Name of facility	City	State	Requested OPO	Designated OPO
Noble Memorial Hospital	Westfield	MA	MAOB	CTHH
Holyoke Hospital	Holyoke	MA	MAOB	CTHH
Crestline Memorial Hosptial	Crestline	OH	OHLC	OHLP
River Valley Health System	Ironton	OH	KYDA	OHLP
Samaritan Health System	Lake Havasu	AZ	AZOB	NVLV
Kingman Regional Medical Center	Kingman	AZ	AZOB	NVLV

In addition, the following hospital has requested a waiver that is unrelated to changes made as a result of recent redesignations of OPO service areas. This hospital's request was made on a prospective basis. Therefore, our determination on this request will be made only upon receipt of public comments and completion of our review. Any approval of this request will be prospective.

Name of facility	City	State	Requested OPO	Designated OPO
Hutcheson Medical Center	Fort Oglethorpe	GA	GALL	TNDS

IV. Keys to the OPO Codes

The keys to the acronyms used in the listings to identify OPOs and their addresses are as follows:

AZOB
DONOR NETWORK OF ARIZONA, 3877 North Seventh Street, Phoenix, AZ 85014

CTHH NORTHEAST OPO AND TISSUE BANK, Hartford Hospital, 80 Seymour Street, Hartford, CT 06102–5037

GALL LIFELINK OF GEORGIA, 3715 Northside Parkway, 100 Northcreek, Suite 300, Atlanta, GA 30327

KYDA
KENTUCKY ORGAN DONOR AFFILIATES, 105 East Broadway, Louisville, KY 40202

MAOB
NEW ENGLAND ORGAN BANK, One Gateway Center, Newton, MA 02158

NVLV
NEVADA DONOR NEWTWORK, 4580 Southeastern Avenue, Suite 33, Las Vegas, NV 89119

OHLC
LIFE CONNECTION OF OHIO, 1545 Holland Road, Suite C, Maumee, OH 43537

OHLP
LIFELINE OF OHIO, 770 Kinnear Road, Suite 200, Columbus, OH 43212

TNDS
TENNESSEE DONOR SERVICES, 1714 Hayes Street, Nashville, TN 37203

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information to be collected.

The information collection requirement and the burden associated with requiring a Medicare or Medicaid participating hospital to have an agreement with the OPO designated for its area or to submit a waiver request to HCFA for approval to have an agreement with a designed OPO other than the OPO designated for its service area currently are approved under OMB approval number 0938–0688 (HCFA-R-13), with an expiration date of November 30, 1997.

Authority: Section 1138 of the Social Security Act (42 U.S.C. 1320b–8).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, and No. 93.778, Medical Assistance Program)

Dated: March 21, 1997.

Barbara Wynn,

Acting Director, Bureau of Policy Development, Health Care Financing Administration.

[FR Doc. 97–10144 Filed 4–18–97; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[BPO–141–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—Third 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 that were published during July, August, and September 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 time frame.

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 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, and guidelines of general applicability not issued as regulations. We published our first notice June 9, 1988 (53 FR 21730).

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 through September 1996.

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 and are initiating the inclusion of HCFA Rulings.

II. How To Use the Addenda

This notice is organized so that a reader may review the subjects of all manual issuances, memoranda, substantive and interpretive regulations, or 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 lists the publication dates of the most recent quarterly listing of program issuances.

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 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).

Addendum V lists a HCFA Ruling that was issued during the period covered by this notice. A HCFA ruling which is a statement of policy or interpretation that has not been published in the **Federal Register** as part of a regulation or of a notice implementing regulations, but which has been adopted by HCFA as having precedent.

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 covered by the notice.

III. 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, A TTN: New Orders, 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. Additionally, all manuals are available at the following Internet address: http//www.hcfa.gov/pubforms/progman.htm.

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 24× 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 WAIS client software, or by telnet to swais.access.gpo.gov, then log in as guest (no password required). Dial-in users should use communications software and modem to call (202) 512–1661; type swais, then log in 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.

IV. 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 1,400 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 Remittance Advice,'' use the Superintendent of Documents No. HE 22.8/6–3 and the HCFA transmittal number 127.

V. 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, N2–05–03, 7500 Security Boulevard, Baltimore, 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 Boulevard, 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, C5–12–16, 7500 Security Boulevard, 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: April 10, 1997.

Gary Kavanagh,

Acting Director, Bureau of Program Operations.

Addendum I

This addendum lists the publication dates of the most recent quarterly listings of program issuances.

July 26, 1995 (60 FR 38344)

November 15, 1995 (60 FR 57435)

April 8, 1996 (61 FR 15491)

June 26, 1996 (61 FR 33119)

December 18, 1996 (61 FR 66676)

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 1996]

Trans. No.	Manual/Subject/Publication Number
	Intermediary Manual **Part 1—Fiscal Administration (HCFA Pub. 13–1)** **(Superintendent of Documents No. HE 22.8/6–3)**
127	• Electronic Remittance Advice
	Intermediary Manual **Part 3—Claims Process** **(HCFA Pub. 13–3)** **(Superintendent of Documents No. HE 22.8/6)**
1684	• Reporting Outpatient Surgery and Other Services
1685	• Review of Form HCFA–1450 for Inpatient and Outpatient Bills Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines
1686	• Billing for Clinical Diagnostic Laboratory Services Other Than to Inpatients Laboratory Tests Utilizing Automated Equipment Organ or Disease Oriented Panels Modification of EOMB Process
1687	• Outpatient Observation Services Bill Review for Partial Hospitalization Services Provided in Community Mental Health Centers Hospital Outpatient Partial Hospitalization Services Billing for Hospitalization Outpatient Services Furnished by Clinical Social Workers
1688	• Reporting Outpatient Services Using HCFA Common Procedures Coding System HCPCS Codes for Diagnostic Services and Medical Services Ambulance Services
	Carriers Manual **Part 1—Fiscal Administration (HCFA Pub. 14–1)** **(Superintendent of Documents No. HE 22.8/7–2)**
121	• Electronic Remittance Advice
	Carriers Manual **Part 3—Claims Process (HCFA Pub. 14–3)** **(Superintendent of Documents No. HE 22.8/7)**
1548	• ANSI ASC X12 270 Health Care Eligibility/Benefit Inquiry and the ANSI ASC X12 271 Health Care Eligibility/Benefit Information Transaction Sets
1549	• Beneficiary Address Change
1550	• Reasonableness and Necessity
1551	• Billing for Pneumococcal, Hepatitis B, and Influenza Virus Vaccines General Claims Processing Requirements HCPCS Coding Billing Requirements Payment Requirements No Legal Obligation to Pay Simplified Roster Bills Specialty Code/Place of Service Processing Requirements Payment Requirements Health Maintenance Organization Processing Requirements Suppression of EOMBs
	Carriers Manual **Part 4—Professional Relations (HCFA Pub. 14–4)** **(Superintendent of Documents No. HE 22.8/7–4)**
13	• Provider of Service or Supplier Information • Patient and Insured Information
	Program Memorandum **Intermediaries (HCFA Pub. 60A)** **(Superintendent of Documents No. HE 22.8/6–5)**
A–96–2	• Medicare's Partial Hospitalization Benefit-Eligibility and Scope of Services
A–96–3	• Proposed Changes to Form HCFA–2552–96
A–96–4	• Cost Report Processing for Form HCFA–2552–92
A–96–5	• Fiscal Intermediary Coordination of Benefits File Format and ANSI X12 837 Transaction
A–96–6	• Skilled Nursing Facility's Request for Exemptions to the Cost Limits
A–96–7	• Policy Clarification: Provider-Based Designation

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July through September 1996]

Trans. No.	Manual/Subject/Publication Number
	Program Memorandum Carriers (HCFA Pub. 60B) (Superintendent of Documents No. HE 22.8/6–5)
B–96–2	• Carrier Coordination of Benefits File Format and ANSI X12 837 Transaction
	Program Memorandum Intermediaries/Carriers (HCFA Pub. 60A/B) (Superintendent of Documents No. HE 22.8/6–5)
AB–96–7	• Expanded Denial Codes for Medicare Secondary Payer
AB–96–8	• Clarification for the New Modifier QP for Laboratory Services
AB–96–9	• Clarification Regarding Medicare Coverage and Claims Processing Responsibility for Refill Kits, Implantable Infusion Pumps, and the Drugs Used With These Pumps
	Program Memorandum State Survey Agencies (HCFA Pub. 65) (Superintendent of Documents No. HE 22.8/6–5)
96–1	• Informal Dispute Resolution
	Regional Office Manual Standards and Certification (HCFA Pub. 23–4) (Superintendent of Documents No. HE 22.8/8–3)
62	• Definitions Findings of Compliance Findings of Noncompliance Redesignation of OPOs OPOs Operating in a Noncontiguous U.S. State Interim Designations Opening a Service Area for Competition Changes in Ownership or Service Area Termination of Organ Procurement Organizations Model Letter: Organ Procurement Organization Corrective Action Notice Model Letter: Organ Procurement Organization, Notice of Termination Model Letter: Organ Procurement Organization Notice to Public and State Medicaid/Medicare Agencies Model Letter: Organ Procurement Organization's Notice to Bordering OPOs Organ Procurement Organization Report Review Procedures and Guidelines for Organ Procurement Organizations OPO Application Process United Network of Organ Sharing Members Forms HCFA–576, HCFA 576A, Organ Procurement Organization Application and Agreement Organ Procurement Organizations Citations OPO Initial Designation Requirements Public Health Service Grantees OPO Network Membership Designation of OPO for a Service Area OPO Designation Procedures in Service Areas with Competing Applications Model Letter: Organ Procurement Organization Approval Model Letter: Organ Procurement Organization Denial—Failure to Meet Requirements Model Letter: Organ Procurement Organization Denial—Competing Applications
	Peer Review Organization Manual (HCFA Pub. 19) (Superintendent of Documents No. HE 22.8/8–15)
62	• Introduction Qualifications Responsibilities Communications Personnel
	Hospital Manual (HCFA Pub. 10) Superintendent of Documents No. HE 22.8/2)
696	• Reporting Outpatient Surgery and Other Services HCPCS for Hospital Outpatient Radiology and Other Diagnostic Procedures
697	• Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July through September 1996]

Trans. No.	Manual/Subject/Publication Number
698	• Billing for Clinical Diagnostic Laboratory Services Other Than to Inpatients Laboratory Tests Utilizing Automated Equipment Organ or Disease Oriented Panels Modification of EOMB Process
699	• Outpatient Observation Services Billing for Hospital Outpatient Partial Hospitalization Services Billing for Hospital Outpatient Services Furnished by Clinical Social Workers
700	• Ambulance Service Claims HCPCS Reporting Requirement Reporting Outpatient Services Using HCFA Common Procedure Coding System
	Christian Science Sanatorium Hospital Manual Supplement (HCFA Pub. 32) (Superintendent of Documents No. HE 22.8/2–2)
37	• Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines
	Home Health Agency Manual (HCFA Pub. 11) (Superintendent of Documents No. HE 22.8/5)
280	• Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines
	Skilled Nursing Facility Manual (HCFA Pub. 12) (Superintendent of Documents No. HE 22.8/3)
345	• Special Billing Instructions for Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines
	Renal Dialysis Facility Manual (Non-Hospital Operated) (HCFA Pub. 29) (Superintendent of Documents No. HE 22.8/13)
75	• Pneumococcal Pneumonia and Influenza Virus Vaccines
76	• Pneumococcal Pneumonia and Influenza Virus Vaccines
	Hospice Manual (HCFA Pub. 21) (Superintendent of Documents No. HE 22.8/18)
50	• Special Billing Instructions for Pneumococcal Pneumonia, Influenza Virus, and Hepatitis B Vaccines
	Outpatient Physical Therapy and Comprehensive Outpatient Rehabilitation Facility Manual (HCFA Pub. 9) (Superintendent of Documents No. HE 22.8/9)
126	• Billing Instructions for Partial Hospitalization Services Provided in Community Mental Health Centers
127	• Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccine
	Coverage Issues Manual (HCFA Pub. 6) Superintendent of Documents No. HE 22.8/14)
88	• Human Tumor Stem Cell Drug Sensitivity Assays
89	• Incontinence Control Devices Bladder Stimulators
	Provider Reimbursement Manual Part 1—(HCFA Pub.15–1) (Superintendent of Documents No. HE 22.8/4)
395	• Definition Formal Plan Commercial Insurance as a Funding Mechanism Deferred Compensation Defined Contribution Deferred Compensation Plans Pension Plans Costs Not Related to Patient Care, Unallowable Costs Not Related to Patient Care Physician Billing Costs Vested Benefits

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July through September 1996]

Trans. No.	Manual/Subject/Publication Number
396	• Methodology for Determining Per Diem Prospective Payment Rates Effective for Cost Reporting Periods Beginning On or After October 1, 1992, and Before October 1, 1993
	Provider Reimbursement Manual **Part II—Provider Cost Reporting Forms and Instructions (HCFA Pub. 15–II–AB)** **(Superintendent of Documents No. HE 22.8/4)**
10	• Cost Reporting Instructions Electronic Reporting Specifications
	Provider Reimbursement Manual **Part II—Provider Cost Reporting Forms and Instructions (HCFA Pub. 15–II–AH)** **(Superintendent of Documents No. HE 22.8/4)**
4	• Reclassification and Adjustment of Trial Balance of Expenses Adjustment of Expenses
	Provider Reimbursement Manual **Part II—Provider Cost Reporting Forms and Instructions (HCFA Pub. 15–II–AI)** **(Superintendent of Documents No. HE 22.8/4)**
1	• Skilled Nursing Facility and Skilled Nursing Facility Complex Cost Report Form HCFA 2540–96
	State Medicaid Manual—Part 2 **State Organization and General Administration** **(HCFA Pub. 45–2)** **(Superintendent of Documents No. HE 22.8/10)**
87	• Annual Report on Home and Community-Based Services Waivers Form HCFA–372 and Form HCFA–372(S)
88	• Statistical Report on Medical Care: Eligibles, Recipients, Payments, and Services Federal Reporting Requirements Statistical Report on Medical Care: Eligibles, Recipients, Payments, and Services (Form HCFA–2082) Requirements for State Participation in the Medicaid Statistical Information System
	State Medicaid Manual—Part 5 **Early and Periodic Screening, Diagnosis, and Treatment** **(HCFA Pub. 45–5)** **(Superintendent of Documents No. HE 22.8/10)**
11	• Screening Service Content
	State Medicaid Manual—Part 6 **Payment for Services** **(HCFA Pub. 45–6)** **(Superintendent of Documents No. HE 22.8/10)**
31	• Physician Services to Children Under 21 Physician Services to Pregnant Women
	Medicare/Medicaid **Sanction—Reinstatement Report** **(HCFA Pub. 69)**
96–7	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—June 1996
96–8	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—July 1996

Medicare Coverage Issues Manual

For the Medicare Coverage Issues Manual instructions that were published during the quarter covered by this notice, we give the transmittal number, the title of the section, and a brief synopsis of the revisions. The full text of these revisions is available at the following Internet address: http://www.hcfa.gov/pubforms/pub6/pub6toc.htm.

Transmittal No. 88

Clarification—Effective Date: Not Applicable.

Section 50–41, Human Tumor Stem Cell Drug Sensitivity Assays, clarifies that while the fluorescent cytoprint assay (FCA) is not based upon the same or a similar procedure as the human tumor stem cell drug sensitivity assay, it is sufficiently alike that it is included under this subject. The basic difference is that the FCA incorporates the use of microorgan systems and a fluorescent dye. The test is performed as an in vitro chemosensitivity test for the effectiveness of drugs for cancer treatment. Medicare considers the clinical application of this procedure as experimental and not covered by the program at this time.

Transmittal No. 89

Changed Implementing Instructions—Effective Date: For services furnished on or after 10/07/96.

Section 65–9, Incontinence Control Devices, is revised to reflect that in female patients the Abdominal Leak Point Pressure (ALPP) measurement is amended from less than 65 cm H_20 to an ALPP of less than 100 cm HH_20, if the diagnosis of intrinsic sphincter deficiency (ISD) is established. HCFA is amending the leak point pressure measurement in female patients without urethral hypermobility and with abdominal leak point pressures of 65 cm H_20 to 100 cm H_20.

For patients whose incontinence showed no improvement after the initial five treatments, no further treatments are covered. HCFA is amending the lifetime limitation of five treatment sessions for patients who have received successful treatments in the past to allow latitude for the treating physician to decide whether additional sessions of collagen injection may be beneficial. For these patients, medical documentation must accompany claims for additional treatments beyond five. HCFA is deleting the requirement that patients must have shown no improvement in their incontinence for at least 12 months prior to collagen therapy in order to be eligible for coverage.

In addition, the coverage guidelines for pelvic floor stimulators that were previously in § 65–11 under the bladder stimulators policy are being moved to § 65–9 since pelvic floor stimulators are more appropriately identified as incontinence control devices. Section 65–9 is also revised to indicate that pelvic floor stimulators are not covered for the reason that the effectiveness of these devices is unproven. The previous policy in § 65–11 indicated that both the safety and effectiveness of pelvic floor stimulators were unproven.

Section 65–11, Bladder Stimulators, is revised to eliminate the use of name brand products. HCFA now identifies devices according to a general categorization of products rather than by specific brand names. In addition, the coverage guidelines for pelvic floor stimulators have been moved to § 65–9.

ADDENDUM IV.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER

Publication date	FR vol. 61 page	CFR part(s)	File code*	Regulation title	End of comment period	Effective date
07/01/96	33928–33936		BPD–847-CN	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1997 Rates; Correction.	.....	.....
07/01/96	34344–34365		BPD–867-NC	Medicare Program; Schedule of Limits on Home Health Agency Costs Per Visit for Cost Reporting Periods Beginning on or After July 1, 1996.	08/30/96	070196
07/02/96	34614–34662	405, 410, 415	BPD–852-P	Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 1997.	09/03/96	.....
07/05/96	35307	405, 417, 431, 473, 498	BPD–704-FC	Medicare and Medicaid Programs; Provider Appeals; Technical Amendments; Correction.	.....	07/24/96
07/16/96	37011–37015	413	BPD–647-F	Medicare Program; Reporting of Interest From Zero Coupon Bonds.	.....	08/15/96
07/23/96	38207–38212		BPD–849-PN	Medicare Program; Recognition of the Ambulatory Surgical Center Standards of the Joint Commission on the Accreditation of Healthcare Organizations and the Accreditation Association for Ambulatory Health Care.	08/22/96	.....
07/24/96	38395–38399		MB–099-F	Medicaid Program; Medicaid Eligibility Quality Control, Progressive Reductions in Federal Financial Participation for FYs 1982–1984, Payment for Physician Billing for Clinical Laboratory Services, and Utilization Control of Skilled Nursing Facility Services: Removal of Obsolete Requirements.	.....	08/23/96
07/24/96	38395	417	OMC–009-FC	Medicare Program; Qualified Health Maintenance Organizations; Correction.	.....	10/01/95
08/01/96	40236–40242		BPO–139-N	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances and Coverage Decisions-First Quarter 1996.	.....	.....
08/02/96	40343–40347	406, 407, 408, 416	BPD–752-FC	Medicare Program; Special Enrollment Periods and Waiting Period.	10/01/96	09/03/96
08/15/96	42385–42386	417, 473, 498	BPD–704-CN	Medicare and Medicaid Programs: Provider Appeals; Technical Amendments; Corrections.	.....	07/24/96
08/15/96	42385	415	BPD–827-CN	Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1996; Correction.	.....	[1] 01/01/96

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

Publication date	FR vol. 61 page	CFR part(s)	File code*	Regulation title	End of comment period	Effective date
08/16/96	42637–42638		ORD–090-N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: June 1996.	.....	.....
08/30/96	46166–46328	412, 413, 489	BPD–847-F	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1997 Rates.	.....	10/01/96
09/03/96	46466–46478		BPD–842-NC	Medicare Program; Schedule of Prospectively Determined Payment Rates for Skilled Nursing Facility Inpatient Routine Service Costs.	11/04/96	10/01/96
09/03/96	46384–46385	417	OMC–010-FC	Medicare and Medicaid Programs; Requirements for Physician Incentive Plans in Prepaid Health Care Organizations; Correction.	11/04/96	09/03/96
09/04/96	46579–46603	418	BPD–820-P	Medicare Program; Hospice Wage Index.	11/04/96	.....
09/09/96	47423–47434	482	BPD–633-F	Medicare and Medicaid Program; Hospital Standard for Potentially HIV Infectious Blood and Blood Products.	.....	11/08/96
09/11/96	47946–47950	ORD–091-N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act	.....	.....	
09/11/96	47950–47951		OPL–011-N	Medicare Program; September 30, 1996 Meeting of the Practicing Physicians Advisory Council.	.....	.....
09/19/96	49269–49271	401, 405	BPD–869-F	Medicare Program; Waiver of Recovery of Overpayments.	.....	10/21/96
09/19/96	49271–49276	421	BPO–105-F	Medicare Program; Part B Advance Payments to Suppliers Furnishing Items or Services Under Medicare Part B.	.....	10/21/96
09/23/96	49781–49785		MB–100-N	Medicaid Program; Final Limitations on Aggregate Payments to Disproportionate Share Hospitals; Federal Fiscal Year 1996.	.....	.....
09/26/96	50493		ORD–092-N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: August 1996.		
09/30/96	51021		BPD–704-CN	Medicare and Medicaid Programs; Provider Appeals: Technical Amendments; Correction.	.....	07/24/96

[1] And 07/01/96 (part 415 only).

Addendum V.—HCFA Ruling

HCFAR–96–1 Medicare Program; Medicare Supplementary Medical Insurance (Part B); Clarification of the Terms ''Orthotics,'' ''Braces,'' and ''Durable Medical Equipment'' under Medicare Part B. Issued September 18, 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.

G960032 A1
G960055 A
G960069 A2
G960125 A1
G960140 A2
G960143 A2
G960154 A2
G960169 A2

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

G940026 B
G950128 B3
G960005 B1
G960022 B2
G960050 B2
G960059 B2
G960077 B3
G960080 B3
G960092 B4
G960114 B4
G960116 B4
G960117 B2
G960120 B1
G960121 B3
G960122 B2
G960123 B1
G960126 B2
G960127 B4
G960128 B1
G960129 B3
G960130 B
G960132 B4
G960133 B2
G960135 B1
G960136 B2
G960139 B4
G960141 B
G960142 B2
G960148 B
G960150 B2
G960151 B4
G960152 B4
G960153 B2
G960155 B1
G960156 B
G960157 B
G960158 B4
G960159 B
G960161 B
G960162 B
G960165 B
G960168 B1
G960170 B4
G960171 B3
G960172 B3
G960173 B
G960175 B2
G960176 B1
G960177 B3
G960179 B1
G960180 B4
G960182 B2
G960221 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. 97–10138 Filed 4–18–97; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Indian Child Protection and Child Abuse Prevention

AGENCY: Indian Health Service, HHS.

ACTION: Notice of availability of funds for Competitive Grants for Indian Child Protection and Child Abuse Prevention Demonstration Projects for Mental Health/Social Services for American Indians/Alaska Natives.

SUMMARY: The Indian Health Services (IHS) announces that approximately $900,000 is available for support of competitive grants for approximately five to six projects to Tribal, Urban and non-profit Indian organizations for Demonstration Projects for Indian Child Protection and Child Abuse Prevention for Mental Health/Social Services for American Indians/Alaska Natives. This program is established under the authority of Section 301(a), of the Public Health Service Act, as amended. There will be only one funding cycle during fiscal year (FY) 1997 (see Fund Availability and Period of Support). This program is described at 93.933 in the Catalog of Federal Domestic Assistance. Executive Order 12372 requiring intergovernmental review is not applicable to this program. The Public Health Service (PHS) urges applicants submitting applications to address specific objectives of *Health People 2000*. Such interested applicants may obtain a copy of *Health People 2000* (Full Report; Stock No. 017–001–00474–0) or *Health People 2000* (Summary Report; Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325 (telephone 202–512–1800).

SMOKE-FREE WORKPLACE: The PHS strongly encourages all grant recipients to provide a smokefree workplace and promote the non-use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

DUE DATE: An original and two (2) copies of the completed grant application must be submitted, with all required documentation, to the Grants Management Branch, Division of Acquisition and Grants Management, Twinbrook Metro Plaza-Suite 100, 12300 Twinbrook Parkway, Rockville, MD 20852, by close of business MAY 30, 1997.

Applications shall be considered as meeting the deadline if they are either: