room 121, 8800 Wisconsin Ave., Bethesda, MD. This meeting will be held by a telephone conference call. A speaker telephone will be provided in the conference room to allow public participation in the meeting.

Contact Person: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12388. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the intramural scientific program of the Laboratory of Enteric and Sexually Transmitted Diseases.

Procedure: On December 4, 1997, from 12:30 p.m. to 1:15 p.m., and 2:30 p.m. to 3:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 26, 1997. Oral presentations from the public will be scheduled between approximately 2:30 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 26, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On December 4, 1997, from 1:15 p.m. to 2:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The meeting will be closed to discuss personal information concerning individuals associated with the research program.

FDA regrets that it was unable to publish this notice 15 days prior to the December 4, 1997, Vaccines and Related Biological Products Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Vaccines and Related Biological Products 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: November 17, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–30613 Filed 11-20-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccine and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on December 11, 1997, 10:30 a.m. to 5:45 p.m., and December 12, 1997, 8 a.m. to 5 p.m.

Location: Holiday Inn Bethesda, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12388. Please call the Information Line for up-to-date information on this meeting.

Agenda: On December 11, 1997, the committee will meet in closed session to discuss trade secret and/or confidential commercial information relevant to pending investigational new drug applications or pending product licensing applications. On December 12, 1997, in open session, the committee will consider the safety and efficacy of a new vaccine for the prevention of Rotavirus Diarrhea in children. The vaccine, RotaShield™, is made for infant indication by Wyeth-Lederle Vaccines and Pediatrics.

Procedure: On December 12, 1997, from 9:30 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 3, 1997. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 3, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On December 11, 1997, from 10:30 a.m. to 5:45 p.m., and on December 12, 1997, from 8 a.m. to 9:30 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information. These portions of the meeting will be closed to discuss pending investigational new drug applications or pending product licensing applications (5 U.S.C. 552b(c)(4)).

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

Dated: November 17, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–30708 Filed 11–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[BPO–151–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—Second 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 April, May, and June 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).
Pam 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 April through June 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. 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, 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 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 Intermediary Manual, Part 2—Audits, Reimbursement Program Administration (HCFA Pub. 13–2) transmittal entitled ''Maximum Payment Per Visit For Rural Health Clinics,'' use the Superintendent of Documents No. HE 22.8/6–2 and the HCFA transmittal number 409.

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 Pam 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: October 31, 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)
November 3, 1997 (62 FR 59358)

Addendum II—Description of Manuals, Memoranda, and HCFA Rulings

An extensive descriptive listing of Medicare manuals and memoranda was published on June 9, 1988, at 53 FR 21730 and supplemented on September 22, 1988, at 53 FR 36891 and December 16, 1988, at 53 FR 50577. Also, a complete description of the Medicare Coverage Issues Manual was published on August 21, 1989, at 54 FR 34555. A brief description of the various Medicaid manuals and memoranda that we maintain was published on October 16, 1992, at 57 FR 47468.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS

[April 1997 through June 1997]

Trans. No.		Manual/Subject/Publication No.
		Intermediary Manual Part 2—Audits, Reimbursement Program Administration (HCFA Pub. 13–2) (Superintendent of Documents No. HE 22.8/6–2)
409	•	Maximum Payment Per Visit For Rural Health Clinics.
	•	Maximum Payment Per Visit For Freestanding Federally Qualified Health Centers.
410	•	List of MR Codes, Categories, and Conversion Factors.
		Intermediary Manual Part 3—Claims Process (HCFA Pub. 13–3) (Superintendent of Documents No. HE 22.8/6)
1709	•	Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines.
1710	•	Review of Form HCFA–1450 For Inpatient and Outpatient Bills. Self-Administered Drugs and Biologicals. Oral Cancer Drugs. Self-Administered Antiemetic Drugs. Mammography Quality Standards Act. Self-Administered Drug Administered In An Emergency Situation. Hospital Outpatient Partial Hospitalization Services.
1711	•	Special Consideration When Processing ESRD Bills Under Method I. Special Consideration When Processing ESRD Bills Under Method II. Medical—Subject to Waiver.
1712	•	Drugs and Biologicals.
1713	•	Pneumoccal Pneumonia, Influenza Virus, and Hepatitis B Vaccines.
1714	•	Laboratory Test for Hemodialysis, Intermittent Peritoneal Dialysis, Continuous Cycling Peritoneal Dialysis, and Hemofiltration.
		Carriers Manual Part 3—Claims Process (HCFA Pub. 14–3) (Superintendent of Documents No. HE 22.8/7)
1564	•	Coverage of Supplies and Accessories. New Supplier Effective Billing Date.
1565	•	Assignment of a Partially Paid Bill.
1566	•	Method for Computing Fee Schedule Amount. Bundled Services/Supplies. Supervising Physicians in Teaching Settings. Anesthesia Claims Modifiers. Services of Portable X-ray Suppliers. Special Situations. Interpretation of Diagnostic Tests.
1567	•	Completing Quarterly Report on Provider Enrollment.
1568	•	Screening Mammography Examinations. Identifying a Screening Mammography Claim. Adjudicating the Claim.
1569	•	Bill Review of Laboratory Services.
1570	•	Self-Administered Drug and Biologicals.
1571	•	Paper Remittance Notice.
1572	•	Bill Review of Laboratory Services.
		Program Memorandum Intermediaries (HCFA Pub. 60A) (Superintendent of Documents No. HE 22.8/6–5)
A–97–4	•	Two Month Extension for Implementation of Filing Electronically Prepared Cost Reports for Skilled Nursing Facilities and Home Health Agencies.
		Program Memorandum Intermediaries/Carriers (HCFA Pub. 60A/B) (Superintendent of Documents No. HE 22.8/6–5)
AB–97–6	•	Current Status of Medicare Program Memorandums And Letters Issued Before Calendar Year 1997.
AB–97–7	•	Revision on Program Memorandum Transmittal No. AB–97–5, New Panels Approved by CPT.
AB–97–8	•	Hematocrit Levels for Erythropoietin.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April 1997 through June 1997]

Trans. No.		Manual/Subject/Publication No.
AB–97–9	•	New Code for HIV–1 Viral Load Testing.
		Program Memorandum Medicaid State Agencies (HCFA Pub. 17) (Superintendent of Documents No. HE 22.8/6–5)
97–1	•	Current Status of Medicaid Program Memorandums and Action Transmittals Issues Before Calendar Year 1997.
		Program Memorandum Regional Offices (HCFA Pub. 54) (Superintendent of Documents No. HE 22.28/5:90–1)
97–1	•	Civil Money Penalty Collection Procedures.
		State Operations Manual Provider Certification (HCFA Pub. 7) (Superintendent of Documents No. HE 22.8/12)
281	•	Interpretive Guidelines—Home Health Agencies.
282	•	Model Letter to Provider. Model Letter Notifying Provider of Results of Revisit. Model Letter to Provider (Imposition of Remedies). (Immediate Jeopardy Exists). Informal Dispute Resolution.
		Regional Office Manual Standards and Certification (HCFA Pub. 23–4) (Superintendent of Documents No. HE 22.8/8–3)
63	•	OPO Designation Procedures in Service Areas With Competing Applications.
		Hospital Manual (HCFA Pub. 10) (Superintendent of Documents No. HE 22.8/2)
712	•	Self-Administered Drugs and Biologicals. Oral Cancer Drugs. Self-Administered Antiemetic Drugs. Self-Administered Drug Administered In An Emergency Situation. Billing for Hospital Outpatient Partial Hospitalization Services. Completion of Form HCFA–1450 For Inpatient And/Or Outpatient Billing.
713	•	Review of Hospital Admissions of Patients Who Have Elected Hospice Care.
714	•	Outpatient Therapeutic Services.
715	•	Laboratory Test for Hemodialysis, Intermittent Peritoneal Dialysis, and Continuous Cycling Peritoneal Dialysis Included in Composite Rate.
		Rural Health Clinic Manual and Federally Qualified Health Centers Manual (HCFA Pub. 27) (Superintendent of Documents No. HE 22.8/19:985)
25	•	Rural Health Clinics. Federally Qualified Health Centers.
26	•	Billing of Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines By Rural Health Clinics and Federally Qualified Health Centers.
		Renal Dialysis Facility Manual (Non-Hospital Operated) (HCFA Pub. 29) (Superintendent of Documents No. HE 22.8/13)
78	•	Pneumoccal Pneumonia, Influenza Virus, and Hepatitis B Vaccines.
79	•	Completion of Form HCFA–1450 by Independent Facilities for Home Dialysis Items and Services Billed Under the Composite Rate (Method I).
80	•	Epoetin.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April 1997 through June 1997]

Trans. No.		Manual/Subject/Publication No.
81	•	Laboratory Test for Hemodialysis, Intermittent Peritoneal Dialysis, and Continuous Cycling Peritoneal Dialysis.
		Coverage Issues Manual (HCFA Pub. 6) (Superintendent of Documents No. HE 22.8/14)
94	•	Artificial Hearts and Related Devices.
95	•	Electrostimulation in the Treatment of Wounds. Intrapulmonary Percussive Ventilator.
96	•	Breast Reconstruction Following Mastectomy Obsolete or Unreliable Diagnostic Test.
97	•	Urinary Drainage Bags.
98	•	–Electrostimulation in the Treatment of Wounds Intrapulmonary Percussive Ventilator.
99	•	Laser Procedures. Refractive Keratoplasty. Magnetic Resonance Angiography.
100	•	Electrostimulation in the Treatment of Wounds. Intrapulmonary Percussive Ventilator.
101	•	Laboratory Test-CRD Patients.
		Provider Reimbursement Manual Part 1—(HCFA Pub.15–1) (Superintendent of Documents No. HE 22.8/4)
399	•	Regional Medicare Swing-Bed SNF Rates. Changing Cost Finding Methods. Changing Bases for Allocating Costs Centers or Order in Which Cost Centers Are Allocated.
		Provider Reimbursement Manual Part 1—(HCFA Pub.15–1–27) (Superintendent of Documents No. HE 22.8/4)
27	•	Separately Billable ESRD Laboratory Services.
28	•	Epoetin.
		Provider Reimbursement Manual Part II—Provider Cost Reporting Forms and Instructions (HCFA Pub. 15–II–AF) (Superintendent of Documents No. HE 22.8/4)
5	•	Electronic Reporting Specifications for Form HCFA 1728–94.
		Medicare Provider Reimbursement Manual Part II—Provider Cost Reporting Forms and Instructions (HCFA Pub. 15–11–AI) (Superintendent of Documents No. HE 22. 8/4)
2	•	Cost Center Coding. Electronic Reporting Specifications for Form HCFA 2540–96.
		Medicare/Medicaid Sanction—Reinstatement Report (HCFA Pub. 69)
97–5	•	Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—March 1997.
97–6	•	Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—April 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
04/08/97	16894–16976	144, 146, 148 ...	BPD–890–IFC	Interim Rules for Health Insurance Portability for Group Health Plans.	07/07/97	06/07/97
04/08/97	16985–17004	148	BPD–882–IFC	Individual Market Health Insurance Reform: Portability From Group to Individual Coverage; Federal Rules for Access in the Individual Market; State Alternative Mechanisms to Federal Rules.	07/07/97	04/08/97

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
04/08/97	17004		BPD–882–CN BPD–890–CN	Interim Rules for Health Insurance Portability for Group Health Plans and Individual Market Health Insurance Reform: Portability from Group to Individual Coverage; and Federal Rules for Access in the Individual Market; State Alternative Mechanisms to Federal Rules; Correction.		04/08/97
04/17/97	18776–18777		ORD–098–N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: February 1997.		
04/21/97	19326–19328		BPD–894–NC	Medicare and Medicaid Programs; Announcement of Additional Applications From Hospitals Requesting Waivers for Organ Procurement Service Area.	06/20/97	
04/21/97	19328–19337		BPO–141–N	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—Third Quarter 1996.		
04/28/97	22995	413	BPD–808–P	Medicare and Medicaid Programs; Salary Equivalency Guidelines for Physical Therapy, Respiratory Therapy, Speech Language Pathology, and Occupational Therapy Services; Correction.		
04/29/97	23251–23253		HSQ–232–N	Medicare Program; Initiative Involving Facilities That Furnish Hemodialysis Treatments.		10/28/96
04/29/97	23140	433	MB–112–F	Medicaid Program; Third Party Liability (TPL) Cost-Effectiveness Waivers; Correcting Amendment.		09/08/95
04/30/97	23368–23376	417	OMC–025–FC	Medicare Program; Establishment of an Expedited Review Process for Medicare Beneficiaries Enrolled in Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans.	06/30/97	06/30/97
05/05/97	24483–24491		BPD–816–N	Medicare Program; Update of the Reasonable Compensation Equivalent Limits for Services Furnished by Physicians.		05/05/97
05/12/97	25844–25855	405, 417, 473	BPD–453–FC	Medicare Programs; Medicare Appeals of Individual Claims.	07/11/97	07/11/97
05/12/97	25855–25858	493	HSQ–237–FC	Medicare, Medicaid and CLIA Programs; Clinical Laboratory Requirements— Extension of Certain Effective Dates for Clinical Laboratory Requirements Under CLIA.	07/11/97	05/12/97
05/12/97	25957		ORD–099–N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: March 1997.		
05/12/97	25957–25964		BPO–148–N	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances; Fourth Quarter 1996.		
05/14/97	26545–26550		MB–103–NC	Medicaid Program; Allocation of Enhanced Federal Matching Funds for Increased Administrative Costs Resulting From Welfare Reform.	06/13/97	05/14/97
05/19/97	27262–27265		HSQ–242–N	Approval of the Commission on Office Laboratory Accreditation for Immunohematology.		05/19/97–11/1/97
05/19/97	27210	413	BPD–788-CN	Medicare Program; Electronic Cost Reporting for Skilled Nursing Facilities and Home Health Agencies; Correction.		05/19/97
05/30/97	29355–29356		OPL–015–N	Medicare Program; June 16, 1997, Meeting of the Practicing Physicians Advisory Council.		

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
06/02/97	29902–30037	412, 413, 489	BPD–878–P	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1998 Rates.	08/01/97	
06/04/97	30604–30605		ORD–100–N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: April 1997.		
06/10/97	31669–31670	144, 146	BPD–890–CN	Interim Rules for Health Insurance Portability for Group Health Plans; Correction.		
06/17/97	32715–32733	410, 424	BPD–813–P	Medicare Program; Ambulance Services.	08/18/97	
06/18/97	33158–33305	400, 405, 410, 414.	BPD–884–P	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.	08/18/97	
06/19/97	33459		MB–103–NC	Medicaid Program; Allocation of Enhanced Federal Matching Funds for Increased Administrative Costs Resulting From Welfare Reform; Correction.		

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.

G960260 A1
G970007 A2
G970015 A2
G970018 A2
G970022 A2
G970068 A2
G970069 A2
G970076 A2
G970093 A2
G970121 A2

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

G960033 B4
G960209 B4
G960222 B2
G960233 B4
G960240 B5
G960261 B2
G970033 B4
G970043 B4
G970049 B3
G970060 B3
G970062 B1
G970063 B4
G970064 B2
G970065 B3
G970066 B4
G970067 B2
G970072 B2
G970077 B1
G970079 B2
G970080 B4
G970083 B4
G970085 B2
G970090 B4
G970091 B3
G970092 B2
G970098 B4
G970104 B2
G970105 B2
G970108 B1
G970109 B3
G970113 B4
G970115 B4
G970117 B4

[FR Doc. 97–30568 Filed 11–20–97; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4263–N–56]

Submission for OMB Review: Comment Request

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due date: December 22, 1997.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name and/or OMB approval number and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Kay F. Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) the title of the