ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Federal Tax Offset contact	54	1	2 minutes	1.8 hours.
Update Spec	54	1	2 minutes	1.8 hours.
Issuance of pre-offset notice	54	1	2 minutes	1.8 hours.
Contact point for OCSE Pre-offset notice	30	1	1 minute	0.9 hours.
Non-TANF Tax Refund Offset Information	1,744	40,735	10 minutes	6,789.2 hours.
Offset notice address/phone number change	54	1	10 minutes	9.0 hours.
Personal computer data	54	1	5 minutes	4.5 hours.
Notice of intention	25	1	2 minutes	0.8 hours.

Estimated Total Annual Burden Hours: 31,816.3.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Ms. Wendy Taylor.

Dated: October 28, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97–28965 Filed 10–31–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Current Topics in Immunohematologic Testing; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Current Topics in Immunohematologic Testing.'' The topics to be discussed include specificity and sensitivity of Anti-D Blood Grouping Reagents; the development of performance standards for antiglobulin control cells and blood bank saline; user interpretation of labeling information; and the validation and use of blood grouping instrumentation.

Date and Time: The workshop will be held on December 10, 1997, 8 a.m. to 5 p.m.

Location: The workshop will be held at Natcher Auditorium, National Institutes of Health, 9000 Rockville Pike, Bldg. 45, Bethesda, MD.

Contact Person: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514, FAX 301–827–2843.

SUPPLEMENTARY INFORMATION: The goals of the workshop are specific to each topic and include the following: (1) Distinguish between those issues that are medically important and those issues that are primarily of scientific interest with respect to Anti-D specificity and sensitivity; (2) present examples of significant problems attributable to the variability seen within two types of product, antiglobulin control cells and blood bank saline, due to the lack of standards; (3) identify areas of immunohematologic product labeling which need to be modified to provide the user with a better understanding of its uses and limitations; and (4) discuss user validation of complete systems as well as partial or site-assembled systems regarding blood grouping instrumentation. The information obtained from these presentations and discussions will assist FDA in taking the necessary steps for assuring the safety and effectiveness of these medical devices.

Registration and Requests for Oral Presentations: Send or fax registration information (including name, title, firm name, address, telephone, and fax number), written material, and requests to make oral presentations by November 28, 1997, to Cody Bridges, 14504 Greenview Dr., suite 500, Laurel, MD 20708, 301–490–5500, FAX 301–490–7260, e-mail CBRIDGES@lcgnet.com. Registration at the site will be done on a space available basis on the day of the workshop beginning at 7:30 a.m. There is no registration fee for the workshop.

If you need special accommodations due to a disability, please contact Cody Bridges at least 7 days in advance.

Transcripts: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the workshop at a cost of 10 cents per page.

Dated: October 24, 1997.

William K. Hubbard.

Associate Commissioner for Policy Coordination.

[FR Doc. 97–29049 Filed 10–31–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[BPO–150–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—First Quarter 1997

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 January, February, and March of 1997 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).
Betty Stanton, (410) 786–3247 (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). 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 January through March 1997.

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 five addenda. Addendum I lists the publication dates of the most recent quarterly listings 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).

On September 19, 1995, we published a final rule (60 FR 48417) establishing in regulations at 42 CFR 405.201 *et seq.* 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 V includes listings of the Food and Drug Administration-approved investigational device exemption numbers that have been approved or revised 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.

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, ATTN: New Orders, PO Box 371954, Pittsburgh, PA 15250–7954, Telephone (202) 512–1800, Fax number (202) 512–2250 (for credit card orders).
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 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 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 have, on occasion, published Rulings in the **Federal Register**. In addition, Rulings, beginning with those released in 1995, are available online, through the HCFA Home Page. The Internet address is http://www.hcfa.gov/regs/rulings.htm.

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 Social Security Act.
- HCFA-related regulations.
- HCFA manuals and monthly revisions.
- HCFA program memoranda.

The titles of the Compilation of the Social Security Act 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 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 3—Claims Process (HCFA Pub 13–3) transmittal entitled ''Oral Cancer Drugs,'' use the Superintendent of Documents No. HE 22.8/6 and the HCFA transmittal number 1700.

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, Office of Communications and Operations Support, Division of Regulations and Issuances, Health Care Financing Administration, Telephone (410) 786–5248.

Questions concerning Medicaid items in Addendum III may be addressed to Betty Stanton, Center for Medicaid State Operations, Policy Coordination and Planning Group, Health Care Financing Administration, C4–25–02, 7500 Security Boulevard, Baltimore, MD 21244–1850, Telephone (410) 786–3247.

Questions concerning Food and Drug Administration-approved investigational device exemptions may be addressed to Sharon Hippler, Office of Clinical Standards and Quality, Coverage Analysis Group, 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, Office of Communications and Operations Support, Division of Regulations and Issuances, 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: October 10, 1997.

Pamela J. Gentry,

Director, Office of Communications and Operations Support.

Addendum I

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

June 26, 1996 (61 FR 33119)
December 18, 1996 (61 FR 66676)
April 21, 1997 (62 FR 19328)
May 12, 1997 (62 FR 25957)

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

[January 1997 through March 1997]

Trans. No.		Manual/Subject/Publication No.
		Intermediary Manual Part 3—Claims Process (HCFA Pub. 13–3) (Superintendent of Documents No. HE 22.8/6)
1696	○	Review of Form HCFA–1450 for Inpatient and Outpatient Bills. Bill Review for Partial Hospitalization Services Provided in Community Mental Health Centers. Pneumoccocal Pneumonia Influenza Virus and Hepatitis B Vaccines.
1697	○	Laboratory Tests for Hemodialysis, Intermittent Peritoneal Dialysis and Continuous Cycling Peritoneal Dialysis Included in Composite Rate. Laboratory Tests for CAPD Covered Routinely and Separately Billable.
1698	○	Review of Form HCFA–1450 for Inpatient and Outpatient Bills. Review of Hospice Bills.
1699	○	Medical—Subject to Waiver.
1700	○	Oral Cancer Drugs. Self-Administered Antiemetic Drugs Mammography Quality Standards Act.
1701	○	Hospital Outpatient Partial Hospitalization Services.
1702	○	Billing for Durable Medical Equipment Orthotic/Prosthetic Devices and Surgical Dressings.
1703	○	Applicability of Limitation on Liability to Items or Services Furnished by Providers of Services Payable Under Part A When to Make Limitation on Liability Decisions.
1704	○	Contractor Data Security and Confidentiality Requirements. File Specifications, Records Specifications, and Data Element Definitions for EMC Bills. Electronic Media Claims. Requirements for Submission of EMC Data. Claims Processing Timeliness.
1705	○	Federal BL Program Address.
1706	○	Ambulance Services.
1707	○	Review of Form HCFA–1450 for Inpatient and Outpatient Bills. EMC Flat File Record for ESRD Medical Documentation—Record Type (RT) 76. Flat File Requirements for RT 76, ESRD Medical Documentation. Provider Electronic Billing File and Record Format. Alphabetic Listing of Data Elements. Medical Review Attachment Data Definitions and Codes.
1708	○	Routine Services and Appliances.
		Carriers Manual Part 2—Program Administration (HCFA Pub. 14–2) (Superintendent of Documents No. HE 22.8/7–3)
13	○	Claims Processing Timeliness. Functional Standards for Claims Processing Operations.
		Carriers Manual Part 3—Claims Process (HCFA Pub. 14–3) (Superintendent of Documents No. HE 22.8/7)
1555	○	Reasonableness and Necessity.
1556	○	Beneficiary Address Change.
1557	○	Laboratory Tests. Separately Billable Tests Furnished to Patients of Independent Dialysis Facilities.
1558	○	Type of Service.
1559	○	Reasonableness and Necessity.
1560	○	Contractor Data Security and Confidentiality Requirements. EMC Testing and Verification. Data Sets and Formats for EMC and Electronic Remittance Advice. Requirements for Processing EMC. Technical Requirements. Requirements for Processing EMC.
1561	○	Federal Black Lung Program Address. Charges by Relative or Member of Immediate Household. Duplicate and/or Overlapping Bills With Discrepant Charges. Evidence of Medical Necessity for Parenteral and Enteral Nutrition. TPP Pays Primary Benefits When Not Required. Federal Government's Right to Sue and Collect Double Damages. Documentation of Conformance. When Medicare Secondary Benefits are Payable. When Medicare Secondary Benefits are Not Payable. Calculating Medicare Secondary Payments for Services Reimbursed on Reasonable Charge or Other Basis Under Part B. Effect of Failure to File Proper Claim. Effect of Primary Payments on Deductibles and Coinsurance. Right of Physician or Supplier to Charge Beneficiary. Charging Expenses Against Annual Limit on Incurred Expenses for Services of Independently Practicing Physical Therapist. Nondiscrimination. Medicare Secondary Payment for Managed Care Organization Copayments. Individuals Receiving Delayed Compensation Payments Subject to FICA Taxes. Referral to Internal Revenue Services. Primary Payer is Bankrupt or Insolvent.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[January 1997 through March 1997]

Trans. No.		Manual/Subject/Publication No.
		Determining Size of Employers.
		Current Employment Status.
		Limitation on Payment for Services to Individuals Entitled to Benefits on the Basis of ESRD Who are Covered by GHPs.
		Prohibition Against Taking into Account, Medicare Eligibility or Entitlement and Benefit Differentiation During Coordination Period.
		Determining Period During Which Medicare May Be Secondary Payer.
		Dual Eligibility/Entitlement Situations.
		Effect of ESRD MSP on Consolidated Omnibus Budget Reconciliation Act Continuation Coverage.
		Medicare Secondary Payer Provision for Disabled Beneficiaries
		Items and Services Furnished on or After August 10, 1993 and Before October 1, 1998.
		Individuals Not Subject to MSP Provision.
		The 100-or-More Employees Requirement.
		Disabled Individuals Who Return to Work.
		Dually-Entitled Individuals.
		Items and Services Furnished on or After January 1, 1987 and Before August 10, 1993.
		Prohibition Against Financial and Other Incentives.
		Federal Government's Right to Sue and Collect Double Damages.
		Excise Tax Penalties for Contributors to Nonconforming Group Health Plans.
1563	○	Paper Remittance Notice Requirements.
		Program Memorandum Intermediaries (HCFA Pub. 60A) (Superintendent of Documents No. HE 22.8/6–5)
A–97–1	○	Extension of Due Date for Filing Provider 2552–96 Cost Reports.
A–97–2	○	Hospital Outpatient Procedures: Medicare Changes for Radiology and Other Diagnostic Coding Due to the 1997 HCPCS Update and New Dermatology HCPCS Codes.
A–97–3	○	Cost Report Filing Requirements for Hospitals with Multiple Skilled Nursing Facilities.
		Program Memorandum Intermediaries/Carriers (HCFA Pub. 60A/B) (Superintendent of Documents No. HE 22.8/6–5)
AB–96–12	○	Sterile Intravitreal Implant with Cytovene (Trade Name: Vitrasert).
AB–96–13	○	Revaccination of Beneficiaries Who Received Recalled Influenza Virus Vaccine.
AB–97–1	○	New Interest Rate Payable on Clean Claims Not Paid Timely.
AB–97–2	○	Calculation Methodology for Hematocrit Levels Used to Determine the Applicability of Payment for EPO Provided to ESRD Patients.
AB–97–3	○	Binding Contractor Hearing Officers to L/RMRP.
AB–97–4	○	Common Working File (CWF) Crossover Edits in Release 97.1.
AB–97–5	○	New Panels Approved by CPT.
		State Operations Manual Provider Certification (HCFA Pub. 7) (Superintendent of Documents No. HE 22.8/12)
279	○	Model Letter to Provider (Send with Form HCFA–2567) (Immediate Jeopardy Does Not Exist) Model Letter Notifying Provider Acceptance of Allegation of Compliance.
		Model Letter Notifying Provider of Results of Revisit.
		Notice Requirements.
		Timing of CMPs.
		Procedures for Recommending Enforcement Remedies When Immediate Jeopardy Does Not Exist.
		Response to Allegation of Compliance.
		Basis for Imposing CMPs.
280	○	Updates of Interpretive Guidelines and Survey Procedures for Hospitals.
		Hospital Manual (HCFA Pub. 10) (Superintendent of Documents No. HE 22.8/2)
704	○	Outpatient Therapeutic Services.
705	○	Pneumococcal Pneumonia Influenza Virus and Hepatitis B Vaccines.
706	○	Laboratory Tests for Hemodialysis, Intermittent Peritoneal Dialysis (IPD) and Continuous Cycling Peritoneal Dialysis (CCPD) Included in Composite Rate.
		Laboratory Tests for CAPD Covered Routinely and Separately Billable.
707	○	Oral Cancer Drugs.
		Self-Administered Antiemetic Drugs.
708	○	Billing for Hospital Outpatient Partial Hospitalization Services.
709	○	Billing for DME, Orthotic/Prosthetic Devices and Surgical Dressings.
710	○	Ambulance Service Claims.
711	○	Outpatient Therapeutic Services.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[January 1997 through March 1997]

Trans. No.		Manual/Subject/Publication No.
		Home Health Agency Manual (HCFA Pub. 11) (Superintendent of Documents No. HE 22.8/5)
282	○	Billing for Oral Cancer Drugs. Self-Administered Antiemetic Drugs.
		Medicare Renal Dialysis Facility Manual (Non-Hospital Operated) (HCFA Pub. 29) (Superintendent of Documents No. HE 22.8/13)
77	○	Laboratory Tests for Hemodialysis, IPD and CCPD.
		Medicare Outpatient Physical Therapy and Comprehensive Outpatient Rehabilitation Facility Manual (HCFA Pub. 9) (Superintendent of Documents No. HE 22.8/9)
129	○	Billing Instructions for Partial Hospitalization Services Provided in Community Mental Health Centers.
		Medicare Coverage Issues Manual (HCFA Pub. 6) (Superintendent of Documents No. HE 22.8/14)
91	○	Laboratory Tests—CRD Patients.
92	○	Osteogenic Stimulation.
93	○	Treatment of Motor Function Disorders with Electric Nerve Stimulation. Transmyocardial Revascularization With Laser—Not Covered. Intraocular Lenses (IOL). Partial Ventriculectomy (Also known as Ventricular Reduction, Ventricular Remodeling or Heart Volume Reduction Surgery). Cryosurgery of Prostate. Vertebral Axial Decompression (VAX-D). Infusion Pumps.
		Medicare Provider Reimbursement Manual Part 1—(HCFA Pub.15–1) (Superintendent of Documents No. HE 22.8/4)
398	○	Regional Medicare Swing-Bed SNF Rates.
		Provider Reimbursement Manual Part II—Provider Cost Reporting Forms and Instructions (HCFA Pub. 15–II–AF) (Superintendent of Documents No. HE 22.8/4)
3	○	Home Health Agency Complex Identification Data. Adjustments to Expenses. Cost Allocation—General Service Costs, and Cost Allocation—Statistical Basis.
4	○	Home Health Agency Cost Report. Home Health Agency Complex Identification Data. Cost Allocation—General Service Costs, and Cost Allocation—Statistical Basis. Cost Center Coding.
		State Medicaid Manual—Part 3—Eligibility (HCFA Pub. 45–3) (Superintendent of Documents No. HE 22.8/10)
67	○	Changes Due to Welfare Reform. Changes in SSI Definition of Disability Due to Welfare Reform. Citizenship and Alienage. Aliens.
		State Medicaid Manual—Part 4—Services (HCFA Pub. 45–4) (Superintendent of Documents No. HE 22.8/10)
70	○	Home Respiratory Care for Ventilator-Dependent Individuals. Home and Community-Based Services—Basis, Scope, and Purpose. Description of Waiver Participants. Definition of Services. Safeguards—Assurances and Documentation. Evaluations—Assurances and Documentation. Cost Effectiveness—Assurances and Documentation. Annual Report—Assurances and Documentations. Independent Assessment of the Waiver. Home and Community-Based Services—Model Waiver Request. Home and Community-Based Services—Procedures to Request Renewal of Approved Waivers. Home and Community-Based Services—Amendments.
		State Medicaid Manual—Part 6 Payment for Services (HCFA Pub. 45–6) (Superintendent of Documents No. HE 22.8/10)
33	○	Physician Services to Children Under 21. Physician Services to Pregnant Women.
		Medicare/Medicaid Sanction—Reinstatement Report (HCFA Pub. 69)
97–1	○	Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—December 1996.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[January 1997 through March 1997]

Trans. No.		Manual/Subject/Publication No.
97–2	○	Cumulative Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Sanctioned/Reinstated.
97–3	○	Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—January 1997.
97–4	○	Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—February 1997.

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
01/02/97	26–31	413	BPD–788–F	Medicare Program; Electronic Cost Reporting for Skilled Nursing Facilities and Home Health Agencies.		02/01/97
01/13/97	1682–1685	435	MB–105–FC	Medicaid Program; Redeterminations of Medicaid Eligibility Due to Welfare Reform.	03/14/97	01/13/97
01/13/97	1768–1776		BPD–882–N	Notification Procedures for States Implementing ''Alternative Mechanisms'' in the Individual Health Insurance Market.		
01/16/97	2373–2374		ORD–095–N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: November 1996.		
01/23/97	3563		BPD–886–N	Department of Health and Human Services, Health Care Financing Administration; Department of Labor, Pension and Welfare Benefits Administration; and Department of the Treasury, Office of Tax Policy and Internal Revenue Service (the Agencies); Health Insurance Portability; Correction.		
01/29/97	4305–4311		ORD–089–N	Medicare and Medicaid Programs; Small Business Innovation Research Grants for Fiscal Year 1997.		
01/31/97	4772–4776		MB–104–N	Medicaid Program; Preliminary Limitations on Aggregate Payments to Disproportionate Share Hospitals: Federal Fiscal Year 1997.		
02/05/97	5433–5442		HSQ–244–N	CLIA Program; Clinical Laboratory Improvement Amendments of 1988—Denial of Exemption of Laboratories in the Commonwealth of Puerto Rico.		10/28/96
02/21/97	7945–7946	410 415	BPD–852–CN	Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1997; Correction.		01/01/97
02/25/97	8451–8452		ORD–096–N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: December 1996.		
03/06/97	10286		OPL–014–N	Medicare Program; March 24, 1997 Meeting of the Practicing Physicians Advisory Council.		
03/10/97	11035–11064	484	HSQ–238–P	Medicare and Medicaid Programs; Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies.	06/09/97	
03/10/97	11005–11035	484	BPD–819–P	Medicare and Medicaid Programs; Conditions of Participation for Home Health Agencies.	06/09/97	
03/28/97	14851–14878	413	BPD–808–P	Medicare and Medicaid Programs; Salary Equivalency Guidelines for Physical Therapy, Respiratory Therapy, Speech Language Pathology, and Occupational Therapy Services.	05/27/97	
03/31/97	15187–15191		ORD–097–N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: January 1997 and Supplement to December 1996 Listing.		

Addendum V—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. Also, 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. To obtain more information about the classes or categories, please refer to the **Federal Register** notice published on April 21, 1997 (62 FR 19328).

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

G960213 A2
G960218 A1
G960258 A1
G960266 A1
G970004 A1
G970007 A1
G970015 A2
G970016 A2
G970018 A2
G970022 A2
G970035 A2
G970051 A2
G970053 A2

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

G950115 B1
G956391 B2
G960193 B4
G960199 B2
G960208 B1
G960229 B1
G960230 B2
G960231 B3
G960234 B4
G960235 B3
G960241 B2
G960243 B2
G960245 B2
G960246 B1
G960247 B1
G960248 B4
G960249 B4
G960250 B3
G960252 B2
G960253 B4
G960254 B2
G960255 B2
G960256 B1
G960257 B3
G960259 B4
G960262 B3
G960263 B3
G960264 B3
G960267 B1
G970001 B3
G970002 B4
G970003 B3
G970005 B4
G970011 B2
G970012 B4
G970019 B3
G970023 B4
G970025 B3
G970026 B3
G970028 B3
G970029 B3
G970030 B1
G970031 B3
G970032 B3
G970033 B4
G970034 B4
G970037 B4
G970038 B4
G970039 B4
G970040 B3
G970041 B4
G970046 B1
G970047 B3
G970052 B1
G970054 B4
G970059 B3

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[OACT–057–N]

RIN 0938–AI12

Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 1998

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

ACTION: Notice.

SUMMARY: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 1998 under Medicare's hospital insurance program (Medicare Part A). The Medicare statute specifies the formulae to be used to determine these amounts.

The inpatient hospital deductible will be $764. The daily coinsurance amounts will be: (a) $191 for the 61st through 90th days of hospitalization in a benefit period; (b) $382 for lifetime reserve days; and (c) $95.50 for the 21st through 100th days of extended care services in a skilled nursing facility in a benefit period.

EFFECTIVE DATE: This notice is effective on January 1, 1998.

FOR FURTHER INFORMATION CONTACT: John Wandishin, (410) 786–6389. For case-mix analysis only: Gregory J. Savord, (410) 786–1521.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1813 of the Social Security Act (the Act) provides for an inpatient hospital deductible to be subtracted from the amount payable by Medicare for inpatient hospital services furnished to a beneficiary. It also provides for certain coinsurance amounts to be subtracted from the amounts payable by Medicare for inpatient hospital and extended care services. Section 1813(b)(2) of the Act requires us to determine and publish between September 1 and September 15 of each year the amount of the inpatient hospital deductible and the hospital and extended care services coinsurance amounts applicable for services furnished in the following calendar year.

II. Computing the Inpatient Hospital Deductible for 1998

Section 1813(b) of the Act prescribes the method for computing the amount of the inpatient hospital deductible. The inpatient hospital deductible is an amount equal to the inpatient hospital deductible for the preceding calendar year, changed by our best estimate of the payment-weighted average of the applicable percentage increases (as defined in section 1886(b)(3)(B) of the Act). This estimate is used for updating the payment rates to hospitals for discharges in the fiscal year that begins on October 1 of the same preceding calendar year and adjusted to reflect real case mix. The adjustment to reflect real case mix is determined on the basis of the most recent case mix data available. The amount determined under this formula is rounded to the nearest multiple of $4 (or, if midway between two multiples of $4, to the next higher multiple of $4).

Section 4401(a) of the Balanced Budget Act of 1997 (Public Law 105–33, enacted on August 5, 1997) amended section 1886(b)(3)(B)(i) of the Act by making the percentage increase for hospitals paid under the prospective payment system 0 percent for fiscal year 1998. Section 4411(a) of the Balanced Budget Act of 1997 similarly amended section 1886(b)(3)(B)(ii) of the Act by making the percentage increase for hospitals excluded from the prospective payment system 0 percent for fiscal year 1998. Therefore, our best estimate of the payment-weighted average of the increase in the payment rates for fiscal year 1998 is 0 percent.

To develop the adjustment for real case mix, an average case mix was first calculated for each hospital that reflects the relative costliness of that hospital's