trials bearing on the same question. This most commonly involves the statistical combination of summary statistics from the various trials, but the term is sometimes also used to refer to the combination of the raw data.

Multicenter trial—A clinical trial conducted according to a single protocol but at more than one site and, therefore, carried out by more than one investigator.

Noninferiority trial—A trial with the primary objective of showing that the response to the investigational product is not clinically inferior to a comparative agent (active or placebo control).

Preferred and included terms—In a hierarchical medical dictionary, for example, the World Health Organization's Adverse Reaction Terminology (WHO-Art), the included term is the lowest level of dictionary term to which the investigator description is coded. The preferred term is the level of grouping of included terms typically used in reporting frequency of occurrence. For example, the investigator text ''Pain in the left arm'' might be coded to the included term ''Joint pain,'' which is reported at the preferred term level as ''Arthralgia.''

Per protocol set (valid cases, efficacy sample, evaluable subjects sample)—The set of data generated by the subset of subjects who complied with the protocol sufficiently to ensure that these data would be likely to exhibit the effects of treatment according to the underlying scientific model. Compliance covers such considerations as exposure to treatment, availability of measurements, and absence of major protocol violations.

Safety and tolerability—The safety of a medical product concerns the medical risk to the subject, usually assessed in a clinical trial by laboratory tests (including clinical chemistry and hematology), vital signs, clinical adverse events (diseases, signs and symptoms), and other special safety tests (e.g., electrocardiograms, ophthalmology). The tolerability of the medical product represents the degree to which overt adverse effects can be tolerated by the subject.

Statistical analysis plan—A statistical analysis plan is a document that contains a more technical and detailed elaboration of the principal features of the analysis described in the protocol, and includes detailed procedures for executing the statistical analysis of the primary and secondary variables and other data.

Superiority trial—A trial with the primary objective of showing that the response to the investigational product is superior to a comparative agent (active or placebo control).

Surrogate variable—A variable that provides an indirect measurement of effect in situations where direct measurement of clinical effect is not feasible or practical.

Treatment effect—An effect attributed to a treatment in a clinical trial. In most clinical trials, the treatment effect of interest is a comparison (or contrast) of two or more treatments.

Treatment emergent—An event that emerges during treatment, having been absent pretreatment, or worsens relative to the pretreatment state.

Trial statistician—A statistician who has a combination of education/training and experience sufficient to implement the principles in this guidance and who is responsible for the statistical aspects of the trial.

Dated: September 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–24754 Filed 9–15–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–9879–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—First 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 January, February, and March 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: 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);

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. 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 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 ''Treatment Codes for Home Health Services,'' use the

Superintendent of Documents No. HE 22.8/5 and the HCFA transmittal number 286.

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 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: September 8, 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.

May 12, 1997 (62 FR 25957)
November 3, 1997 (62 FR 59358)
November 21, 1997 (62 FR 62325)
June 4, 1998 (63 FR 30499)
August 11, 1998 (63 FR 42857)

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

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

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS

[January 1998 Through March 1998]

Trans. No.	Manual/Subject/Publication No.
	Intermediary Manual Part 3—Claims Process (HCFA Pub. 13–3) (Superintendent of Documents No. HE 22.8/6)
1731	• Reporting Outpatient Surgery and Other Services. Use of Modifiers in Reporting Hospital Outpatient Services.
1732	• Medicare Secondary Payment Modules. Payment Calculation for Inpatient Bills. Payment Calculation for Outpatient Bills.
1733	• Definition of Medicare Secondary Payer/Common Working File Terms.
1734	• Medical Review of Home Health Services. Home Health Certification and Plan of Care Data Elements. Treatment Codes for Home Health Services. Plan of Care. Medical Review of Skilled Nursing and Home Health Aide Hours for Determining Part-Time or Intermittent. Treatment Codes for Professional Services Required. Acceptable V Codes.
1735	• Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines. Mammography Screening.
1736	• Eligibility Data Available Part A Eligibility Data Security Requirements.
	Carriers Manual Part 3—Claims Process (HCFA Pub. 14–3) (Superintendent of Documents No. HE 22.8/7)
1584	• Medicare Participating Physicians/Suppliers Directory.
1585	• Application of Foot Care Exclusions to Physicians' Services.
1586	• Medicare Secondary Payment Modules. Payment Calculation for Physician/Supplier Claims.
1587	• Identifying a Screening Mammography Claim. Medicare Summary Notice and Explanation of Medicare Benefits Messages. Remittance Advice Messages.
1588	• Chiropractic Services.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[January 1998 Through March 1998]

Trans. No.	Manual/Subject/Publication No.
1589	• Medicare Secondary Payer Claims Processing Under Common Working File.
1590	• The Carrier Advisory Committee.
1591	• Payment for Oral Anti-Emetic Drugs When Used as Full Replacement for Intravenous Anti-Emetic Drugs as Part of a Cancer Chemotherapeutic Regimen.
1592	• Requirements for Processing Electronic Media Claims.
1593	• Definition of a Claim. Splitting Claims for Processing.
1594	• Durable Medical Equipment, Prosthetic, and Orthotic Supplies. Safeguards in Making Monthly Payments. Evidence of Medical Necessity—Oxygen Claim.
1595	• Claims Review for Global Surgeries.
1596	• Positron Emission Tomography Scans. Conditions for Medicare Coverage of Positron Emission Tomography Scans for Noninvasive Imaging of the Perfusion of the Heart. Conditions of Coverage of Positron Emission Tomography Scans for Characterization of Solitary Pulmonary Nodules and Positron Emission Tomography Scans Using FDG to Initially Stage Lung Cancer. Billing requirements for Positron Emission Tomography Scans. HCFA Common Procedures Coding System and Modifiers for Positron Emission Tomography Scans. Claims Processing Instructions for Positron Emission Tomography Scan Claims.
	Program Memorandum Intermediaries (HCFA Pub. 60A) (Superintendent of Documents No. HE 22.8/6–5)
A–97–22	• Claims Processing for the Restructured Hospice Benefit Periods and Billing Clarification for Place of Service.
A–98–1	• Processing Claims for the Home Health Part A and Part B Shift.
A–98–2	• Developing Medicare Ambulance Rates.
A–98–3	• Medicare Home Health Benefit—Section 4615 of the Balanced Budget Act of 1997—Clarification That No Home Health Benefits are Authorized Based Solely On Drawing Blood.
A–98–4	• Implementation of Surety Bond Requirement for Home Health Agencies.
A–98–5	• 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–98–6	• Screening Pap Smear and Pelvic Examinations—The Balanced Budget Act of 1997.
A–98–7	• Extension of Due Date for Filing Provider 2552-96 Cost Reports.
A–98–8	• Reporting Outpatient Rehabilitation Services and All Comprehensive Outpatient Rehabilitation Facility Services Using HCFA Common Procedure Coding System.
A–98–9	• Positron Emission Tomography Scans.
	Program Memorandum Carriers (HCFA Pub. 60B) (Superintendent of Documents No. HE 22.8/6–5)
B–97–14	• Maintenance Process for the 1998 Medicare Physician Fee Schedule Database.
B–97–15	• Screening Pap Smear and Pelvic Examinations—The Balanced Budget Act of 1997.
B–97–16	• Changes to Correct Coding Edits, Version 4.1.
B–97–17	• Private Contracts Between Beneficiaries and Physicians/Practitioners.
B–98–1	• Evaluating the Medical Necessity for Laboratory Panel Current Procedural Terminology Codes.
B–98–2	• Payment for the Services of a Certified Registered Nurse Anesthetist and a Anesthesiologist in a Single Anesthesia Procedure.
B–98–3	• Resolution of Problems in the Initial National Provider Identifier Enumeration Effort from the Unique Physician Identification Number Registry.
B–98–4	• Instructions to Implement the New Medicare Summary Notice.
B–98–5	• Provider Material to be Published in Carrier Bulletins.
B–98–6	• 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 Prescriptions Drugs.
B–98–7	• Ongoing Maintenance Process for the 1998 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Fee Schedule.
B–98–8	• Changes to the 1998 Medicare Physician Fee Schedule Database.
B–98–9	• Millennium Changes for Forms HCFA–1491, 1490S, and 1490U.
B–98–10	• Corrections to Correct Coding Edits, Version 4.0.
B–98–11	• Provider Material to be Published in Carrier Bulletin.
	Program Memorandum Intermediaries/Carriers (HCFA Pub. 60AB) (Superintendent of Documents No. HE 22.8/6–5)
AB–97–25	• Implementation of the New Payment Limit for Drugs and Biologicals.
AB–97–26	• Coverage and Interim Billing Instructions of Oral Anti-Nausea Drugs as Full Therapeutic Replacements for Intravenous Dosage Forms as Part of a Cancer Chemotherapeutic Regimen.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[January 1998 Through March 1998]

Trans. No.		Manual/Subject/Publication No.
AB–97–27	•	Implementing Instructions—Positron Emission Tomography Scans for Characterizing Solitary Pulmonary Nodules or Staging Lung Cancer Performed on or After January 1, 1998.
AB–98–1	•	Balanced Budget Act Requirement to Furnish Diagnostic Information.
AB–98–2	•	Suspension of National Coverage Policy on Electrostimulation for Wound Healing—(Clarification of Program Memorandum B–97–11).
AB–98–3	•	Temporary National HCFA Common Procedures Coding System Codes.
AB–98–4	•	Implementation of the Office of the Inspector's General Fraud Hot Line Number on Medicare Beneficiary Notices.
AB–98–5	•	Gap-Filling Fee Schedule Amounts for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Using Fee Schedule Amounts for Comparable Items.
AB–98–6	•	Identifying Employer in Other-than-Data Match Group Health Plan Medicare Secondary Payer Recovery Situations.
AB–98–7	•	Implementation of 1998 Clinical Diagnostic Laboratory Fee Schedule and Mapping for 1998 Laboratory Coding Changes.
AB–98–8	•	New Interest Rate Payable on Clean Claims Not Paid Timely.
AB–98–9	•	Revised Inherent Reasonableness Policy for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies.
AB–98–10	•	Modification of Medicare Coverage of Erythropoietin.
		Program Memorandum Regional Office General (HCFA Pub. 51) (Superintendent of Documents No. HE 22.28/5:90–1)
98–1	•	Surety Bond Regulation.
98–2	•	Home Health Agency Surety Bond Requirements.
		Program Memorandum Insurance Commissioners/Insurance Issuers (HCFA Pub. 82) (Superintendent of Documents No. HE 22.8/6–5)
98–01	•	Agent Commissions and Application Processing Delays.
		State Operations Manual Provider Certification (HCFA Pub. 7) (Superintendent of Documents No. HE 22.8/12)
286	•	Survey Procedures and Interpretive Guidelines for End-Stage Renal Disease Facilities.
1	•	The State Operations Manual Has Been Combined With the Material From the Regional Office Manual, and Will Serve as a Basic Guide to Policies and Procedures for Certification Purposes.
		Medicare Hospital Manual (HCFA Pub. 10) (Superintendent of Documents No. HE 22.8/2)
726	•	Reporting Outpatient Surgery and Other Services. Use of Modifiers in Reporting Hospital Outpatient Services.
727	•	Billing for Mammography Screening
		Home Health Agency Manual (HCFA Pub. 11) (Superintendent of Documents No. HE 22.8/5)
286	•	Home Health Certification and Plan of Care. Treatment Codes for Home Health Services. Plan of Care. Coverage Compliance Review. Documentation of Skilled Nursing and Home Health Aide Hours. Treatment Codes for Professional Services Required. Acceptable V Codes.
		Skilled Nursing Facility (HCFA Pub. 12) (Superintendent of Documents No. HE 22.8/3)
352	•	Billing for Mammography Screening.
		Rural Health Clinic and Federally Qualified Health Centers Manual (HCFA Pub. 27) (Superintendent of Documents No. HE 22.8/19:985)
29	•	Billing for Mammography Screening by Rural Health Clinics and Federally Qualified Health Centers.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[January 1998 Through March 1998]

Trans. No.	Manual/Subject/Publication No.
	Coverage Issues Manual (HCFA Pub. 6) (Superintendent of Documents No. HE 22.8/14)
103	• Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer.
	Provider Reimbursement Manual Part I (HCFA Pub. 15–I) (Superintendent of Documents No. HE 22.8/4)
401	• Regional Medicare Swing-Bed Skilled Nursing Facility Rates.
402	• Acquisitions. Betterments and Improvements.
	Provider Reimbursement Manual Part II—Provider Cost Reporting Forms and Instructions (HCFA Pub. 15–II–AH) (Superintendent of Documents No. HE 22.8/4)
5	• Independent Renal Dialysis Facility Statistical Data.
	State Medicaid Manual Part III—Eligibility (HCFA Pub. 45–3) (Superintendent of Documents No. HE 22.8/10)
69	• Medicaid Payment for Recipients Under Group Health Plans.
	Medicare/Medicaid Sanction—Reinstatement Report (HCFA Pub. 69)
98–1	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—December 1997.
97–2	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—January 1998.
97–3	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—February 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
01/02/98 ...	89–105	.....	HCFA–1904–NC	Medicare Program; Schedule of Limits on Home Health Agency Costs Per Visit for Cost Reporting Periods Beginning on or After October 1, 1997.	03/03/98	10/01/97
01/05/98 ...	292–355	413, 440, 441, 489	HCFA–1152–FC	Medicare and Medicaid Programs; Surety Bond and Capitalization Requirements for Home Health Agencies.	03/06/98	01/01/98
01/07/98 ...	687–690	405	HCFA–1908–IFC	Medicare Program; Application of Inherent Reasonableness to All Medicare Part B Services (Other than Physician Services).	03/09/98	03/09/98
01/09/98 ...	1659–1728	411, 424, 435, 455	HCFA–1809–P	Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships.	03/10/98	01/09/98
01/09/98 ...	1646–1658	411	HCFA–1902–IFC	Medicare Program; Physicians' Referrals; Issuance of Advisory Opinions.	03/10/98	01/09/98
01/09/98 ...	1379–1383	413	HCFA–1004–FC	Medicare Program; Limit on the Valuation of a Depreciable Asset Recognized as an Allowance for Depreciation and Interest on Capital Indebtedness After a Change of Ownership.	03/10/98	01/09/98

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
01/20/98 ...	2920–2926	.....	HCFA–1014–NC	Medicare Program; Request for Public Comments on Implementation of the Medicare+Choice Program, and Notice of Timeframes for Submission of Applications for Contracts.	02/19/98	01/20/98
1/20/98	2926–2939	424	HCFA–1864–P	Medicare Program; Additional Supplier Standards.	03/23/98	01/20/98
01/26/98 ...	3752–3756	.....	HCFA–2005–NC	Medicare Program; State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals: Federal Fiscal Year 1998.	03/27/98	01/01/98
01/30/98 ...	5106–5139	413	HCFA–1808–F	Medicare and Medicaid Programs; Salary Equivalency Guidelines for Physical Therapy, Respiratory Therapy, Speech Language Pathology, and Occupational Therapy Services.	.....	04/01/98
01/30/98 ...	4595–4597	400, 405, 410, 411, 414	HCFA–1884–CN	Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule, Other Part B Payment Policies, and Establishment of the Clinical Psychologist Fee Schedule for Calendar Year 1998; Correction.	.....	10/31/97
02/04/98 ...	5809–5811	.....	HCFA–2011–N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: July, August, September, October, and November 1997.	.....	02/04/98
02/11/98 ...	6864–6869	412, 413	HCFA–1731–F	Medicare Program; Payment for Preadmission Services.	.....	03/13/98
02/13/98 ...	7359–7360	.....	HCFA–1037–N	Medicare Program; Meeting of the Negotiated Rulemaking Committee on the Provider-Sponsored Organization Solvency Standards.	.....	02/13/98
02/17/98 ...	7743	416, 482, 485, 489	HCFA–3745–N	Medicare and Medicaid Programs; Hospital Conditions of Participation; Provider Agreements and Supplier Approval; Extension of Comment Period.	03/03/98 04/20/98	02/17/98
02/19/98 ...	8462–8465	.....	HCFA–1897–N	Medicare Program; Update of Ambulatory Surgical Center Payment Rates Effective for Services on or After October 1, 1997.	.....	10/01/97
03/04/98 ...	10732–10733	.....	HCFA–1038–N	Medicare and Medicaid Programs; Surety Bond Requirements for Home Health Agencies.	.....	03/04/98
03/04/98 ...	10730–10731	441, 489	HCFA–1152–F	Medicare and Medicaid Programs; Surety Bond Requirements for Home Health Agencies.	.....	03/04/98
03/04/98 ...	10641–10642	.....	HCFA–1036–N	Medicare Program; March 16–17, 1998, Meeting of the Practicing Physicians Advisory Council.	.....	03/04/98
03/05/98 ...	10921–10927	.....	HCFA–1103–GN	Medicare Program; HCFA Market Research for Providers and Other Partners.	05/04/98	03/04/98
03/06/98 ...	11147–11159	400, 409, 410, 411, 412, 413, 424, 440, 485, 488, 489, 498.	BPD–878–CN	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1998 Rates; Corrections.	.....	10/01/97
03/10/98 ...	11687–11688	.....	HCFA–1013–NC	Medicare and Medicaid Programs; Announcement of Additional Application From Hospital Requesting Waiver for Organ Procurement Service Area.	05/11/98	03/10/98

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
03/10/98 ...	11649	411, 424, 435, 455	HCFA–1809–N	Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Extension of Comment Period.	05/11/98	03/10/98
03/10/98 ...	11686–11687	.....	HCFA–2021–N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: December 1997 and January 1998.	.....	03/10/98
03/18/98 ...	13260–13262	.....	HCFA–3000–N	Medicare Programs; Solicitation of Proposals for a Demonstration Project for the Use of Informatics, Telemedicine, and Education in the Treatment of Diabetes Mellitus in the Rural and Inner-City Medicare Populations.	04/17/98	03/10/98
03/20/98 ...	13590–13608	400, 421	HCFA–7020-P	Medicare Program; Medicare Integrity Program, Intermediary and Carrier Functions, and Conflict of Interest Requirements.	05/19/98	03/20/98
03/25/98 ...	14506–14526	401, 403, 405, 410, 411, 413, 447, 466, 473, 493.	HCFA–1719–P	Medicare Program; ''Without Fault'' and Waiver of Recovery from an Individual as it Applies to Medicare Overpayment Liability.	05/26/98	03/25/98
03/31/98 ...	15315	413	HCFA–1808–CN	Medicare and Medicaid Programs; Salary Equivalency Guidelines for Physical Therapy, Respiratory Therapy, Speech Language Pathology, and Occupational Therapy Services; Revised Effective Date and Technical Correction.	.....	04/10/98
03/31/98 ...	15718–15738	413	HCFA–1905–FC	Medicare Program; Schedule of Per-Beneficiary Limitations on Home Health Agency Costs for Cost Reporting Periods Beginning on or After October 1, 1997.	06/01/98	10/01/98

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.

G970106 A1
G970124 A1
G970252 A2
G970281 A2
G970311 A2
G980018 A2
G980020 A1
G980025 A2
G980040 A2

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

G970219 B1
G970230 B4
G970250 B1
G970264 B1
G970285 B2
G970286 B4
G970294 B4
G970302 B4
G970307 B2
G970308 B1
G970310 B2
G970316 B2
G970317 B2
G970321 B4
G970322 B2
G980001 B2
G980002 B4
G980003 B4
G980006 B3
G980007 B2
G980009 B3
G980010 B2
G980014 B4
G980015 B2
G980016 B4
G980019 B1
G980021 B1
G980023 B2
G980027 B3
G980028 B1
G980029 B4
G980030 B1
G980031 B3
G980034 B2
G980036 B4
G980037 B4
G980038 B4
G980039 B2
G980041 B1

[FR Doc. 98–24804 Filed 9–15–98; 8:45 am]
BILLING CODE 4120–01–P