15266 | | OPL–009–N | Medicare Program; April 22, 1996, Meeting of the Practicing Physicians Advisory Council. |
| 04/08/96 | 15491–15504 | | BPO–136–N | Medicare and Medicaid Programs; Quarterly Listing of Program Issuances and Coverage Decisions; Third Quarter 1995. |
| 04/22/96 | 17677–17682 | 413 | BPD–805–P | Medicare and Medicaid Programs; New Payment Methodology for Routine Extended Care Services Provided in A Swing-Bed Hospital. |
| 05/02/96 | 19722–19760 | 405, 486 | BPD–646–FC | Medicare and Medicaid Programs; Conditions of Coverage for Organ Procurement Organizations (OPOs). |
| 05/03/96 | 19992–20067 | | BPD–846–PN | Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule. |
| 05/09/96 | 21195–21198 | | MB–098–N | Medicaid Program; Limitations on Aggregate Payments to Disproportionate Share Hospitals: Federal Fiscal Year 1996. |
| 05/13/96 | 21969–21973 | 412 | BPD–856–FC | Medicare and Medicaid Program; Criteria for a Rural Hospital To Be Designated as an Essential Access Community Hospital (EACH). |
| 05/14/96 | 24318–24319 | | ORD–086–N | New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: February and March 1996 |
| 05/17/96 | 24941–24946 | | BPD–868–NC | Medicare and Medicaid Programs; Announcement of Applications From Hospitals Requesting Waivers for Organ Procurement Service Area. |
| 05/31/96 | 27444–27708 | 412, 413, and 489 | BPD–847–P | Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1997 Rates. |
| 05/31/96 | 27282–27288 | 417 | OMC–004–F | Health Maintenance Organizations: Employer Contribution to HMO |
| 06/10/96 | 29449 | 412, 413, and 489 | BPD–847–CN | Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1997 Rates; Correction. |
| 06/10/96 | 29418 | | MB–098–CN | Medicaid Program; Limitations on Aggregate Payments to Disproportionate Share Hospitals: Federal Fiscal Year 1996; Correction. |
| 06/10/96 | 29418–29421 | | MB–098–N | Medicaid Program; Limitations on Aggregate Payments to Disproportionate Share Hospitals: Federal Fiscal Year 1996. |
| 06/10/96 | 29409–29410 | | ORD–087–N | New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: April 1996 |
| 06/13/96 | 30072–30075 | | HSQ–231–N | Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Exemption of Laboratories in the State of Oregon. |
| 06/24/96 | 32347–32351 | 405, 417, 431, 473, and 498. | BPD–704–FC | Medicare and Medicaid Programs; Provider Appeals: Technical Amendments. |
| 06/26/96 | 33129 | | BPD–873–N | Medicare Program; Announcement of Collaborative Efforts With the National Institutes of Health to Study the Effectiveness of Lung Volume Reduction Surgery. |
| 06/26/96 | 33119–33129 | | BPO–137–N | Medicare and Medicaid Program; Quarterly Listing of Program Issuances and Coverage Decisions-Fourth Quarter 1995. |
| 06/27/96 | 33532 | | OPL–010–N | Medicare Program; July 22, 1996 Meeting of the Practicing Physicians Advisory Council. |
| 06/27/96 | 33531–33532 | | ORD–088–N | New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: May 1996. |

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

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

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

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

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

Class III devices require premarket approval.

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

G950158 A1
G950168 A2
G950175 A2
G960060 A1
G960066 A2
G960074 A2
G960078 A1
G960101 A2
G960113 A2

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

G950194 B1
G950210 B1
G950218 B1
G960003 B4
G960021 B2
G960040 B4
G960041 B4
G960043 B1
G960046 B1
G960048 B3
G960052 B2
G960054 B3
G950056 B5
G960057 B2
G960059 B2
G960062 B2
G950100 B1
G950224 B3
G960047 B3
G960064 B2
G960067 B4
G960068 B4
G960069 B4
G960071 B2
G960076 B4
G960083 B3
G960084 B4
G960085 B1
G960086 B1
G960087 B3
G960088 B4
G960090 B1
G960091 B1
G960094 B1
G960095 B1
G960097 B1
G950205 B3
G960044 B3
G960045 B4
G960099 B1
G960100 B1
G960102 B1
G960103 B1
G950104 B1
G960105 B1
G960108 B3
G960109 B3
G960111 B2
G960112 B4
G960134 B4

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

[FR Doc. 96–32016 Filed 12–17–96; 8:45 am]

BILLING CODE 4120–01–P

## Health Resources and Services Administration

### Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden.

Proposed Project

1. *AIDS Education and Training Centers Program: National Program and Service Record Data Reporting Form (OMB No. 0915–0154)*—Extension, No change—Under section 2692(a) of the Public Health Service Act, information on training programs and training participants is obtained from 15 AIDS Education Training Centers (ETCs) currently operating in health professions schools and academic health science centers. The goal of the AIDS ETC program is to increase the number of health care providers who are effectively educated and motivated to counsel, diagnose, treat and manage individuals with HIV infection and to assist in the prevention of high risk