Dated: August 3, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–21405 Filed 8–10–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0357]

Determination of Regulatory Review Period for Purposes of Patent Extension; Fareston®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Fareston® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an 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 Fareston® (toremifene citrate). Fareston® is indicated for the treatment of metastatic breast cancer in post menopausal women with estrogen receptor positive or receptor unknown tumors. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Fareston® (U.S. Patent No. 4,696,949) from ORION–YHTYMA OY, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 7, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Fareston® 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 Fareston® is 3,706 days. Of this time, 2,828 days occurred during the testing phase of the regulatory review period, while 878 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*: April 8, 1987. The applicant claims March 17, 1987, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 8, 1987, 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*: January 3, 1995. The applicant claims February 3, 1995, as the date the new drug application (NDA) for Fareston® (NDA 20–497) was initially submitted. However, FDA records indicate that NDA 20–497 was submitted on January 3, 1995.

3. *The date the application was approved*: May 29, 1997. FDA has verified the applicant's claim that NDA 20–497 was approved on May 29, 1997.

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 1,827 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 13, 1998, 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 February 8, 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: July 8, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–21407 Filed 8–10–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–9878–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—Fourth Quarter 1997

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice lists HCFA manual instructions, substantive and interpretive regulations, and other

Federal Register notices that were published during October, November, and December of 1997 that relate to the Medicare and Medicaid programs. It also identifies certain devices with investigational device exemption numbers approved by the Food and Drug Administration that may be potentially covered under Medicare.

Section 1871(c) of the Social Security Act requires that we publish a list of Medicare issuances in the **Federal Register** at least every 3 months. Although we are not mandated to do so by statute, for the sake of completeness of the listing, we are including all Medicaid issuances and Medicare and Medicaid substantive and interpretive regulations (proposed and final) published during this timeframe.

FOR FURTHER INFORMATION CONTACT: Bridget Wilhite, (410) 786–5248 (For Medicare instruction information). Betty Stanton, (410) 786–3247 (For Medicaid instruction information). Sharon Hippler, (410) 786–4633 (For Food and Drug Administration-approved investigational device exemption information). Pamela Gulliver, (410) 786–4659 (For all other information).

SUPPLEMENTARY INFORMATION:

I. Program Issuances

The Health Care Financing Administration (HCFA) is responsible for administering the Medicare and Medicaid programs, which pay for health care and related services for 38 million Medicare beneficiaries and 36 million Medicaid recipients. Administration of these programs involves (1) providing information to Medicare beneficiaries and Medicaid recipients, health care providers, and the public, and (2) effective communications with regional offices, State governments, State Medicaid Agencies, State Survey Agencies, various providers of health care, fiscal intermediaries and carriers that process claims and pay bills, and others. To implement the various statutes on which the programs are based, we issue regulations under the authority granted the Secretary under sections 1102, 1871, and 1902 and related provisions of the Social Security Act (the Act) and also issue various manuals, memoranda, and statements necessary to administer the programs efficiently.

Section 1871(c)(1) of the Act requires that we publish in the **Federal Register** at least every 3 months a list of all Medicare manual instructions, interpretive rules, and guidelines of general applicability not issued as regulations. We published our first notice June 9, 1988 (53 FR 21730). Although we are not mandated to do so by statute, for the sake of completeness of the listing of operational and policy statements, we are continuing our practice of including Medicare substantive and interpretive regulations (proposed and final) published during the 3-month time frame.

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 ''Billing for Durable Medical Equipment, Orthotic/Prosthetic Devices,'' use the Superintendent of Documents No. HE 22.8/5 and the HCFA transmittal number 284.

V. General Information

It is possible that an interested party may have a specific information need and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing information contact persons to answer general questions concerning these items. Copies are not available through the contact persons. Copies can be purchased or reviewed as noted above.

Questions concerning Medicare items in Addendum III may be addressed to Bridget Wilhite, Office of Communications and Operations Support, Division of Regulations and Issuances, Health Care Financing Administration, Telephone (410) 786–5248.

Questions concerning Medicaid items in Addendum III may be addressed to Betty Stanton, Center for Medicaid State Operations, Policy Coordination and Planning Group, Health Care Financing Administration, C4–25–02, 7500 Security Boulevard, Baltimore, MD 21244–1850, Telephone (410) 786–3247.

Questions concerning Food and Drug Administration-approved investigational device exemptions may be addressed to Sharon Hippler, Office of Clinical Standards and Quality, Coverage Analysis Group, Health Care Financing Administration, C4–11–04, 7500 Security Boulevard, Baltimore, MD 21244–1850, Telephone (410) 786–4633.

Questions concerning all other information may be addressed to Pamela Gulliver, Office of Communications and Operations Support, Division of Regulations and Issuances, Health Care Financing Administration, C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, Telephone (410) 786–4659.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance, Program No. 93.774, Medicare—Supplementary Medical Insurance Program, and Program No. 93.714, Medical Assistance Program)

Dated: July 29, 1988.

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.

April 21, 1997 (62 FR 19328)
May 12, 1997 (62 FR 25957)
November 3, 1997 (62 FR 59358)
November 21, 1997 (62 FR 62325)
June 4, 1998 (63 FR 30499)

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

October 1997 through December 1997

Trans. No.	Manual/Subject/Publication No.
	Intermediary Manual **Part 3—Claims Process (HCFA Pub. 13–3)** **(Superintendent of Documents No. HE 22.8/6)**
1727	• Billing for Durable Medical Equipment, Orthotic/Prosthetic Devices and Surgical Dressings.
1728	• Further Development is Not Necessary. Further Development is Required. Coordination With Providers. Returning Bills to Provider. Review of Hospitals With On-Line Admissions Query. Assessment of the Hospital Review.
1729	• HCPCS Codes for Diagnostic Services and Medical Services. Pneumococcal Pneumonia, Influenza Virus and Hepatitis B Vaccines. Hospital Outpatient Partial Hospitalization Services.
1730	• Establishing Pacemaker Registry Records. Pacemaker Related ICD–9–CM Procedure Codes.
	Carriers Manual **Part 3—Claims Process (HCFA Pub. 14–3)** **(Superintendent of Documents No. HE 22.8/7)**
1581	• Type of Service. Screening Mammography.
1582	• Services Eligible for HPSA Bonus Payments. Remittance Messages.
1583	• The Carrier Advisory Committee. DMERC Advisory Process. Data Analysis. Provider Tracking System. Medical Review Program General Information. Coordination With Carrier Fraud Unit. Taking Corrective Actions on Identified Problems. Evaluating Effectiveness of Correction Action. Data Analysis and Functions. Data Analysis. Medicare FMR Status Report. Prepayment Review of Selected Claims. Automated and Manual Prepayment Review. Types of Prepayment Review. Prepayment Edits. Evaluation of Prepayment Edits. Categories of Edits. Developing Claims for Additional Documentation. HCFA Mandated Edits. Personnel and Procedures. Levels of Manual Review. Postpayment Review of Claims. Comprehensive Medical Review Procedures. Conducting Comprehensive Medical Review. Comprehensive Medical Review Corrective Actions. Overpayment Assessment Procedures. Denials Based on § 1862(a)(1)(A) of the Act. Appeal of Denials. Carrier Medical Director and Carrier Coordination With Intermediaries and PROs.
	Program Memorandum **Intermediaries (HCFA Pub. 60A)** **(Superintendent of Documents No. HE 22.8/6–5)**
A–97–15	• New Reporting Requirements for Ambulance Services.
A–97–16	• Medicare Home Health Benefit-The Balanced Budget Act of 1997-Financing Shift of Home Health Services from Part A to Part B.
A–97–17	• Balanced Budget Act of 1997, P.L. 105–33 (H.R. 2015)—Outpatient Rehabilitation Services Payment Provisions.
A–97–18	• Hospital Outpatient Procedures: Medicare Changes for Radiology and Other Diagnostic Coding Due to the 1998 HCPCS Update; Miscellaneous Changes.
A–97–19	• Effects of Balanced Budget Act On Provider Cost Reporting.
A–97–20	• Rural Health Clinic/Federally Qualified Health Center Provisions Enacted by § 4205 of the Balanced Budget Act of 1997.
A–97–21	• Instructions Regarding Requests for New Provider Exemptions and the Impact of the Balanced Budget Act of 1997 on Approved New Provider Exemptions for Medicare Certified Skilled Nursing Facilities.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

October 1997 through December 1997

Trans. No.	Manual/Subject/Publication No.
	Program Memorandum Carriers (HCFA Pub. 60B) (Superintendent of Documents No. HE 22.8/6–5)
B–97–6	• Furnishing 1998 Pricing Data.
B–97–7	• 1998 Annual Participation and Enrollment Process.
B–97–8	• 1998 Fee Screens Edit Package for the Medicare Physician Fee Schedule Database.
B–97–9	• 1998 Participation Enrollment Material.
B–97–10	• Conversion Factors for 1998 for Anesthesia Services.
B–97–11	• Suspension of National Coverage Policy on Electrostimulation for Wound Healing.
B–97–12	• Change in the Reporting of Pricing Localities for Clinical Lab Services and Drugs.
B–97–13	• Implementation of the New Payment Limit for Ambulance Services.
	Program Memorandum Intermediaries/Carriers (HCFA Pub. 60A/B) (Superintendent of Documents No. HE 22.8/6–5)
AB–97–19	• 1998 HCFA Common Procedure Coding System.
AB–97–20	• Changes to the Fiscal Year 1998 Wage Index for Ambulatory Surgical Center Payments for Dates of Service on or After October 1, 1997.
AB–97–21	• File Descriptions and Instructions for Retrieving the 1998 Physician, Clinical Lab, Durable Medical Equipment, Prosthestics/Orthotics and Supplies Fee Schedule Payments Amounts Through Network Data Mover.
AB–97–22	• Coding for Adequacy of Hemodialysis on Claims Form.
AB–97–23	• Implementation of 1998 Clinical Diagnostic Laboratory Fee Schedule and Mapping for 1998 Laboratory Coding Changes.
AB–97–24	• Medicare Coverage of Colorectal Cancer Screening.
	Program Memorandum Medicaid State Agencies (HCFA Pub. 17) (Superintendent of Documents No. HE 22.8/6–5)
97–2	• Title XIX of the Social Security Act, Post-Eligibility Treatment of Income
97–3	• Title XIX of the Social Security Act, Payment of Medicare Part B Premiums
	State Operations Manual Provider Certification (HCFA Pub. 7) (Superintendent of Documents No. HE 22.8/12)
284	• The Quality of Survey and Certification Activity. The State Agency Quality Improvement Program. SAQIP Guiding Principles. SAQIP Terminology. Continuous Quality Improvement Plan. Components of an Individual Quality Improvement Plan.
285	• Minimum Data Set System.
	Hospital Manual (HCFA Pub. 10) (Superintendent of Documents No. HE 22.8/2)
723	• Consistency in Entering Other Insurer Name on Bill. Verification of MSP On-Line Data and Use of Admissions Questions. Admission Questions to Ask Medicare Beneficiaries. Documentation to Support Admission Process. Reviewing Hospital Files. Selection of Bill Sample. Review of Hospitals With On-Line Admissions.
724	• Reporting Outpatient Services Using HCFA Common Procedure Coding System. Pneumococcal Pneumonia, Influenza virus, and Hepatitits B Vaccines. HCPCS Codes for Diagnostic Services and Medical Services. Billing for Hospital Outpatient Partial Hospitalization Services.
725	• Pacemaker Registry.
	Christian Science Sanatorium Hospital Manual Supplement (HCFA Pub. 32) (Superintendent of Documents No. HE 22.8/2)
38	• Pneumococcal Pneumonia, Influenza Virus, and Hepatitis B Vaccines.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

October 1997 through December 1997

Trans. No.	Manual/Subject/Publication No.
	Home Health Agency Manual (HCFA Pub. 11) (Superintendent of Documents No. HE 22.8/5)
284	• Billing for Durable Medical Equipment, and Orthotic/Prosthetic Devices.
285	• Billing for Pneumococcal Pneumonia, Influenza Virus, and Hepatitis B Vaccines.
	Skilled Nursing Facility Manual (HCFA Pub. 12) (Superintendent of Documents No. HE 22.8/3)
351	• Special Billing Instructions for Pneumococcal Pneumonia, Influenza Virus, and Hepatitis B Vaccines.
	Renal Dialysis Facility Manual (Non-Hospital Operated) (HCFA Pub. 29) (Superintendent of Documents No. HE 8/13)
82	• Pneumococcal Pneumonia, and Influenza Virus Vaccines.
	End Stage Renal Dialysis Network Organizations Manual (HCFA Pub. 81) (Superintendent of Documents No. HE 8/13)
5	• Patient Grievances. Introduction. Provision of Educational Information. Provision of Technical Assistance.
	Medicare Hospice Manual (HCFA Pub. 21) (Superintendent of Documents No. HE 8/18)
51	• Special Billing Instructions for Pneumococcal Pneumonia, Influenza Virus, and Hepatitis B Vaccines.
	Provider Reimbursement Manual—Part II Provider Cost Reporting Forms and Instructions (HCFA Pub. 15–II–AI) (Superintendent of Documents No. HE 22.8/4)
3	• Skilled Nursing Facility Complex Cost Report Form HCFA–2540–96.
	Medicare/Medicaid Sanction—Reinstatement Report (HCFA Pub. 69)
97–11	• Cumulative Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—July 1997.
97–12	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—September 1997.
97–13	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—October 1997.
97–14	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—November 1997.

ADDENDUM IV—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER

Publication date	FR Vol. 62 page	CFR part(s)	File code*	Regulation title	End of comment period	Effective date
10/01/97	51536–51550		BPD–895–FNC	Medicare Program; Schedules of Limits and Prospectively Determined Payment Rates for Skilled Nursing Facility Inpatient Routine Service Costs.	12/01/97	10/01/97
10/01/97	51551–51552		BPD–896PN	Medicare Program; Adjustments to Cost Limits for Skilled Nursing Facility Inpatient Routine Service Costs.	12/01/97	10/01/97
10/06/97	52034	410, 412	BPD–878–CN	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1998 Rates; CORRECTION.		10/01/97

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

Publication date	FR Vol. 62 page	CFR part(s)	File code*	Regulation title	End of comment period	Effective date
10/06/97	52034	418	BPD–820–CN	Medicare Program; Hospice Wage Index; CORRECTION.		10/01/97
10/15/97	53571–53572	433	MB–113–F	Medicaid Program; Limitation on Provider-Related Donations and Health Care-Related Taxes; Revision of Waiver Criteria for Tax Programs Based Exclusively on Regional Variations; CORRECTION.		09/13/93
10/28/97	55773–55774		HCFA–1007–N	Medicare Program; Meetings of the Negotiated Rulemaking Committee on the Provider-sponsored Organization Solvency Standards.		10/28/97
10/29/97	56106–56111	489	BPD–748–F	Medicare Program; Changes in Provider Agreement Regulations Related to Federal Employees Health Benefits.		11/28/97
10/31/97	59048–59260	400, 405, 410, 411, 414.	BPD–884–FC	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.	12/30/97	01/01/98
10/31/97	59261–59266		BPD–893–FN	Medicare Program; Physician Fee Schedule Conversion Factor for Calendar Year 1998 and Sustainable Growth Rate for Fiscal Year 1998.		10/01/97 01/01/98
10/31/97	59267–59269	414	BPD–901–NC	Medicare Program; Delay in Implementing the Adjustments to the Practice Expense Relative Value Units Under the Physician Fee Schedule for Calendar Year 1998.	12/30/97	
11/03/97	59358–59365		BPO–150–N	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—First Quarter.		
11/03/97	59366–59368		OACT–056–N	Medicare Program; Part A Premium for 1998 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement.		01/01/98
11/03/97	59365–59366		OACT–057–N	Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 1998.		01/01/98
11/04/97	59715–59720		OACT–055–N	Medicare Program; Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Rate Beginning January 1, 1998.		01/01/98
11/05/97	59818–59820	424	BPD–875–NC	Medicare Program; Home Health Agency Physician Certification Regulations.	01/05/98	12/05/97
11/21/97	62325–62332		BPO–151–N	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—Second Quarter 1997.		
12/02/97	63669–63674	417	HCFA–1911–IFC	Medicare+Choice Program; Collection of User Fees From Medicare Choice Plans and Risk-Sharing Contractors.	02/02/98	01/01/98
12/03/97	63953–63954		HCFA–1024–N	Medicare Program; December 15, 1997, Meeting of the Practicing Phyisicans Advisory Council.		
12/19/97	66726–66763	416, 482, 485, 489	HCFA–3745–P	Medicare and Medicaid Programs; Hospital Conditions of Participation; Provider Agreements and Supplier Approval.	02/17/98	12/19/97
12/22/97	66932–66966	146	HCFA–2891–IFC	Interim Rules for Mental Health Parity	03/23/98	01/01/98

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

Publication date	FR Vol. 62 page	CFR part(s)	File code*	Regulation title	End of comment period	Effective date
12/23/97	67174–67213	483	HCFA–2180–F	Medicare and Medicaid Programs; Resident Assessment in Long Term Care Facilities.		03/23/98 06/22/98
12/29/97	67688–67689	144, 146	HCFA–2017–N	Application of HIPAA Group Market Portability Rules to Health Flexible Spending Arrangements.		12/29/97
12/29/97	67689–67690	144, 146	HCFA–2018–N	Application of HIPAA Group Market Rules to Individuals Who Were Denied Coverage Due to a Health Status-Related Factor.	.....	12/29/97
12/30/97	67881–67882	.....	HCFA–1034–N	Medicare Program; Request for Nominations for Members for the Practicing Physicians Advisory Council.		

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.

G970014 A2
G970171 A1
G970248 A2
G970278 A2
G970281 A2

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

G970087 B2
G970130 B2
G970146 B3
G970160 B1
G970168 B1
G970182 B4
G970186 B4
G970197 B2
G970204 B1
G970207 B3
G970208 B3
G970209 B4
G970211 B1
G970213 B3
G970214 B4
G970216 B1
G970218 B3
G970221 B1
G970223 B4
G970225 B3
G970227 B4
G970229 B1
G970231 B1
G970235 B1
G970236 B4
G970238 B1
G970239 B1
G970240 B1
G970241 B3
G970245 B1
G970250 B1
G970253 B1
G970254 B4
G970255 B4
G970256 B1
G970257 B3
G970258 B4
G970259 B4
G970260 B2
G970261 B2
G970264 B1
G970267 B3
G970268 B4
G970271 B4
G970272 B4
G970274 B2
G970276 B1
G970280 B3
G970282 B3
G970286 B4
G970289 B2
G970290 B4
G970291 B4

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute Proposed Collection; Comment Request Jackson Heart Study Participant Recruitment Survey

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Jackson Heart Study Participant Recruitment Survey. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This survey will be used as a planning tool for the upcoming NHLBI-sponsored Jackson Heart Study. Participation and retention of African-Americans in observational epidemiological studies has been much lower than for white populations. Experience with recruitment and retention of African-Americans in Jackson, Mississippi, is derived from the ongoing ARIC (Atherosclerosis Risk In Communities) study. Initial response was very low, with a 47 percent enrollment rate, and a 70 percent retention rate. The purpose of the proposed survey in this announcement, is to examine facilitators and barriers to long-term participation in observational studies by African-Americans. The findings will be incorporated with the input of the African-American community, into the recruitment and retention plan of the Jackson Heart Study. *Frequency of Response:* One-Time. *Affected Public:* Individuals or households. *Type of Respondents:* Adults ages 35–84.

The annual reporting burden is as follows: Estimated Number of Respondents: 580; *Estimated Number of Respondents per Respondent:* 1; *Average Burden Hours Per Response:* .4207; and *Estimated Total Annual Burden Hours Requested:* 244. The