application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Aggrastat® (tirofiban hydrochloride). Aggrastat® , in combination with heparin, is indicated for the treatment of acute coronary syndrome. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Aggrastat® (U.S. Patent No. 5,292,756) from Merck & Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 11, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Aggrastat® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Aggrastat® is 2,247 days. Of this time, 2,051 days occurred during the testing phase of the regulatory review period, while 196 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: March 21, 1992. The applicant claims March 20, 1992, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 21, 1992, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: October 31, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for Aggrastat® (NDA 20–912) was initially submitted on October 31, 1997.

3. *The date the application was approved*: May 14, 1998. FDA has verified the applicant's claim that NDA 20–912 was approved on May 14, 1998.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 433 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 12, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 11, 1999 for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 29, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–11821 Filed 5–10–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–9000–N]

RIN 0938–AJ37

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—Third 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 July, August, and September of 1998, relating to the Medicare and Medicaid programs. This notice also identifies certain devices with investigational device exemption numbers approved by the Food and Drug Administration that potentially may be 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 also including all Medicaid issuances and Medicare and Medicaid substantive and interpretive regulations (proposed and final) published during this timeframe.

FOR FURTHER INFORMATION CONTACT: 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.

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, (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, (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, (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, C5–16–03, 7500 Security Boulevard, Baltimore, MD 21244–1850, (410) 786–8517.

SUPPLEMENTARY INFORMATION:

I. Program Issuances

The Health Care Financing Administration (HCFA) is responsible for administering the Medicare and Medicaid programs. These programs pay for health care and related services for 39 million Medicare beneficiaries and 35 million Medicaid recipients. Administration of these programs involves (1) Furnishing 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 to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act). We also issue various manuals, memoranda, and statements necessary to administer the programs efficiently.

Section 1871(c)(1) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**. 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) published in 1988, 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 a unique HCFA transmittal number for each instruction in our manuals or Program Memoranda 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;
  + **Federal Register** citation;
  + Parts of the Code of Federal Regulations (CFR) that have changed (if applicable);
  + Agency file code number;
  + Title of the regulation;
  + Ending date of the comment period (if applicable); and
  + Effective date (if applicable).
- 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. 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 our practice to announce all investigational device exemption categorizations, using the investigational device exemption numbers the Food and Drug Administration assigns. 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

Those wishing to subscribe to program manuals should contact either the Government Printing Office (GPO) or the National Technical Information Service (NTIS) at the following addresses:

Superintendent of Documents, Government Printing Office, ATTN: New Orders, PO Box 371954, Pittsburgh, PA 15250–7954, Telephone (202) 512–1800, Fax number (202) 512–2250 (for credit card orders); 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**. 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 and 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 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL.

In addition, individuals may contact regional depository libraries that 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 materials, use the Superintendent of Documents number, plus the HCFA transmittal number. For example, to find the Intermediary Manual, (HCFA Pub. 113–3) transmittal entitled ''Electronic Data Interchange Security, Privacy, Audit and Legal Issues,'' use the Superintendent of Documents No. HE 22.8/6 and the HCFA transmittal number 1748.

(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: April 23, 1999.

Elizabeth Cusick,

Acting 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 21, 1997 (62 FR 62325)
June 4, 1998 (63 FR 30499)
August 11, 1998 (63 FR 42857)
September 16, 1998 (63 FR 49598)
December 9, 1998 (63 FR 67899)

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

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

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS

[July 1998 Through September 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)
1748	• Electronic Data Interchange Security, Privacy, Audit and Legal Issues. Contractor Data Security and Confidentially Requirements. Electronic Data Interchange Audit Trail. Security-Related Requirements for Subcontractor Arrangements With Network Services.
1749	• Completing Quarterly Report on Provider Enrollment. Checking Reports. Type of Provider. Completing Lines Twenty-Seven Through Thirty-One—Age of Applications Pending. Completing Lines Thirty-Two Through Thirty-Seven—Change of Ownership Workloads.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 1998 Through September 1998]

Trans. No.		Manual/Subject/Publication No.
1750	•	Requirements for Submission of Electronic Media Claims Data.
1751	•	Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines. Mammography Screening.
1752	•	Millennium Readiness.
		Carriers Manual Part 3—Claims Process (HCFA Pub. 14–3) (Superintendent of Documents No. HE 22.8/7)
1609	•	Electronic Data Interchange Security, Privacy, Audit and Legal Issues. Contractor Data Security and Confidentiality Requirements. Audit Trails. Security-Related Requirements for Subcontractor Arrangements With Network Services.
1610	•	The System for Processing Electronic Media Claims. Electronic Media Claims Testing and Verification.
1611	•	Identifying a Screening Mammography Claim. Adjudicating the Claim.
		Program Memorandum Intermediaries (HCFA Pub. 60A) (Superintendent of Documents No. HE 22.8/6–5)
A–98–21	•	Payment to Hospitals for Direct Costs of Graduate Medical Education and Operating Indirect Medical Education Costs for Medicare+Choice Enrollees.
A–98–22	•	Hospital Encounter Data Requirements From the Balanced Budget Act of 1997.
A–98–23	•	Coding for Adequacy of Hemodialysis Dialysis on Claim Form—Additional Modifier.
A–98–24	•	Change to Reporting of Outpatient Rehabilitation Services and All Comprehensive Outpatient Rehabilitation Facilities Services Using HCFA Common Procedure Coding System.
A–98–25	•	Home Health Agency Surety Bond Requirements.
A–98–26	•	Prospective Payment System PRICER Changes for Fiscal Year 1999, Including Changes for Discharges to Post-Acute Care Providers and a Millennium Compliant Provider Specific File.
A–98–27	•	Hospice Provisions Enacted by the Balanced Budget Act of 1997.
A–98–28	•	Medicare Home Health Benefit—The Balanced Budget Act of 1997—Clarification of Part-Time or Intermittent Skilled Nursing Care.
A–98–29	•	UB–92 Claims That Are Not Millennium Compliant.
A–98–30	•	Extension of the Effective Date for Intermediary Usage of the 4A.01 Implementation of the Version 3051 Based 835 Transaction for Electronic Remittance Advice.
A–98–31	•	Discharges to Swing Bed Units and Other Post-Acute Care Providers.
		Program Memorandum Carriers (HCFA Pub. 60B) (Superintendent of Documents No. HE 22.8/6–5)
B–98–25	•	Changes to Correct Coding Edits, Version 4.1.
B–98–26	•	Durable Medical Equipment Regional Carrier Instructions to Implement Balanced Budget Act of 1997 Provisions § 4105 to Provide Expanded Coverage of Blood Glucose Monitors and Test Strips for all Diabetics—Implement July 1, 1998.
B–98–27	•	Implementation of Additional Commercial Edits Effective for Dates of Service on or after October 1, 1998.
B–98–28	•	Modifications to Form HCFA–1500 Instructions.
B–98–29	•	Private Contracts Between Beneficiaries and Physicians/Practitioners.
B–98–30	•	Millennium Changes for Forms HCFA–1491, 1490S, and 1490U.
B–98–31	•	Change to Health Insurance Claim Form HCFA–1500 Instructions for Processing Physician Claims in Global Payment Systems.
B–98–32	•	Changes to the 1998 Medicare Physician Fee Schedule Database.
B–98–33	•	Durable Medical Equipment Carrier Operating Instructions to Implement Balanced Budget Act of 1997 Provisions § 4105 to Provide Expanded Coverage of Blood Glucose Monitors and Test Strips for All Diabetes. Implement July 1, 1998. (Corrects and updates Transmittal B–98–17, dated April 1998, Change Request #485).
B–98–34	•	Elimination of Funding Toll-Free Lines for Participating Physicians and Suppliers.
B–98–35	•	Receipt of Electronic Claims That Are Not Millennium Compliant.
B–98–36	•	This document will be released in the fourth Quarter **Federal Register** Notice.
B–98–37	•	Requiring Entities Who Are Ineligible to Receive Direct Medicare Payments for Services Provided by Independent Contractors to Comply with 42 USC 1395u(b)(6), and Medicare Regulations in 42 CFR 424.80(b).
		Program Memorandum Intermediaries/Carriers (HCFA Pub. 60A/B)(Superintendent of Documents No. HE 22.8/6–5)
AB–98–32	•	Standardization of Medicare Coverage of Bone Marrow Measurements.
AB–98–33	•	Medicare Travel Allowance Fees for Collection of Specimens.
AB–98–34	•	Modifications of Medicare Policy for Erythropoietin.
AB–98–35	•	Consolidated Billing for Skilled Nursing Facilities—The Balanced Budget Act of 1997.
AB–98–36	•	Coverage of Diabetes Outpatient Self-Management Training Services, Effective: July 1, 1998.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 1998 Through September 1998]

Trans. No.	Manual/Subject/Publication No.
AB–98–37	• Contractor Coordination of Benefits File Formats and Trading Partner Agreements.
AB–98–38	• Distribution of 1/98 Versions of Form HCFA–855.
AB–98–39	• FDA Approves Two Cancer Tests, the Abbott AxSYM CA 15–3 test and the Abbott Imx CA 15–3 test.
AB–98–40	• New Interest Rate Payable on Clean Claims Not Paid Timely.
AB–98–41	• Promoting Influenza and Pneumococcal Vaccinations.
AB–98–42	• Revision of Troponin (CPT Code 84484 and 84512) Policy.
AB–98–43	• New Waived Tests.
AB–98–44	• Suspension of National Coverage Policy on Electrostimulation for Wound Healing.
AB–98–45	• Consolidated Billing for Skilled Nursing Facilities.
AB–98–46	• Notice of New Interest Rate for Medicare Overpayments and Underpayments.
AB–98–47	• Health Care Financing Administration Public Awareness Activities.
AB–98–48	• Year 2000 Contingency for Non-Millennium Compliant Electronic Transactions and Publication of Year 2000 Article in Provider Bulletins.
AB–98–49	• New Waived Tests.
AB–98–50	• Physician Ownership and Compensation Interest System.
AB–98–51	• Implementation of Section 4105 of the Balanced Budget Act Regarding Coverage of Diabetes Outpatient Self-Management Training Services.
AB–98–52	• Interim Tracking Procedures for Implementing the Medicare Fraud and Abuse Incentive Reward Program.
	State Operations Manual **Provider Certification** **(HCFA Pub. 7)** **(Superintendent of Documents No. HE 22.8/12)**
3	• Medicare Health Care Provider/Supplier Enrollment. Prioritizing State Agency Survey Workload—Initial Surveys and Recertifications. Transmitting Materials. List of Documents in Certification Packet. Notification to Application that the Medicare General Enrollment Health Care Provider/Supplier Application has been Denied. Notification of Pending Involuntary Termination Based on Change of Home Ownership Review of the Medicare General Enrollment Health Care Provider/Supplier Application. Notification of Involuntary Termination Based on Change of Home Ownership Review of the Medicare General Enrollment Health Care Provider/Supplier Application. Medicare and Other Federal Health Care Program General Enrollment Health Care Provider/Supplier Application. Medicare and Other Federal Health Care Program Change of Information Health Care Provider/Supplier Application. Medicare and Other Federal Health Care Program Individual Reassignment of Benefits Health Care Provider/Supplier Application.
	Peer Review Organization Manual **(HCFA Pub. 19)** **(Superintendent of Documents No. HE 22.8/8–15)**
66	• Introduction. Definition. Requirements. Disagreements.
67	• Opportunity to Discuss. Authority. Scope of Review. Referrals. Receive Medical Records. Request for a Review. Timing of Rereview.
68	• Interaction with Beneficiary Groups. Evaluation.
	Hospital Manual **(HCFA Pub. 10)** **(Superintendent of Documents No. HE 22.8/2)**
730	• Billing for Mammography Screening.
	Skilled Nursing Facility Manual **(HCFA Pub. 12)** **(Superintendent of Documents No. HE 22.8/3)**
354	• Billing for Mammography Screening.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 1998 Through September 1998]

Trans. No.	Manual/Subject/Publication No.
	End Stage Renal Disease Network Organizations Manual (HCFA Pub. 81) (Superintendent of Documents No. HE 22.9/4)
7	• Background and Responsibilities. Authority. Purpose of End Stage Renal Disease Network Organizations. Requirements for End Stage Renal Disease Network Organizations. Responsibilities of End Stage Renal Disease Network Organizations. Health Care Quality Improvement Program. Goals. Network Organization's Role in Health Care Quality Improvement Program. Organizational Structure. Network Council. Board of Directors. Medical Review Board. Other Committees. Network Staff. Required Administrative Reports. Internal Quality Control Program. Health Care Financing Administration Meetings. Cooperative Activities with State Survey Agencies and Peer Review Organizations. Annual Report Format. Statutory and Regulatory Requirements. General Requirements. Nonconfidential Information. Confidential Information. Disclosure of Network Deliberations. Disclosure of Confidential Network Information to Officials and Agencies. Disclosure of Network Information Involving Beneficiary Complaints. Disclosure of Network Information for Research Purposes. Disclosure of Network Sanction Information. Redisclosure of Network Information.
8	• Authority. End Stage Renal Disease Health Care Quality Improvement Program. Responsibilities. Quality of Care Improvement Projects. Components of Quality of Care Improvement Projects. Developing and Planning the Project. Identifying and Confirming an Opportunity to Improve Care. Developing a Network Intervention Activity. Measuring Impact and Project Evaluation. Disseminating Results. Identifying Additional Opportunities for Improvement. Project Reporting System. Improvement Plan. End Stage Renal Disease Core Clinical Indicators. Core Indicators—Network National Sample. Core Indicators—Sampling Method. Core Indicators—Data Collection. Core Indicators—Data Validation. Core Indicators—Data Reporting. Health Care Financing Administration-Compiled Data Reports. Quality Improvement Projects Versus Research Studies. Network Resources to Support the National Renal Registry. Core Indicators—Targeted Patient Population, and Clinical Measures. Annual Patient Sample Per Network for Conducting National Renal Registry Special Studies. Network Quality Improvement Project Report.
	Provider Reimbursement Manual—Part 1 (HCFA Pub. 15–1) (Superintendent of Documents No. HE 22.8/4)
405	Low Medicare Volume Prospective Payment Rates for Skilled Nursing Facilities Effective for Cost Reporting Periods Beginning on or After October 1, 1986 and Prior to Cost Reporting Periods Beginning on or After July 1, 1998. Calculation of the Low Medicare Volume Prospective Payment Rate. Methodology for Determining Per Diem Prospective Payment Rates Effective for Cost Reporting Periods Beginning on or After October 1, 1977 and Before July 1, 1998. General Provisions.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 1998 Through September 1998]

Trans. No.	Manual/Subject/Publication No.
	Methodology for Determining Per Diem Prospective Payment Rates Effective for Cost Reporting Periods Beginning on or After July 1, 1998.
	Determination of Facility Specific Per Diem Rates.
	Calculating Payment Under Skilled Nursing Facility Prospective Payment System.
	Use of Skilled Nursing Facility PRICER.
	Skilled Nursing Facility Prospective Payment System—Payment Requirements and Adjustments.
	Reporting Rehabilitative Therapy Minutes on the Minimum Data Set for Purposes of Medicare Payment.
406	Principle of Cost Apportionment.
	State Medicaid Manual—Part 2 State Organization and General Administration (HCFA Pub. 45–2) (Superintendent of Documents No. HE 22.8/10)
90	Annual Report on Home and Community-Based Services Waivers.
91	Statistical Report on Medical Care: Eligibles, Recipients, Payments and Services.
	Federal Reporting Requirements.
	Requirements for the Medicaid Statistical Information System.
	State Medicaid Manual—Part 5 Early and Periodic Screening, Diagnosis, and Treatment (HCFA Pub. 45–5) (Superintendent of Documents No. HE 22.8/10)
12	Screening Service Content.
	State Medicaid Manual—Part 6 Payment for Services (HCFA Pub. 45–6) (Superintendent of Documents No. HE 22.8/10)
35	• Upper Limits for Prescription Drugs.
	State Medicaid Manual—Part 11 Medicaid Management Information System (HCFA Pub. 45–11) (Superintendent of Documents No. HE 22.8/10)
18	• Background.
	Applicable Federal Approval Requirements.
	Approval Process and Documentation Submissions.
	List of Reimbursable Costs for State Systems.
	Eligibility Verification Systems, Switching Companies, Electronic Claims Capture, and Electronic Claims Management System-Overview.
	Electronic Fund Transfer and Electronic Remittance Advices.
	General (System) Requirements.
	Future Additional System Requirements.
	Claims Processing Subsystem.
	Data Requirements.
	Applicable Federal Approval Requirements.
	Acquisition of Automated Data Processing Equipment and Services.
	Implementation Advance Planning Document.
	Approval Process and Documentation Submissions.
	Cost Reimbursable at 75 Percent Federal Financial Participation.
	Cost Reimbursable at 75 Percent Federal Financial Participation for Management Administration Reporting Subsystem and Surveillance and Utilization Review Subsystem.
	List of Reimbursable Costs for State Systems.
	Definitions.
	Considerations and Options.
	Detailed Implementation Schedule.
	Projected Reporting Requirements.
	Preliminary Evaluation.
	Contractual Services.
	Required Assurances.
	Replacement Systems.
	Approval Process and Documentation Submissions.
	Approval of Eligibility Determination Systems—Required System Documentation for Onsite Review.
	General Requirements.
	List of Reimbursable Costs for State Systems.
	Approval of Eligibility Determination Systems.
	Enumeration Verification System as a Component of Medicaid Management Information System.
	Surveillance and Utilization Review Subsystem.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 1998 Through September 1998]

Trans. No.	Manual/Subject/Publication No.
	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 State Survey Agencies (HCFA Pub. 65) (Superintendent of Documents No. HE 22.8/6–5)
98–1	• Home Health Agency Parent, Branch, and Subunit Criteria.
	Medicare/Medicaid Sanction—Reinstatement Report (HCFA Pub. 69)
98–7	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—June 1998.
97–8	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—July 1998.
97–9	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—August 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
07/06/98	36488	422	HCFA–1030–IFC	Medicare Program; Establishment of the Medicare+Choice Program; Correction.		07/06/98
07/13/98	37498–37499	409, 410, 411, 413, 424, 483, and 489.	HCFA–1913–N	Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Extension of Comment Period.	09/11/98	
07/29/98	40534–40536		HCFA–3009–N	Medicare Program; Peer Review Organization Contracts: Solicitation of Statements of Interest From In-State Organizations—Alaska, Delaware, the District of Columbia, Hawaii, Idaho, Illinois, Kentucky, Maine, Nebraska, Nevada, South Carolina, Vermont, and Wyoming.	08/28/98	
07/31/98	40954–41131	405, 412, and 413.	HCFA–1003–F	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1999 Rates		10/01/98
07/31/98	41170–41171	441 and 489	HCFA–1152–2–F	Medicare and Medicaid Programs; Surety Bond Requirements for Home Health Agencies		07/31/98
08/06/98	42055		HCFA–2030–N	Medicaid Program; Decision on Funding for the AIDS Healthcare Foundation START Program		
08/07/98	42270–42275	233	HCFA–2106–FC	Medicaid and Title IV–E Programs; Revision to the Definition of an Unemployed Parent.	10/06/98	08/07/98
08/11/98	42912–42938		HCFA–1035–NC	Medicare Program; Schedules of Per-Visit and Per-Beneficiary Limitations on Home Health Agency Costs for Cost Reporting Periods Beginning On or After October 1, 1998.	10/13/98	10/01/98
08/11/98	42797–42801413		HCFA–1883–P	Medicare Program; Revision of the Procedures for Requesting Exceptions to Cost Limits for Skilled Nursing Facilities and Elimination of Reclassifications.	10/13/98	
08/11/98	42796		HCFA–3250–N	Medicare Program; Negotiated Rulemaking; Coverage and Administrative Policies for Clinical Diagnostic Laboratory Tests; Change in Meeting Time.		
08/11/98	42857–42864		HCFA–9879–N	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—Fourth Quarter 1997.		
08/14/98	43655	416 and 488	HCFA–1885–N	Medicare Program; Update of Rate-setting Methodology, Payment Rates, Payment Policies, and the List of Covered Procedures for Ambulatory Surgical Centers Effective October 1, 1998; Extension of Comment Period.	09/10/98	

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
09/08/98	47506–47513		HCFA–1045–N	Medicare Program; Request for Public Comments on Implementation of Risk Adjusted Payment for the Medicare+Choice Program and Announcement of Public Meeting.	10/06/98	
09/08/98	47513–47514		HCFA–1046–N	Medicare Program; September 23 and 24, 1998, Meeting of the Competitive Pricing Advisory Committee		
09/08/98	47552–48036	409, 410, 411, 412, 413, 419, 489, 493, and 1003.	HCFA–1005–P	Medicare Program; Prospective Payment System for Hospital Outpatient Services.	11/09/98	
09/10/98	48517		HCFA–3432–N	Medicare Program; September 25, 1998, Open Town Hall Meeting to Discuss the Medicare Coverage Process		
09/11/98	48735–48736		HCFA–2029–PN	Medicare and Medicaid Programs; Recognition of the Community Health Accreditation Program, Inc. (CHAP) and Joint Commission for Accreditation of Healthcare Organizations (JCAHO) for Hospices.	10/13/98	
09/11/98	48736–48737		HCFA–1097–N	Medicare Program; September 28, 1998, Meeting of the Practicing Physicians Advisory Council		
09/16/98	49598–49605		HCFA–9879–N	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—First Quarter, 1998		
09/22/98	50545–50547	405, 410, 413, 414, 415, 424, and 485.	HCFA–1006–CN	Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 1999; Correction		
09/23/98	50919–50920		HCFA–1047–NC	Medicare and Medicaid Programs; Announcement of Additional Applications From Hospitals Requesting Waivers for Organ Procurement Service Area.	11/23/98	
09/29/98	52022–52092	400, 430, 431, 434, 435, 438, 440, and 447.	HCFA–2001–P	Medicaid Program; Medicaid Managed Care.	11/30/98	

A*N—General Notice; PN—Proposed Notice; NC—Notice with Comment Period; FN—Final Notice; P—Notice of Proposed Rulemaking (NPRM); F—Final Rule; FC—Final Rule with Comment Period; CN—Correction Notice; IFC—Interim Final Rule with Comment Period

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.

G980020 A1
G980150 A1
G980164 A1
G980165 A1
G980171 A1
G980175 A1
G980176 A2
G980185 A2
G980202 A1
G980207 A1
G980212 A1

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

G970277 B4
G980105 B2
G980108 B1
G980132 B
G980134 B1
G980135 B2
G980136 B2
G980140 B2
G980142 B2
G980144 B2
G980146 B2
G980147 B4
G980152 B2
G980156 B2
G980157 B2
G980160 B4
G980161 B4
G980162 B4
G980163 B4
G980166 B1
G980169 B1
G980174 B1
G980180 B4
G980181 B4
G980182 B4
G980184 B4
G980190 B
G980192 B4
G980194 B4
G980196 B1
G980197 B4
G980198 B3
G980200 B1
G980201 B1
G980205 B4
G980206 B4
G980208 B3
G980209 B2
G980210 B2
G980211 B2
G980213 B2
G980217 B4
G980218 B5
G980219 B4

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