

trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding pending issues and applications.

FDA regrets that it was unable to publish this notice 15 days prior to the Neurological Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Neurological Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 27, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-14913 Filed 6-2-98; 9:28 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-9152-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—Third 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 July, August, and September 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 timeframe.

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).

Pamela Gulliver, (410) 786-4659 (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 July through September 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 timeframe to determine whether any are of particular interest. We expect it to be used in concert with previously published notices. Most notably, those unfamiliar with a description of our Medicare manuals may wish to review Table I of our first three notices (53 FR 21730, 53 FR 36891, and 53 FR 50577) and the notice published March 31, 1993 (58 FR 16837), and those desiring information on the Medicare Coverage Issues Manual may wish to review the August 21, 1989 publication (54 FR 34555).

To aid the reader, we have organized and divided this current listing into five addenda. Addendum I 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. It is HCFA's practice to 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, 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 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 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 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 Home Health Agency Manual, (HCFA Pub. 11) transmittal entitled "Billing for Durable Medical Equipment, Orthotic/Prosthetic Devices," use the Superintendent of Documents No. HE 22.8/5 and the HCFA transmittal number 283.

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 Pamela Gulliver, Office of Communications and

Operations Support, Division of Regulations and Issuances, Health Care Financing Administration, C5-09-26, 7500 Security Boulevard, Baltimore, MD 21244-1850, Telephone (410) 786-4659.

(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: May 5, 1998.

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.

December 18, 1996 (61 FR 66676)

April 21, 1997 (62 FR 19328)

May 12, 1997 (62 FR 25957)

November 3, 1997 (62 FR 59358)

November 21, 1997 (62 FR 62325)

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 1997 Through September 1997

Trans.	Manual/Subject/Publication No.
<p style="text-align: center;">Intermediary Manual Part 1—Fiscal Administration (HCFA Pub. 13-1) (Superintendent of Documents No. HE 22.8/6-3)</p>	
128	<ul style="list-style-type: none"> • Coordination of Medicare and Complementary Insurance Programs. Coordination of Medicare With the Federal Grants in Aid Program (Medicaid).
<p style="text-align: center;">Intermediary Manual Part 3—Claims Process (HCFA Pub. 13-3) (Superintendent of Documents No. HE 22.8/6)</p>	
1715	<ul style="list-style-type: none"> • Self-Administered Drug Administered In An Emergency Situation.
1716	<ul style="list-style-type: none"> • Mammography Screening.
1717	<ul style="list-style-type: none"> • HCPCS for Hospital Outpatient Radiology Services and Other Diagnostic Procedures.
1718	<ul style="list-style-type: none"> • Billing for Durable Medical Equipment, Orthotic/Prosthetic Devices and Surgical Dressings.
1719	<ul style="list-style-type: none"> • CFA Common Procedure Coding System.
1720	<ul style="list-style-type: none"> • Completing Quarterly Report on Provider Enrollment.
1721	<ul style="list-style-type: none"> • Laboratory Tests for Hemodialysis, Intermittent Peritoneal Dialysis, Continuous Cycling Peritoneal Dialysis and Hemofiltration.
	Laboratory Tests.
1722	<ul style="list-style-type: none"> • HCPCS Codes for Diagnostic Services and Medical Services (Correction to Transmittal Number 1719, dated July 1997).
1723	<ul style="list-style-type: none"> • Claims Processing Timeliness.
1724	<ul style="list-style-type: none"> • HCPCS Codes for Diagnostic Services and Medical Services—Correction to Transmittal Number 1722, Dated August 1997.
1725	<ul style="list-style-type: none"> • Mammography Screening.
	Focused Medical Review.
	Focused Medical Review Activity Report.
1726	<ul style="list-style-type: none"> • Review of Form HCFA-1450 for Inpatient and Outpatient Bills.
	Provider Electronic Billing File and Record Formats.
	Alphabetic Listing of Data Elements.
<p style="text-align: center;">Intermediary Manual. Part 4—Audit Procedures (HCFA Pub. 13-4) (Superintendent of Documents No. HE 22.8/6-4)</p>	
33	<ul style="list-style-type: none"> • Home Office Uniform Desk Review.
<p style="text-align: center;">Carriers Manual Part 1—Fiscal Administration (HCFA Pub. 14-1) (Superintendent of Documents No. HE 22.8/7-2)</p>	
122	<ul style="list-style-type: none"> • Coordination of Medicare and Complementary Insurance Programs. • Coordination of Medicare With the Federal Grants in Aid Program (Medicaid).
<p style="text-align: center;">Carriers Manual Part 2—Claims Process (HCFA Pub. 14-2) (Superintendent of Documents No. HE 22.8/7-3)</p>	
136	<ul style="list-style-type: none"> • Functional Standards for Claims Processing Operations.

Trans.	Manual/Subject/Publication No.
<p align="center">Carriers Manual Part 3—Claims Process (HCFA Pub. 14-3) (Superintendent of Documents No. HE 22.8/7)</p>	
1573	<ul style="list-style-type: none"> • Evidence of Medical Necessity for Durable Medical Equipment.
	General Claims Processing Requirements.
	Billing Requirements.
	Simplified Roster Bills.
	Health Insurance Maintenance Organization Processing Requirements.
	Speciality Code/Place of Service Processing Requirements.
	Suppression of EOMBs.
	Billing Requirements for Global Surgeries.
	Claims Review for Global Surgeries.
	Payment for Return Trips to the Operating Room for Treatment of Complications.
	EOMB and Remittance Messages.
	Payment for Eyeglasses, Contact Lenses, and Related Services.
	Interpretation of Diagnostic Tests.
1574	<ul style="list-style-type: none"> • Identifying a Screening Mammography Claim.
1575	<ul style="list-style-type: none"> • Claims Processing Terminology.
	Handling Incomplete or Invalid Claims.
	Conditional Data Element Requirements.
	Data Element Requirements Matrix.
	Data Element Requirements.
	Incomplete or Invalid Claims.
1576	<ul style="list-style-type: none"> • Exception to § 7560 A and B When Physician, Other Practitioner, or Supplier Is Excluded From Participation in Medicare Program.
	Authority to Exclude Practitioners, Providers, and Suppliers of Services.
1577	<ul style="list-style-type: none"> • Evidence of Medicaid Necessity for Durable Medical Equipment (Correction to Transmittal Number 1573, dated July 1997).
1578	<ul style="list-style-type: none"> • Assistant at Surgery Services.
	Purchased Diagnostic Tests.
	Inpatient Dialysis On Same Date As Evaluation and Management.
	Consultations.
	Threshold Times For Codes 99354 and 99355.
1579	<ul style="list-style-type: none"> • Services Eligible for HPSA Bonus Payments.
	Remittance Messages.
1580	<ul style="list-style-type: none"> • Doctor of Medicine and Osteopathy.
<p align="center">Carriers Manual Part 4—Professional Relations (HCFA Pub. 14-4) (Superintendent of Documents No. HE 22.8/7-4)</p>	
14	<ul style="list-style-type: none"> • Patient and Insured Information.
	Provider of Service or Supplier Information.
	Place of Service Codes and Definitions.
<p align="center">Program Memorandum Intermediaries (HCFA Pub. 60A) (Superintendent of Documents No. HE 22.8/6-5)</p>	
A-97-5	<ul style="list-style-type: none"> • Application of Medicare Reasonable Cost Reimbursement Principles to Rural Health Clinics.
A-97-6	<ul style="list-style-type: none"> • Extension of Due Date for Filing Form HCFA-2540-96 and Form HCFA-1728-94 Cost Reports.
A-97-7	<ul style="list-style-type: none"> • Home Health Agency Requests to Intermediaries to Change Cost Center Allocation Sequence or Statistical Allocation Basis.
A-97-8	<ul style="list-style-type: none"> • Instructions to Implement the New Medicare Summary Notice.
A-97-9	<ul style="list-style-type: none"> • Hospital Outpatient Procedures: Medicare Changes Due to 1997 HCPCS Update—New Dermatology Codes (Clarification).
A-97-10	<ul style="list-style-type: none"> • Change in Hospice Payment Rates.
A-97-11	<ul style="list-style-type: none"> • Hospice Provisions Enacted by the Balanced Budget Act of 1997.
A-97-12	<ul style="list-style-type: none"> • Medicare Home Health Benefit—The Balanced Budget Act of 1997 Clarification of Part-Time or Intermittent Skilled Nursing Care.
A-97-13	<ul style="list-style-type: none"> • FY 1998 Prospective Payment System, TEFRA Hospital and Other Bill Processing Changes.
A-97-14	<ul style="list-style-type: none"> • Hospital Outpatient Procedures: Billing for Contrast Material (Clarification).
<p align="center">Program Memorandum Carriers (HCFA Pub. 60B) (Superintendent of Documents No. HE 22.8/6-5)</p>	
B-97-2	<ul style="list-style-type: none"> • Changes to Correct Coding Edits, Version 4.0.
B-97-3	<ul style="list-style-type: none"> • Instructions for CLIA Compliance for Part B Laboratory Claims Submitted to Carriers.
B-97-4	<ul style="list-style-type: none"> • Instructions for CLIA Compliance for Part B Laboratory Claims Submitted to Carriers— Correction to Transmittal Number B-97-3, dated September 1997.
B-97-5	<ul style="list-style-type: none"> • Update of Rates and Wage Index for Ambulatory Surgical Center Payments Effective October 1, 1997.

Trans.	Manual/Subject/Publication No.
<p align="center">Program Memorandum Intermediaries/Carriers (HCFA Pub. 60A/B) (Superintendent of Documents No. HE 22.8/6-5)</p>	
AB-97-10	• Claims for Separately Billable End Stage Renal Disease Laboratory Services Performed by Certified Independent Dialysis Facilities.
AB-97-11	• Counting of Non-Medicare Home Health Visits and the Reporting of the Associated Costs in Determining the Average Cost Per Visit for Home Health Services.
AB-97-12	• New Implementation Date for Hematocrit Levels for Erythropoietin.
AB-97-13	• Extension of the Limitation on Payment for Services to Individuals Entitled to Benefits on the Basis of End Stage Renal Disease Who are Covered by Group Health Plans.
AB-97-14	• Extension of the Limitation on Payment for Services to Individuals Entitled to Benefits on the Basis of End Stage Renal Disease Who are Covered by Group Health Plans (GHP)— Correction to Program Memorandum Number AB-97-13, dated September 1997.
AB-97-15	• Update to the Hospice Wage Index.
AB-97-16	• Balanced Budget Act of 1997, P.L. 105-33 (H.R. 2015)—Home Health Payment Provisions.
AB-97-17	• New Panels Approved by Common Procedural Terminology—Clarification of Program Memorandum AB-97-5.
AB-97-18	• Balanced Budget Act of 1997, P.L. 105-33 (H.R.)—Home Health Payment Provisions.
<p align="center">State Operations Manual Provider Certification (HCFA Pub. 7) (Superintendent of Documents No. HE 22.8/12)</p>	
283	• Interpretive Guidelines and Survey Procedures.
<p align="center">Peer Review Organization Manual (HCFA Pub. 19) (Superintendent of Documents No. HE 22.8/8-15)</p>	
64	• Opportunity to Discuss. Authority. Scope of Review. Complaints That Do Not Meet Statutory Requirements. Referrals. Review Process.
<p align="center">Hospital Manual (HCFA Pub. 10) (Superintendent of Documents No. HE 22.8/2)</p>	
716	• Self-Administered Drug Administered In An Emergency Situation.
717	• Billing for Mammography Screening.
718	• HCPCS for Hospital Outpatient Radiology Services and Other Diagnostic Procedures.
719	• Billing for Durable Medical Equipment, Orthotic/Prosthetic Devices, and Surgical Dressings.
720	• HCFA Common Procedure Coding System.
721	• HCPCS Codes for Diagnostic Services and Medical Services.
722	• Billing for Mammography Screening.
<p align="center">Home Health Agency Manual (HCFA Pub. 11) (Superintendent of Documents No. HE 22.8/5)</p>	
283	• Billing for Durable Medical Equipment, Orthotic/Prosthetic Devices.
<p align="center">Skilled Nursing Facility Manual (HCFA Pub. 12) (Superintendent of Documents No. HE 22.8/3)</p>	
348	• Billing for Mammography Screening.
349	• Billing for Durable Medical Equipment (DME), Orthotic/Prosthetic Devices, and Surgical Dressings.
350	• Billing for Mammography Screening.
<p align="center">Outpatient Physical Therapy and Comprehensive Outpatient Rehabilitation Facility Manual (HCFA Pub. 9) (Superintendent of Documents No. HE 22.8/9)</p>	
130	• Billing for Durable Medical Equipment Orthotic/Prosthetic Devices, and Surgical Dressings.
<p align="center">Coverage Issues Manual (HCFA Pub. 6) (Superintendent of Documents No. HE 22.8/18)</p>	
102	• Hyperbaric Oxygen Therapy

Trans.	Manual/Subject/Publication No.
	Lung Volume Reduction Surgery (Reduction Pneumoplasty, Also Called Lung Shaving or Lung Contouring) Unilateral or Bilateral by Open or Thoracoscopic Approach for Treatment of Emphysema or Chronic Obstructive Pulmonary Disease.
Provider Reimbursement Manual—Part 1 (HCFA Pub. 15-1) (Superintendent of Documents No. 22.8/4)	
400	<ul style="list-style-type: none"> • Provider Requests Regarding Applicability of Cost Limits. Request for Exemption From Skilled Nursing Facility Cost Limits.
Provider Reimbursement Manual—Part I Chapter 27—Reimbursement for ESRD and Transplant Services (HCFA Pub. 15-1-27) (Superintendent of Documents No. 22.8/4)	
29	<ul style="list-style-type: none"> • Allowable Compensation for Physician Owners and Medical Directors Allowable Compensation for Owners, Administrators, and Assistant Administrators. Submission of Documentation.
Provider Reimbursement Manual—Part II Provider Cost Reporting Forms and Instructions (HCFA Pub. 15-II-A) (Superintendent of Documents No. 22.8/4)	
19	<ul style="list-style-type: none"> • Electronic Submission of Cost Reports. Electronic Submission of Hospital Cost Reports. Electronic Submission of SNF and HHA Cost Reports.
Provider Reimbursement Manual—Part II Provider Cost Reporting Forms and Instructions (HCFA Pub. 15-II-A) (Superintendent of Documents No. 22.8/4)	
3	<ul style="list-style-type: none"> • Hospital and Hospital Health Care Complex Cost Report, Form HCFA-2552-96.
State Medicaid Manual—Part 2 State Organization and General Administration (HCFA Pub. 45-2) (Superintendent of Documents No. HE22.8/10)	
89	<ul style="list-style-type: none"> • 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 3 Eligibility (HCFA Pub. 45-3) (Superintendent of Documents No. HE22.8/10)	
68	<ul style="list-style-type: none"> • Retroactive Medicaid Coverage.
State Medicaid Manual—Part 6 Payment for Services (HCFA Pub. 45-6) (Superintendent of Documents No. HE22.8/10)	
34	<ul style="list-style-type: none"> • Ingredient Prices Used by States to Establish Upper Limits for Prescription Drugs.
Rural Health Clinic Manual and Federally Qualified Health Centers Manual (HCFA Pub. 27) (Superintendent of Documents No. HE22.8/19:985)	
27	<ul style="list-style-type: none"> • Billing for Mammography Screening by Rural Health Clinics and Federally Qualified Health Centers.
28	<ul style="list-style-type: none"> • Billing for Mammography Screening by Rural Health Clinics and Federally Qualified Health Centers.
Program Memorandum State Survey Agencies (HCFA Pub. 65)	
97-1	<ul style="list-style-type: none"> • Policy Clarification: Home Health Agency Parent, Branch, and Subunit Criteria.
Medicare/Medicaid Sanction—Reinstatement Report (HCFA Pub. 69)	
97-7	<ul style="list-style-type: none"> • Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—May 1997.

Trans.	Manual/Subject/Publication No.
97-8	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—June 1997.
97-9	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—July 1997.
97-10	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—August 1997.

ADDENDUM IV.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER

Publication date	FR Vol. 62, page	CFR part(s)	File code*	Regulation title	End of comment period	Effective date
07/01/97	35513–35516	HSQ-243-N	Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Continuance of Exemption of Laboratories Licensed by the State of Washington.	07/01/97
07/01/97	35608–35634	BPD-889-NC	Medicare Program; Schedule of Limits on Home Health Agency Costs Per Visit for Cost Reporting Periods Beginning on or After July 1, 1997.	09/02/97	07/01/97
07/02/97	35824–35826	HSQ-207-NC	Medicare Program; Description of the Health Care Financing Administration's Evaluation Methodology for the Peer Review Organization 5th Scope of Work Contracts.	09/02/97	07/02/97
07/16/97	38100–38107	BPD-845-PN	Medicare Program; Special Payment Limits for Home Oxygen.	09/15/97	07/16/97
07/17/97	38314–38315	ORD-101-N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: May 1997.	07/17/97
07/29/97	40568	BPD-889-NC	Medicare Program; Schedule of Limits on Home Health Agency Costs Per Visit for Cost Reporting Periods Beginning on or After July 1, 1997; CORRECTION.	07/01/97
08/08/97	42860–42883	418	BPD-820-F	Medicare Program; Hospice Wage Index	10/01/97
08/14/97	43541–43542	ORD-102-N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: June 1997.	08/14/97
08/15/97	43657–43674	412 413 414	BPD-763-F	Medicare Program; End-Stage Renal Disease (ESRD) Payment Exception Requests and Organ Procurement Costs.	08/15/97
08/18/97	43962–43963	400 405 410 414	BPD-884-CN	Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Other Part B Payment Policies, and Establishment of the Clinical Psychologist Fee Schedule for Calendar Year 1998; CORRECTION.
08/18/97	43931–43937	431 442 488 489 498	HSQ-139-F	Medicare and Medicaid Programs; Effective Dates of Provider Agreements and Supplier Approvals.	09/17/97
08/20/97	44221	488	HSQ-156-CN	Medicare and Medicaid Programs; Survey, Certification and Enforcement of Skilled Nursing Facilities and Nursing Facilities.	07/01/95
08/29/97	45815–45821	HSQ-219-GNC	CLIA Program; Fee Schedule Revision	10/28/97	01/01/98
08/29/97	45823	OPL-016-N	Medicare Program; September 22, 1997, Meeting of the Practicing Physician Advisory Council.
08/29/97	45966–46140	400 409 410 411 412 413 424 440 485 488 489 498	BPD-878-FC	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1998 Rates.	10/28/97	10/01/97
09/04/97	46698–46707	416	BPD-831-P	Medicare Program; Adjustment in Payment Amounts for New Technology Intraocular Lenses.	11/03/97	09/04/97
09/08/97	47237	416	BPD-878-FC	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1998 Rates; CORRECTION.
09/11/97	47896–47903	440	MB-071-F	Medicaid Program; Coverage of Personal Care Services.	11/10/97
09/12/97	48098–48105	MB-115-N	State Children's Health Insurance Program; Reserved Allotments to States for Fiscal Year 1998; Enhanced Federal Medical Assistance Percentages.
09/15/97	48292–48297	MB-110-N	Medicaid Program; Final Limitations on Aggregate Payments to Disproportionate Share Hospitals: Federal Fiscal Year 1997.

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

Publication date	FR Vol. 62, page	CFR part(s)	File code*	Regulation title	End of comment period	Effective date
09/17/97	48872–48873	BPD–898–NC ...	Medicare and Medicaid Programs; Announcement of Additional Applications From Hospitals Requesting Waivers for Organ Procurement Service Area.	11/17/97
09/18/97	49049	400 409 410 411 412 413 424 440 485 488 489 498	BPD–878–FC ...	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1998 Rates; CORRECTION.
09/23/97	49649–49654	OMC–029–N	Medicare Program; Solvency Standards for Provider-Sponsored Organizations; Intent To Form Negotiated Rulemaking Committee.	10/08/97
09/23/97	49726	440	MB–071–F	Medicaid Program; Coverage of Personal Care Services; CORRECTION.
09/24/97	49937–49938	473	BPD–453–CN ...	Medicare Program; Medicare Appeals of Individual Claims; CORRECTION.	06/11/97

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.

G960082 A1
G970008 A4
G970044 A2
G970058 A2
G970069 A2
G970073 A2
G970088 A2
G970118 A2
G970121 A2
G970128 A1
G970131 A1
G970136 A2
G970147 A1
G970151 A2
G970169 A2
G970176 A2

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

G910187 B1
G960161 B4
G970014 B2
G970015 B4
G970024 B4
G970045 B4
G970081 B4

G970094 B3
G970096 B1
G970112 B2
G970116 B1
G970117 B4
G970122 B4
G970123 B4
G970129 B2
G970132 B3
G970133 B3
G970134 B4
G970135 B4
G970137 B4
G970138 B4
G970140 B1
G970141 B2
G970142 B1
G970149 B3
G970150 B1
G970157 B4
G970161 B4
G970168 B1
G970178 B2
G970179 B2
G970180 B4
G970183 B1
G970189 B4
G970191 B1
G970193 B2
G970194 B2

[FR Doc. 98–14834 Filed 6–3–98; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings:

Name of Committee: National Human Genome Research Institute Initial Review Group, Ethical, Legal, and Social Implications Subcommittee.

Agenda/Purpose: To review and evaluate grant applications and/or contract proposals.
Date: June 4, 1998.

Time: 9:00 am–5:00 pm.

Place: Holiday Inn Hotel, Bethesda, Maryland.

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

Name of Committee: National Human Genome Research Institute, Special Emphasis Panel 01.

Agenda/Purpose: To review and evaluate grant applications and/or contract proposals.
Date: June 30, 1998.

Time: 8:30–12 Noon.

Place: Holiday Inn Hotel, Bethesda, Maryland.

Name of Committee: National Human Genome Research Institute Initial Review Group, Genome Research Review Subcommittee.

Agenda/Purpose: To review and evaluate grant applications and/or contract proposals.
Date: June 20, 1998.

Time: 1:00–5:00 pm.

Place: Holiday Inn Hotel, Bethesda, Maryland.

Name of Committee: National Human Genome Research Institute, Special Emphasis Panel 02.

Agenda/Purpose: To review and evaluate grant applications and/or contract proposals.
Date: June 30, 1998.

Time: 8:30 am–5:00 pm.

Place: Holiday Inn Hotel, Bethesda, Maryland.

Name of Committee: National Human Genome Research Institute, Special Emphasis Panel 03.

Agenda/Purpose: To review and evaluate grant applications and/or contract proposals.
Date: July 1–2, 1998.

Time: 8:30 am–5:00 pm.

Place: Holiday Inn Hotel, Bethesda, Maryland.