

1995, and plans to conduct further quality assurance oversight of the IND process. The review procedure of the committee is designed to afford an opportunity for a sponsor who does not wish to seek formal reconsideration of a pending clinical hold to have that clinical hold considered

"anonymously." The committee consists of senior managers of CBER, a senior official from the Center for Drug Evaluation and Research, and the FDA Chief Mediator and Ombudsman.

Clinical holds to be reviewed will be chosen randomly. In addition, the committee will review some of the clinical holds proposed for review by biological product sponsors. In general, a biological product sponsor should consider requesting review when it disagrees with FDA's scientific or procedural basis for the decision.

Requests for committee review of a clinical hold should be submitted to the FDA Chief Mediator and Ombudsman, who is responsible for selecting clinical holds for review. The committee and CBER staff, with the exception of the FDA Chief Mediator and Ombudsman, are never advised, either in the review process or thereafter, which of the clinical holds were randomly chosen and which were submitted by sponsors. The committee will evaluate the selected clinical holds for scientific content and consistency with FDA regulations and CBER policy.

The meetings of the oversight committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding confidential commercial information, 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 meeting, at a cost of 10 cents per page. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

For each meeting, FDA invites biological product companies to submit to the FDA Chief Mediator and Ombudsman the name and IND number of any investigational biological product trial that was placed on clinical hold during the past 12 months that they want the committee to review. Submissions should be made by January 5, 1999, for the February meeting; by March 30, 1999, for the May meeting; by June 29, 1999, for the August meeting; and by September 28, 1999, for the November meeting to Amanda Bryce

Norton, FDA Chief Mediator and Ombudsman (address above).

Dated: December 1, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-32643 Filed 12-8-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-9002-N]

RIN 0938-A113

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—Second Quarter, 1998

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 1998 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:

Bridgett 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).

Kristy Nishimoto, (410) 786-8517 (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.

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. 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). 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 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. (Updated titles of the Social Security Laws are available on the Internet at http://www.ssa.gov/OP_Home/ssact/comp-toc.htm.) 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 Hospital Manual,

(HCFA Pub. 10) transmittal entitled "Claims Processing Timeliness Requirements," use the Superintendent of Documents No. HE 22.8/2 and the HCFA transmittal number 729.

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, S2-26-13, 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 and 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 Kristy Nishimoto, Office of Communications and Operations Support, Division of Regulations and Issuances, Health Care Financing Administration, C5-13-07, 7500 Security Boulevard, Baltimore, MD 21244-1850, Telephone (410) 786-8517.

(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: November 24, 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.

November 3, 1997 (62 FR 59358)

November 21, 1997 (62 FR 62325)

June 4, 1998 (63 FR 30499)

August 11, 1998 (63 FR 42857)

September 16, 1998 (63 CFR 49598)

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 1998 through June 1998]

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)

- 411 • 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)

- 1737 • This transmittal number will not be used.
- 1738 • Provider Electronic Billing File and Records Formats.
Alphabetic Listings of Data Elements.
- 1739 • Electronic Media Claims.
ANSI ASC X12 837 Health Care Claim Transaction Set.
Electronic UB-92 Change Request Procedures.
Electronic UB-92 Change Request Forms.
Millennium Ready Free Billing Software.
Millennium Readiness.
Paper Bills
- 1740 • Provider Access to Limited Eligibility Data.
Eligibility Data Available.
- 1741 • Electronic Data Interchange Enrollment Form.
- 1742 • Payment for Blood Clotting Factor.
Administered to Hemophilia Inpatients.
- 1743 • Provider Electronic Billing File and Record Formats.
- 1744 • Claims Processing Timeliness.
- 1745 • Corrective Actions.
Withholding Payment for Payable Claims.
Cases Referred to and Accepted by Office of Investigations.
Law Enforcement Agrees There is Fraud, but Declines the Case Because it Does Not Meet Criteria.
Overpayment Recoupment in Potential Fraud Cases.
Model Suspension Letter.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April 1998 through June 1998]

Trans. No.	Manual/subject/publication No.
1746	• Bill Review for Partial Hospitalization Services Provided in Community Mental Health Centers.
1747	• Review of Form HCFA-1450 for Inpatient and Outpatient Bills. • Provider Electronic Billing File and Record Formats. • Alphabetic Listings of Data Elements.
Carriers Manual Part 2—Program Administration (HCFA Pub. 14-2) (Superintendent of Documents No. HE 22.8/7-3)	
137	• Functional Standards for Claims Processing Operations.
138	• Functional Standards for Claims Processing Operations.
Carriers Manual Part 3—Claims Process (HCFA Pub. 14-3) (Superintendent of Documents No. HE 22.8/7)	
1597	• Requirements for Processing Electronic Media Claims. • Establishing a System to Process Electronic Media Claims. • Standard Electronic Formats. • 835 and National Standard Format Health Care Claim Payment/Advice Transactions. • Medicare Standard PC-Print-B Software. • National Standard Format Maintenance Procedures. • Paper Remittance Notice.
1598	• Jurisdiction of Requests for Payment. • Area Carrier—Physician's Services.
1599	• Contractor Millennium Contingency Plan. • Millennium Ready Free Billing Software.
1600	• Electronic Data Interchange Enrollment Form.
1601	• HCPCS Codes.
1602	• Medicare Physician Fee Schedule Database 1998 File Layout. • Medicare Physician Fee Schedule Database Status Indicators.
1603	• Simplified Roster Bills.
1604	• Postpayment Review of Claims Denial of Payment. • Suspension of Payment. • Overpayment Recoupment. • Referral to State Agencies or Other Organizations. • Model Suspension of Payment Letters.
1605	• Who May Be Paid Benefits. • Benefit Checks. • Additional Benefits Payable Because Prior Determination Revised. • Death of Enrollee or Assignee Before Claim is Settled.
1606	• Otologic Evaluations. • Allergy Testing and Immunotherapy. • Evaluation/Treatment of Speech Language, Voice, Communication, and/or Auditory Processing, Including Evaluating Aural Rehabilitation Status of Providing Aural Rehabilitation Services. • Physical Therapy/Occupational Therapy Provided by Physicians and Physician Employees. • Method for Computing Fee Schedule Amount. • Physicians' Services Furnished on Day of Dialysis. • Inpatient Dialysis on Same Date As Evaluation and Management. • Consultation Versus Visit. • 1998 Geographic Practice Cost Indices by Medicare Carrier and Locality.
1607	• This transmittal corrects pagination error in Transmittal 1597 dated April 1998.
1608	• Integumentary System.

Program Memorandum
Intermediaries
(HCFA Pub. 60A)
(Superintendent of Documents No. HE 22.8/6-5)

A-98-10	• Year 2000 Update Pages for the Accredited Standards Committee X12 837 Version 3051 Implementations 3A.01 and 1A.C1 Institutional Claim/Coordination of Benefits.
A-98-11	• Extension of Due Date for Skilled Nursing Facility Providers Utilizing the HCFA Free Software to File Form HCFA-2540-96 Cost Reports.
A-98-12	• Interim Rate Changes Due to the Elimination of the Formula Driven Overpayment.
A-98-13	• Review of Home Health Agency Related Businesses.
A-98-14	• Billing Requirements for Claims With Dates of Service on or After April 1, 1998, for Oral Anti-Nausea Drugs as Full Therapeutic Replacements for Intravenous Dosage Forms as Part of a Cancer Chemotherapeutic Regimen.
A-98-15	• Policy Clarification: Provider-Based Designation.
A-98-16	• Coverage and Claims Processing for Prospective Payment for Skilled Nursing Facilities—The Balance Budget Act of 1997.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued
[April 1998 through June 1998]

Trans. No.	Manual/subject/publication No.
A-98-17	• Clarification of Provider Cost Report Filing Requirements.
A-98-18	• Revised Medicare Bad Debt Treatment for Qualified Medicare Beneficiaries.
A-98-19	• Managed Care Electronic Data Interchange Enrollment Form.
A-98-20	• Claims Processing For Prospective Payment for Skilled Nursing Facilities—The Balanced Budget Act of 1997.

**Program Memorandum
Carriers
(HCFA Pub. 60B)
(Superintendent of Documents No. HE 22.8/6-5)**

B-98-12	• Private Contracts Between Beneficiaries and Physicians/Practitioners.
B-98-13	• Temporary National HCPCS Code.
B-98-14	• Year 2000 Update Changes to the Part B ASC X12N 270/271 Version 3051 Implementation for the Health Care Eligibility Benefit Inquiry and Response.
B-98-15	• Billing for the Technical Component of a Laboratory Test.
B-98-16	• Screening Pap Smear and Pelvic Examinations—The Balanced Budget Act of 1997.
B-98-17	• Durable Medical Equipment Regional Carrier Instructions to Implement Balanced Budget Act of 1997 Provisions, § 4105, to Provide Expanded Coverage of Blood Glucose Monitors and Testing Strips for all Diabetics—Implement July 1, 1998.
B-98-18	• Durable Medical Equipment Regional Carrier Instructions for Denying Claims and Recovering Overpayments for Prescription Drugs Billed and/or Paid to Suppliers Not Licensed to Dispense Prescription Drugs.
B-98-19	• Change to Health Insurance Claim Form HCFA-1500 Instructions for Processing Physician Claims in Global Payment Systems.
B-98-20	• Changes to the 1998 Medicare Physician Fee Schedule Database.
B-98-21	• Notification of Updates to the X12 835 3051.4B and National Standard Format Version 2.01.
B-98-22	• Change in Screening Mammography Coverage.
B-98-23	• Health Professional Shortage Area Bonus Payment Clarification.
B-98-24	• Carrier Updating of the International Classification of Diseases, Ninth Revision, Clinical Modification.

**Program Memorandum
Intermediaries/Carriers
(HCFA Pub. 60A/B)
(Superintendent of Documents No. HE 22.8/6-5)**

AB-98-11	• Contractor Codes for Processing Centers of Excellence Demonstration Claims.
AB-98-12	• New Waived Tests.
AB-98-13	• Payments for Physicians Services Affected by Global Payment Demonstrations.
AB-98-14	• Claims Processing Instructions for the National Institutes of Health National Emphysema Treatment Trial.
AB-98-15	• Increased Medicare Payment and Billing Requirements for Nurse Practitioners, Physician Assistants, and Clinical Nurse Specialists— Balanced Budget Act of 1997.
AB-98-16	• Medicare Secondary Payer Denial Indicator and the Source Code Changes.
AB-98-17	• Provider Notification of Millennium Instructions for Claims-Related Standards.
AB-98-18	• Consolidated Billing for Skilled Nursing Facilities.
AB-98-19	• Implementation of Court Order in National Medical Care v. Shalala.
AB-98-20	• This transmittal number will not be used.
AB-98-21	• This transmittal number will not be used.
AB-98-22	• Temporary Codes Established for Screening Pap Smears by Automated Thin Layer Preparation Method.
AB-98-23	• HCFA-1522, Monthly Contractor Financial Report, Reconciliation.
AB-98-24	• Provider Overpayment Recovery/Physicians Supplier Overpayment Recovery Systems Overpayments Transferred to the Debt Collection Center for Cross Servicing.
AB-98-25	• New Waived Tests.
AB-98-26	• Current Status of Medicare Program Memoranda and Letters Issued Before Calendar Year 1998.
AB-98-27	• Current Status of Medicare Program Memoranda and Letters Issued Before Calendar Year 1998.
AB-98-28	• Grace Period for Deleted Automated Multi-Channel Tests—Clarification of Program Memorandum AB-97-17.
AB-98-29	• Notice of New Interest Rate for Medicare Overpayments and Underpayments.
AB-98-30	• Suppression of Notice of Utilization, Explanation of Medicare Benefits, and Medicare Summary Notices for Certain Claim Types—Implementation February 1998.
AB-98-31	• Clarification of Program Memorandum A-97-8 (July 1997) and Program Memorandum B-98-4 (January 1998)—Medicare Summary Notice Instructions.

**State Operations Manual
Provider Certification
(HCFA Pub. 7)
(Superintendent of Documents No. HE 22.8/12)**

2	• Background. Interpretative Guidelines and Investigative Procedures for Responsibilities of Medicare Participating Hospitals in Emergency Cases.
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ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April 1998 through June 1998]

Trans. No.	Manual/subject/publication No.
Program Memorandum Medicaid State Agencies (HCFA Pub. 17) (Superintendent of Documents No. HE 22.8/6.5)	
98-1	• Title XIX of the Social Security Act, Payment of Medicare Part B Premiums.
98-2	• Current Status of Medicaid Program Memoranda and Action Transmittals Issued Before Calendar Year 1988
Peer Review Organization Manual (HCFA Pub. 19) (Superintendent of Documents No. HE 22.8/8-15)	
65	• Interaction with Beneficiary Groups. Evaluation.
Hospital Manual (HCFA Pub. 10) (Superintendent of Documents No. HE 22.8/2)	
728	• Payment for Blood Clotting Factor Administered to Hemophilia Inpatients.
729	• Claims Processing Timeliness Requirements.
Skilled Nursing Facility Manual (HCFA Pub. 12) (Superintendent of Documents No. HE 22.8/3)	
353	• Billing for Mammography Screening.
End Stage Renal Disease Network Organizations Manual (HCFA Pub. 81) (Superintendent of Documents No. HE 22.9/4)	
6	• Authority. Network's Role Prior to Initiating Sanction Recommendation. Written Documentation Requirements for Sanction Recommendation. Forwarding Sanction Recommendation to Appropriate Regional Office. Project Officer's Role in Sanction Procedures. Regional Office Role in Notice and Appeal Rights. Duration and Removal of Alternative Sanction. Quality of Care Referrals.
Outpatient Physical Therapy, Comprehensive Outpatient Rehabilitation Facility, and Community Mental Health Center Manual (HCFA Pub. 9) (Superintendent of Documents No. HE 22.8/9)	
1	• Outpatient Physical Therapy, Comprehensive Outpatient Rehabilitation Facility, and Community Mental Health Center Manual—First Publication.
2	• Billing Instructions for Partial Hospitalization Services Provided in Community Mental Health Centers. Pneumococcal Pneumonia Influenza Virus and Hepatitis B Vaccines.
Coverage Issues Manual (HCFA Pub. 6) (Superintendent of Documents No. HE 22.8/4)	
104	• Cochlear Implantation.
105	• Cytogenetic Studies.
Provider Reimbursement Manual—Part 1 (HCFA pub. 15-1) (Superintendent of Documents No. HE 22.8/4)	
403	• Principle. Prevailing Salary. Standard Travel Allowance. Optional Travel Allowance for Home Health Agencies and Other Providers. Guideline Application. Application of Travel Allowance. Identification of Services Furnished By Outside Suppliers.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April 1998 through June 1998]

Trans. No.	Manual/subject/publication No.
404	Physical Therapy, Occupational Therapy, and Speech-Language Pathology Assistants and Aides, and Respiratory Therapy Aides and Trainees. Exception Because of Binding Contract. Exception Because of Unique Circumstances or Special Labor Market Conditions. Provider Recordkeeping and Reporting Requirements. • Cost Not Related to Patient Care. Unallowable Costs Not Related to Patient Care.
Provider Reimbursement Manual—Part 2 Provider Cost Reporting Forms and Instructions Chapter 37 (HCFA Pub. 15–2–AK) (Superintendent of Documents No. HE 22.8/4)	
1	• This transmittal introduces Chapter 37, Skilled Nursing Facility Cost Report Form.
State Medicaid Manual—Part 3 Eligibility (HCFA Pub. 45–3) (Superintendent of Documents No. HE 22.8/10)	
70	• Coverage of Qualifying Individuals for Medicare Part B Premiums.
71	• Medicaid Eligibility for Disabled Children Who Lose SSI Payment.
72	• Continuous Eligibility.
73	• Buy-In to Medicaid for the Working Disabled.
State Medicaid Manual—Part 4 Services (HCFA Pub. 45–4) (Superintendent of Documents No. HE 22.8/10)	
71	• Home and Community-Based Services—Basis, Scope, and Purpose. Definition of Services. Home and Community-Based Services—Model Waiver Request. Home and Community-Based Services—Amendments.
Program Memorandum Regional Office—General (HCFA Pub. 51) (Superintendent of Documents No. HE 22.28/5:90–1)	
98–3	• Home Health Agency Surety Bond Requirements.
Program Memorandum Regional Offices—Standards and Certification (HCFA Pub. 54) (Superintendent of Documents No. HE 22.28/5:90–1)	
98–1	• Civil Money Penalty Collection Procedures.
Medicare/Medicaid Sanction—Reinstatement Report (HCFA Pub. 69)	
98–4	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—March 1998.
97–5	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—April 1998.
97–6	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—May 1998.

ADDENDUM IV.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER

Publication date	FR vol. 63 page	CFR part(s)	File code*	Regulation title	End of comment period	Effective date
04/09/98	17429–17431	HCFA–2246–N	Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1998 Continuance of Approval as an Accrediting Organization; the Joint Commission on Accreditation of Healthcare Organizations, the American Association of Blood Banks, and the American Osteopathic Association.	06/30/99 07/20/01
04/14/98	18124–18135	422	HCFA–1027–IFC	Medicare Program; Definition of Provider-Sponsored Organization and Related Requirements.	06/15/98	05/14/98
04/22/98	19926	HCFA–1040–N	Medicare Program; May 7, 1998, Meeting of the Competitive Pricing Advisory Committee.	04/22/98
04/23/98	20110–20131	410, 417, 424, 482	HCFA–3706–F	Medicare Program; Scope of Medicare Benefits and Application of the Outpatient Mental Health Treatment Limitation to Clinical Psychologist and Clinical Social Worker Services.	06/22/98
04/30/98	23790–23791	HCFA–2008–PN	Medicare and Medicaid Programs; Recognition of the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. for Ambulatory Surgical Centers Program.	06/01/98	04/30/98
05/07/98	25320–25357	142	HCFA–0045–P	National Standard Health Care Provider Identifier.	07/06/98	05/07/98
05/07/98	25272–25320	142	HCFA–0149–P	Health Insurance Reform: Standards for Electronic Transactions.	07/06/98	05/07/98
05/07/98	25360–25379	422	HCFA–1011–IFC	Medicare Program; Waiver Requirements and Solvency Standards for Provider-Sponsored Organizations.	07/06/98	06/08/98
05/08/98	25576–25715	405, 412, 413	HCFA–1003–P	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1999 Rates.	07/07/98	05/08/98
05/12/98	26318–26360	410, 412, 413, 415, 485.	HCFA–1878–F	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1998 Rates.	06/11/98
05/12/98	26252–26316	409, 410, 411, 413, 424, 483, 489.	HCFA–1913–IFC	Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities.	07/13/98	07/01/98
05/13/98	26565–26566	405, 412, 413	HCFA–1003–CN	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1999 Rates; Corrections.	05/13/98
05/14/98	26722–26738	493	HCFA–2239–F	CLIA Program; Simplifying CLIA Regulations Relating to Accreditation, Exemption of Laboratories Under a State Licensure Program, Proficiency Testing, and Inspection.	06/15/98
05/14/98	26811–26812	HCFA–3888–NC	Medicare and Medicaid Programs; Request for Public Comments on the Quality Improvement System for Managed Care.	05/26/98	05/14/98
05/18/98	27251–27253	413	HCFA–1876–P	Medicare Program; Revision to Accrual Basis of Accounting Policy.	07/17/98	05/18/98
06/01/98	29648–2966	441, 489	HCFA–1152–1–F	Medicare and Medicaid Programs; Surety Bond Requirements for Home Health Agencies.	07/01/98

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

Publication date	FR vol. 63 page	CFR part(s)	File code*	Regulation title	End of comment period	Effective date
06/01/98	29743	HCFA-3782-NC	Medicare Program; Withdrawal of Proposed Notice and Request for Assessment on the Salitron System for the Treatment of Xerostomia (Dry Mouth) Secondary to Sjorgren's Syndrome.	07/31/98	06/01/98
06/03/98	30166-30173	HCFA-3250-NOI	Medicare Program; Coverage and Administrative Policies for Clinical Diagnostic Laboratory Tests; Intent to Form Negotiated Rule-making Committee.	07/06/98	06/03/98
06/04/98	30499-30506	HCFA-9152-N	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—Third Quarter 1997.	06/04/98
06/08/98	31123-31129	420	HCFA-6144-FC	Medicare Program; Incentive Programs—Fraud and Abuse.	08/07/98	07/08/98
06/09/98	31513-31514	HCFA-1044-N	Medicare Program; June 22, 1998, Meeting of the Practicing Physicians Advisory Council.	06/09/98
06/11/98	32015-32018	HCFA-1104-N	Medicare Program; Notice for the Solicitation for Proposals for a Case Management Demonstration Project Focused on Congestive Heart Failure or Diabetes Mellitus.	07/13/98	06/11/98
06/11/98	32019	HCFA-1043-N	Medicare Program; June 24 and 25, 1998, Meeting of the Competitive Pricing Advisory Committee.	06/11/98
06/12/98	32290-32521	416, 488	HCFA-1885-P	Medicare Program; Update of Ratesetting Methodology, Payment Rates, Payment Policies, and the List of Covered Surgical Procedures for Ambulatory Surgical Centers Effective October 1, 1998.	08/11/98	06/12/98
06/15/98	32669	493	HCFA-2239-F	CLIA Program; Simplifying CLIA Regulations Relating to Accreditation, Exemption of Laboratories Under a State Licensure Program, Proficiency Testing, and Inspection; Correction.	06/15/98
06/16/98	32784-32798	142	HCFA-0047-P	Health Insurance Reform; National Standard Employer Identifier.	08/17/98	06/16/98
06/16/98	32889-32890	HCFA-2028-N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: February 1998 and March 1998.	06/16/98
06/22/98	33856-33875	482	HCFA-3005-F	Medicare and Medicaid Programs; Hospital Conditions of Participation; Identification of Potential Organ, Tissue, and Eye Donors and Transplant Hospitals' Provision of Transplant-Related Data.	08/21/98
06/22/98	33882-33890	410, 414	HCFA-1906-P	Medicare Program; Payment for Teleconsultations in Rural Health Professional Shortage Areas.	08/21/98	06/22/98
06/24/98	34320-34328	410	HCFA-3004-IFC	Medicare Program; Medicare Coverage of and Payment for Bone Mass Measurements.	08/24/98	07/01/98
06/26/98	34968-35116	400, 403, 410, 411, 417, 422.	HCFA-1030-IFC	Medicare Program; Establishment of the Medicare+Choice Program.	09/24/98	07/27/98

Addendum V—Categorization of Food and Drug Administration-Allowed 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.

- G970312 A1
- G980008 A2
- G980046 A2
- G980059 A2
- G980077 A1
- G980093 A1
- G980094 A1
- G980117 A2

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

- G970168 B1
- G970215 B3
- G970249 B2
- G970275 B2
- G970287 B1
- G970303 B4
- G980013 B3
- G980044 B4
- G980048 B4
- G980049 B4
- G980050 B4
- G980052 B4
- G980053 B4
- G980054 B2
- G980055 B3
- G980057 B2
- G980058 B2
- G980061 B2
- G980062 B3

- G980065 B4
- G980066 B4
- G980067 B2
- G980068 B2
- G980069 B4
- G980070 B4
- G980071 B3
- G989072 B1
- G980073 B1
- G980075 B3
- G980076 B1
- G980079 B4
- G980082 B4
- G980086 B1
- G980087 B4
- G980089 B2
- G980090 B4
- G980092 B2
- G980096 B4
- G980097 B1
- G980098 B3
- G980099 B4
- G980100 B4
- G980101 B2
- G980102 B2
- G980103 B4
- G980106 B5
- G980114 B4
- G980116 B3
- G980120 B4
- G980121 B2
- G980122 B1
- G980127 B1
- G980137 B3

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Announcement of Office of Management and Budget (OMB) Control Numbers for Agency Information Collections Approved Under the Paperwork Reduction Act of 1995

AGENCY: Health Care Financing Administration.

This notice announces and displays OMB control numbers for Health Care Financing Administration (HCFA) information collections that have been approved by OMB.

Under OMB's regulations implementing the Paperwork Reduction Act (PRA), 44 U.S.C. § 3501, each agency that proposes to collect information must submit its proposal for OMB review and approval in accordance with 5 CFR part 1320. Once OMB has approved an agency's proposed collection of information and issues a control number, the agency must display the control number.

OMB regulations provide for alternative methods of displaying OMB control numbers. In the case of collections of information published in regulations, display is to be "provided in a manner that is reasonably calculated to inform the public." To meet this requirement an agency may display such information in the **Federal Register** by publishing such information in the preamble or the regulatory text, or in a technical amendment to the regulation, or in a separate notice announcing OMB approval of the collection of information.

To comply with this requirement HCFA has chosen to publish this notice announcing OMB approval of the collections of information published in regulations. As stated above, this notice announces and displays the assigned OMB control numbers for HCFA's information collections that have been approved by OMB.

42 CFR	OMB control Nos.
403.210	0938-0640.
405.262	0938-0267.
405.376	0938-0270.
405.427	0938-0155.
405.465, 405.481	0938-0301.
405.711	0938-0045.
405.807	0938-0033.
405.821	0938-0034.
405.2100-2171	0938-0386.
405.2110, 405.2112	0938-0657, & 0658.
405.2133	0938-0046, 0447, & 0448.
405.2135-2171	0938-0360.
406.7	0938-0251.
406.13	0938-0080.
406.15	0938-0501.
406.28	0938-0025.
407.10, 407.11	0938-0245.
407.18	0938-0679.
407.27	0938-0025.