

substance, (3) testing for photosensitivity (photoirritation and photoallergy), (4) testing for the enhancement of UV-associated skin carcinogenesis (direct photochemical carcinogenicity or indirect effects in skin), (5) reasons for a separate approach to testing nonphotosensitizing drugs for long-term photosafety, and (6) current needs for assay development.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on testing for photosafety. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations, or both.

Interested persons may, on or before April 10, 2000, submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 29, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00-429 Filed 1-7-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-R-0209 and HCFA-R-0245]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment.

Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The

necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection Request: Revision of a currently approved collection.

Title of Information Collection: Medicare and Medicaid Programs: Reporting Outcome and Assessment Information Set (OASIS) Data as Part of the Conditions of Participation for Home Health Agencies (HCFA-3006-IFC) and Supporting Regulations in 42 CFR 484.11 and 484.20.

Form No.: HCFA-R-0209 (OMB# 0938-0761).

Use: The information collection requirements contained in the HCFA-3006 regulation state that HHAs must report data from the OASIS data set as a condition of participation for HHAs. Specifically, the above named rule provides guidelines for HHAs for the electronic transmission of the OASIS data set as well as responsibilities of the State agency or OASIS contractor in collecting and transmitting this information to HCFA. These requirements are necessary to establish a prospective payment system for HHAs and to achieve broad-based, measurable improvement in the quality of care furnished through Federal programs.

Frequency: As determined by HHA and monthly.

Affected Public: Business or other for profit, Not for profit institutions, Federal Government, and State, Local, or Tribal Government.

Number of Respondents: 8,200.

Total Annual Responses: 8,200.

Total Annual Hours: 996,368.

2. Type of Information Collection Request: Revision of a currently approved collection.

Title of Information Collection: Medicare and Medicaid Programs: Use of Outcome and Assessment Information Set (OASIS) as Part of the Conditions of Participation for Home Health Agencies (HCFA-3007-F) and Supporting Regulations in 42 CFR 484.55.

Form No.: HCFA-R-0245 (OMB# 0938-0760).

Use: These information collection requirements revise the existing conditions of participation that home health agencies (HHAs) must meet to participate in the Medicare program.

Specifically, this final rule requires that each patient receive from the HHA a patient-specific, comprehensive assessment that identifies the patient's need for home care and that meets the patient's medical, nursing, rehabilitative, social and discharge planning needs. In addition, this final rule requires that as part of the comprehensive assessment, HHAs use a standard core assessment data set, the OASIS, when evaluating adult, non-maternity patients. These changes are an integral part of the Administration's efforts to achieve broad-based improvements in the quality of care furnished through Federal programs and in the measurement of that care.

Frequency: Upon patient assessment.

Affected Public: Business or other for profit, Not for profit institutions, Federal Government, and State, Local, or Tribal Government.

Number of Respondents: 8,200.

Total Annual Responses: 8,200.

Total Annual Hours: 967,600.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: November 29, 1999.

John Parmigiani,

Acting HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00-518 Filed 1-7-00; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-9005-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—Second Quarter, 1999

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

ACTION: Notice.

SUMMARY: This notice lists HCFA manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published during April, May, and June of 1999, 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, C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244-1850, (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 Trenesha Fultz, Office of Communications and Operations Support, Division of Regulations and Issuances, Health Care Financing Administration, C5-12-08, 7500

Security Boulevard, Baltimore, MD 21244-1850, (410) 786-3822.

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, 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/nara/index.html>, 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, Part 1—Fiscal Administration (HCFA Pub. 13-1) transmittal entitled "General," use the Superintendent of Documents No. HE 22.8/6-3 and the HCFA transmittal number 129.

(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: December 21, 1999.

Elizabeth Cusick,

Director, Office of Communications and Operations Support.

Addendum I

This addendum lists the publication dates of the most recent quarterly listings of program issuances.

June 4, 1998 (63 FR 30499)
August 11, 1998 (63 FR 42857)
September 16, 1998 (63 FR 49598)
December 9, 1998 (63 FR 67899)
May 11, 1999 (64 FR 25351)
November 2, 1999 (64 FR 59185)
December 7, 1999 (64 FR 68357)

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 (57 FR 47468).

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS

[April 1999 through June 1999]

Trans. No.	Manual/Subject/Publication No.
Intermediary Manual Part 1—Fiscal Administration (HCFA Pub. 13-1) (Superintendent of Documents No. HE 22.8/6-3)	
129	<ul style="list-style-type: none"> • General. Instructions for Completing the HCFA-750A/B, Contractor Financial Reports. Due Date. Certification. Instructions for Completing the HCFA-751A/B, Status of Accounts Receivable. Line Item Instructions.
Intermediary Manual Part 2—Audits-Reimbursements Program Administration (HCFA Pub. 13-2) (Superintendent of Documents No. HE 22.8/6-2)	
412	<ul style="list-style-type: none"> • List of Medical Review Codes, Categories, and Conversion Factors.
Intermediary Manual Part 3—Claims Process (HCFA Pub. 13-3) (Superintendent of Documents No. HE 22.8/6)	
1773	<ul style="list-style-type: none"> • Screening Pap Smears and Screening Pelvic Examinations.
1774	<ul style="list-style-type: none"> • Prostate Cancer Screening Tests and Procedures.
1775	<ul style="list-style-type: none"> • Transmittal 1775 was omitted from the sequence and will never be released.
1776	<ul style="list-style-type: none"> • HCFA Common Procedure Coding System for Hospital Outpatient Radiology Services and Other Diagnostic Procedures.
1777	<ul style="list-style-type: none"> • Payment for Blood Clotting Factor Administered to Hemophilia Inpatients.
Carriers Manual Part 1—Fiscal Administration (HCFA Pub. 14-1) (Superintendent of Documents No. HE 22.8/7-2)	
123	<ul style="list-style-type: none"> • General. Instructions for Completing the HCFA-750B, Contractor Financial Reports. Due Date. Certification. Instructions for Completing the HCFA-751A/B, Status of Accounts Receivable. Line Item Instructions.
Carriers Manual Part 3—Claims Process (HCFA Pub. 14-3) (Superintendent of Documents No. HE 22.8/7)	
1631	<ul style="list-style-type: none"> • Area Carrier-Supplier's Services.
1632	<ul style="list-style-type: none"> • Correct Coding Initiative.
1633	<ul style="list-style-type: none"> • Positron Emission Tomography Scans.
.....	<ul style="list-style-type: none"> Conditions of Coverage of Positron Emission Tomography Scans for Recurrence of Colorectal Cancer, Staging and Characterization of Lymphoma, and Recurrence of Melanoma.
.....	<ul style="list-style-type: none"> Billing Requirements for Positron Emission Tomography Scans.
.....	<ul style="list-style-type: none"> HCFA Common Procedure Coding System and Modifiers for Positron Emission Tomography Scans.
.....	<ul style="list-style-type: none"> Claims Processing Instructions for Positron Emission Tomography Scan Claims.
1634	<ul style="list-style-type: none"> • Pancreas Transplants.
.....	<ul style="list-style-type: none"> Billing for Pancreas Transplants.
1635	<ul style="list-style-type: none"> • Transmittal number 1635 was omitted from the sequence and will never be released.
1636	<ul style="list-style-type: none"> • Chiropractors.
1637	<ul style="list-style-type: none"> • Prostate Cancer Screening Tests and Procedures.
1638	<ul style="list-style-type: none"> • Colorectal Cancer Screening.
1639	<ul style="list-style-type: none"> • Private Contracts Between Beneficiaries and Physician/Practitioners.
.....	<ul style="list-style-type: none"> General Rules of Private Contracts.
.....	<ul style="list-style-type: none"> Effective Date of the Opt Out Provision.
.....	<ul style="list-style-type: none"> Definition of Physician/Practitioners.
.....	<ul style="list-style-type: none"> When a Physician or Practitioner Opt's Out of Medicare.
.....	<ul style="list-style-type: none"> Definition of a Private Contract.
.....	<ul style="list-style-type: none"> Physician or Practitioner Who Has Never Enrolled in Medicare.
.....	<ul style="list-style-type: none"> The Relationship Between This Provision and Medicare Participation Agreements.
.....	<ul style="list-style-type: none"> Participating Physicians and Practitioners.
.....	<ul style="list-style-type: none"> Physicians or Practitioners Who Choose to Opt Out of Medicare.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April 1999 through June 1999]

Trans. No.	Manual/Subject/Publication No.
	Maintaining Information on Opt Out Physicians. Informing Managed Care Plans Who the Opt Out Physicians or Practitioners Are. Informing the National Supplier Clearinghouse Who the Opt Out Physicians or Practitioners Are. Organizations that Furnish Physician or Practitioner Services. Private Contracting Rules When Medicare is the Secondary Payer. System Identification. Emergency and Urgent Care Situations. Denial of Payment to Employers of Opt Out Physicians and Practitioners. Denial of Payment to Beneficiaries and Others. Payment of Medically Necessary Services Ordered or Prescribed By an Opt Out Physician or Practitioner. Mandatory Claims Submission. Claims Denial Notices to Opt Out Physicians and Practitioners. Claims Denial Notices to Beneficiaries. Effect of Beneficiary Agreements Not to Use Medicare Coverage. When Payment May Be Made to a Beneficiary for Service of an Opt Out Physician or Practitioner. Requirements of a Private Contract. Requirements of the Opt Out Affidavit. Failure to Properly Opt Out. Failure to Maintain Opt Out. Actions to be Taken in Cases of Failure to Maintain Opt Out. Non-Participating Physicians or Practitioners Who Opt Out of Medicare. Excluded Physicians and Practitioners. Relationship to Non-Covered Services. The Difference Between Advance Beneficiary Notices. Registration and Identification of Physicians or Practitioners Who Opt Out. Definition of Emergency and Urgent Care Situations. Renewal of Opt Out. Early Termination of Opt Out. Appeals. Application to Medicare+Choice Contracts. Reporting.
1640	• Bone Mass Measurements.
1641	• Medicare Participating Physician or Supplier Agreement.

Carriers Manual
Part 4—Professional Relations
(HCFA Pub. 14-4)
(Superintendent of Documents No. HE 22.8/7)

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

A-99-13	• Reopenings for Sole Community Hospital and Medicare Dependent Hospital Cost Reports Due to the Change to the Cost Report Instructions in Calculating the Hospital-Specific Amount on Form HCFA-2552-96 and Form HCFA-2552-92.
A-99-14	• Positron Emission Tomography Scans.
A-99-15	• Cryosurgery of the Prostate Gland.
A-99-16	• Claims Processing Instructions for Pancreas Transplantation.
A-99-17	• Claims Processing Instructions for Cost Outlier Bills With Benefits Exhausted.
A-99-18	• Clarification of Provider Cost Report Filing Requirements.
A-99-19	• Removal of Edits Requiring Providers to Submit Home Health Claims in Sequence.
A-99-20	• Payment Safeguard Review of Skilled Nursing Facility Prospective Payment Bills.
A-99-21	• Claims Processing Instructions for Hospice Claims Received Out of Sequence.
A-99-22	• Intermediary Review of Hospital Admission Questionnaires.
A-99-23	• Managed Care Electronic Data Interchange Enrollment Form.
A-99-24	• Policy Clarifications: Provider-Based Designation.
A-99-25	• Extended Repayment Schedules for Home Health Agencies Affected by the Interim Payment System.
A-99-26	• Extension of Due Date for Filing Provider Cost Reports.
A-99-27	• Home Health Agency Surety Bond Requirements.
A-99-28	• Surety Bonds From Home Health Agencies.
A-99-29	• Provider Education Information for Home Health Agencies—Regional Home Health Intermediaries Only.
A-99-30	• Provider Education Information for Home Health Agencies—Regional Home Health Intermediaries Only.

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

B-99-13	• Changes to Correct Coding Edits, Version 5.2, Effective July 1, 1999.
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ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued
[April 1999 through June 1999]

Trans. No.	Manual/Subject/Publication No.
B-99-14	• Reviewing Reassignment Agreements of Five or More.
B-99-15	• Returns From Year 2000 Mailing.
B-99-16	• Discontinuing the Use of Modifiers for Processing of Claims for Nurse Practitioners, Physician Assistants, and Clinical Nurse Specialists.
B-99-17	• Establishment of Temporary National Modifiers to Allow Monitored Anesthesia Care for Complex, Complicated, or Markedly Invasive Surgical Procedures and for At Risk Patients.
B-99-18	• Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Medicare Approved Ambulatory Surgical Centers.
B-99-19	• Extraction of HCFA Form-484 Certificate of Medical Necessity Data.
B-99-20	• Durable Medical Equipment Regional Carriers Processing Claims When a Chiropractor is the Supplier.
B-99-21	• Establishment of Four Temporary National "K" Codes as Part of Planned Changes to the Durable Medical Equipment Regional Carriers Medical Review Policy on Respiratory Assist Devices.
B-99-22	• Correction of the Published National Standard Format Mapping for Remittance Advice.
B-99-23	• Issues Involving Certificates of Medical Necessity and Cover Letters for Certificates of Medical Necessity.
B-99-24	• Changes to the 1999 Medicare Physician Fee Schedule Database.
B-99-25	• Billing for Mammography Screening: Delay in Carrier Implementation and Coding Clarification—Implementation of the GH Modifier.
B-99-26	• Claims Processing Instructions for Cryosurgery of the Prostate Gland.
B-99-27	• Consent Settlement for Medical Review Audits.
B-99-28	• Correction to Change Request 888 to Provide Changes to the 1999 Medicare Physician Fee Schedule Database.

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

AB-99-12	• Coverage of Testing for Hepatitis C in Patients Exposed to Infected Blood.
AB-99-13	• Notification to Medicare Providers and Suppliers of Beneficiary Right to an Itemized Statement.
AB-99-14	• New Waived Tests.
AB-99-15	• Medicare Coverage of Abortion Services.
AB-99-16	• Changes to the FY 1999 Hospital Inpatient Operating Prospective Payment System Wage Index Geographic and Standardized Amounts, and Capital Prospective Payment System Adjustment Factors and Federal Rates.
AB-99-17	• Extension of the Limitation on Payment for Services to Individuals Entitled to Benefits on the Basis of End Stage Renal Disease Who Are Covered by Group Health Plans.
AB-99-18	• Promoting Influenza and Pneumococcal Vaccinations.
AB-99-19	• Expanded Implementation of the Office of the Inspector General's Fraud Hotline Number on Medicare Beneficiary Notices, Effective July 1, 1999.
AB-99-20	• Limited Medicare Coverage and Billing Instructions for Enhanced External Counterpulsation.
AB-99-21	• Claims Processing Instructions for Hyperbaric Oxygen Therapy.
AB-99-22	• Transmyocardial Revascularization for Treatment of Severe Angina.
AB-99-23	• Reimbursement for Ambulance Services to Non-hospital-Based Dialysis Facilities.
AB-99-24	• Y2K—Data Match/MPARTS Mailout Record Layout.
AB-99-25	• Beneficiary Right to Itemized Statement.
AB-99-26	• Procedures for Write-Off and Adjustment/Reclassification of Medicare Contractor NON-Medicare Secondary Payer Accounts Receivable.
AB-99-27	• Implementation of Calendar Year 2000 Fee Schedules and Pricing Updates.
AB-99-28	• HCFA-1522, Monthly Contractor Financial Report, Reconciliation.
AB-99-29	• Notice of New Interest Rate for Medicare Overpayments and Underpayments.
AB-99-30	• Implementation of §4105 of the Balanced Budget Act Regarding Coverage of Diabetes Outpatient Self-Management Training Services.
AB-99-31	• Assisted Suicide Funding Restriction Act of 1997 (P.L. 105-12).
AB-99-32	• Claims Processing Instructions for Hyperbaric Oxygen Therapy.
AB-99-33	• Tracking and Reporting Procedures for Unsolicited/Voluntary Refund Checks from Providers/Suppliers-Interim Instructions.
AB-99-34	• Intermediary and Carrier Billing and Claims Processing Instructions for Magnetic Resonance Angiography.
AB-99-35	• Current Status of Medicare Program Memoranda Issued Before Calendar Year 1999.
AB-99-36	• Reserved for Y2K Contingency Planning Instructions.
AB-99-37	• Reserved for Y2K Contingency Planning Instructions.
AB-99-38	• Reserved for Y2K Contingency Planning Instructions.
AB-99-39	• Reserved for Y2K Contingency Planning Instructions.
AB-99-40	• Reserved for Y2K Contingency Planning Instructions.
AB-99-41	• Reserved for Y2K Contingency Planning Instructions.
AB-99-42	• Reserved for Y2K Contingency Planning Instructions.
AB-99-43	• Reserved for Y2K Contingency Planning Instructions.
AB-99-44	• Reserved for Y2K Contingency Planning Instructions.
AB-99-45	• Reserved for Y2K Contingency Planning Instructions.
AB-99-46	• Coverage of Diabetes Outpatient Self-Management Training Services, Effective: July 1, 1998.
AB-99-47	• New Waived Tests—Effective Date of Receipt.
AB-99-48	• Medicare Secondary Payer Denial Indicator and the Source Code Changes.
AB-99-49	• Medicare Travel Allowance Fees for Collection of Specimens.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April 1999 through June 1999]

Trans. No.	Manual/Subject/Publication No.
Program Memorandum Medicaid State Agencies (HCFA Pub. 17) (Superintendent of Documents No. HE 22.8/6-5)	
99-2	• Current Status of Medicaid Program Memoranda and Action Transmittals Issued Before Calendar Year 1999.
99-3	• Title XIX of the Social Security Act, Elimination of Waste, Fraud and Abuse.
Program Memorandum Regional Offices—Standards and Certification (HCFA Pub. 54) (Superintendent of Documents No. HE 22.28/5:90-1)	
99-1	• Civil Monetary Penalty Collection Procedures.
State Operations Manual Provider Certification (HCFA Pub. 7) (Superintendent of Documents No. HE 22.8/12)	
8	• Resident Assessment in Long Term Care Facilities.
9	• Medicare Rural Hospital Flexibility Program.
Peer Review Organization Manual (HCFA Pub. 19) (Superintendent of Documents No. HE 22.8/8-15)	
71	• Critical Access Hospital Acute Care Inpatient Stays Review.
72	• Introduction. Staffing Functions. Mandatory System Use. Operations. Communication. Confidentiality of System. Applicable Documentation. Process for Moving. Standard Data Processing System Engineering Review Board Process-Approved Software and Hardware. Hardware Maintenance Process.
73	• Standard Data Processing System Data Management Plan. Request for Information Model Cover Letter. Request for Information Model Form. Final Response to Inquirer Model Notice (Concern Involved Practitioner). Final Response to Inquirer Model Notice (Concern Involved Provider (Facility)). Beneficiary Complaint Timetable for Retrospective Review (Fee-for-Service and Managed Care).
Beneficiary Complaint Timetable for Concurrent Review (Fee-for-Service and Managed Care). Hospital Manual (HCFA Pub. 10) (Superintendent of Documents No. HE 22.8/2)	
742	• Screening Pap Smears and Screening Pelvic Examinations.
743	• Payment for Blood Clotting Factor Administered to Hemophilia Inpatients.
744	• Coding for Adequacy of Hemodialysis.
End Stage Renal Disease Network Organizations Manual (HCFA Pub. 81) (Superintendent of Documents No. HE 22.9/4)	
9	• Background. Definition. Requirements. Disagreements. HCFA Office of Clinical Standards and Quality Requirements. Statutory and Regulatory Requirements. Office of Management and Budget Clearance. Items Not Subject to Office of Management and Budget Clearance. Request for Exception from Office of Management and Budget Review. Survey Justification and Methods. Additional Considerations. Documentation for HCFA.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued
[April 1999 through June 1999]

Trans. No. Manual/Subject/Publication No.

**Coverage Issues Manual
(HCFA Pub. 6)
(Superintendent of Documents No. HE 22.8/14)**

- 109 • Cardiac Output Monitoring by Electrical Bioimpedance.
Prostate Cancer Screening Tests.
- 110 • Transmyocardial Revascularization for Treatment of Severe Angina.
Cryosurgery of the Prostate.
- 111 • Enhanced External Counterpulsation.
- 112 • Hyperbaric Oxygen Therapy.
- 113 • Positron Emission Tomography Scans.
- 114 • Vagus Nerve Stimulation for the Treatment of Seizures.
- 115 • Pancreas Transplants.
Implantation of Automatic Defibrillators.
- 116 • Home Use of Oxygen.
- 117 • Magnetic Resonance Angiography.

**Provider Reimbursement Manual—Part 2
Provider Cost Reporting Forms and Instructions
Chapter 36—Form HCFA-2552-96
(HCFA Pub. 15-2-36)
(Superintendent of Documents No. HE 22.8/4)**

- 5 • Hospital and Hospital Health Care Complex Cost Reporting Form.

**Provider Reimbursement Manual—Part 2
Provider Cost Reporting Forms and Instructions
Chapter 38—Form HCFA-1984-99
(HCFA Pub. 15-2-38)
(Superintendent of Documents No. HE 22.8/4)**

- 1 • Hospice Cost Reporting Form.

**Medicare/Medicaid
Sanction—Reinstatement Report
(HCFA Pub. 69)**

- 99-3 • Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated-February 1999.
- 99-4 • Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated-March 1999.
- 99-5 • Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated-April 1999.
- 99-6 • Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated-May 1999.

ADDENDUM IV.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER

Publication Date	FR Vol. 64 Page	CFR ¹ Part(s)	File Code ²	Regulation title	End of comment period	Effective date
04/08/99	17184-17185	HCFA-1071-N	Medicare Program; April 23, 1999, Open Town Hall Meeting to Discuss the Skilled Nursing Facility Prospective Payment System (SNF/PPS) and Quality of Care in Nursing Facilities.	
04/26/99	21196-21301	21 CFR Ch. 1; 42 CFR Chs. I-V; and 45 CFR Subtitle A, Chs. II, III, and XIII.	Unified Agenda of Federal Regulatory and Deregulatory Actions.	
04/27/99	22619-22626	HCFA-3432-GN	Medicare Program; Procedures for Making National Coverage Decisions.	06/28/99
05/03/99	23653-23654	HCFA-1101-N2	Medicare Program; Meetings of the Competitive Pricing Demonstration Area Advisory Committee, Maricopa County, AZ.	

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

Publication Date	FR Vol. 64 Page	CFR ¹ Part(s)	File Code ²	Regulation title	End of comment period	Effective date
05/07/99	24550-24551	42 CFR Part 405.	HCFA-1002-N	Medicare Program; Meetings of the Negotiated Rule-making Committee on Ambulance Fee Schedule.	
05/07/99	24716-24864	412, 413, 483, and 485.	HCFA-1053-N	Medicare Program; Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2000 Rates.	07/06/99.	
05/10/99	24956-24957	498	HCFA-3139-F	Medicare Program and Medicaid Programs; Effective Dates of Provider Agreements and Supplier Approvals; Correction.	09/17/97
05/11/99	25351-25359	HCFA-9000-N	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances-Third Quarter, 1998.	
05/12/99	25456-25460	405, 410, 413, 414, 415, 424, and 485.	HCFA-1006-CN	Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1999; Correction.	01/01/99
05/14/99	26426-26427	HCFA-1072-N	Medicare Program; June 14, 1999, Meeting of the Practicing Physicians Advisory Council.	
05/28/99	29186-29188	45 CFR Subtitle A.	Coverage for Breast Reconstruction and Related Services After a Mastectomy.	06/28/99.	
06/04/99	30042-30043	HCFA-1075-N	Medicare Program; June 25, 1999, Public Meeting To Discuss the Payment Classification for Respiratory Assist Devices.	
06/09/99	31006-31007	HCFA-1080-N	Medicare Program; Meeting of the Competitive Pricing Demonstration Area Advisory Committee, Maricopa County, AZ.	
06/10/99	31281-31282	HCFA-1081-N	Medicare Program; June 24, 1999, Meeting of the Competitive Pricing Advisory Committee and the Area Advisory Committee for the Kansas City Metropolitan Area.	
06/15/99	31995-32021	412, 413, 483, and 485.	HCFA-1053-CN	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2000 Rates; Correction.	
06/16/99	32198-32206	416	HCFA-3831-F	Medicare Program; Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers.	07/16/99
06/18/99	32881-32886	HCFA-2039-FN	Medicare Program; Recognition of the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) for Hospices.	06/18/99-06/18/03
06/18/99	32983-32991	HCFA-3020-N	Medicare and Medicaid Programs; Mandatory Use, Collection, Encoding, and Transmission of Outcome and Assessment Information Set (OASIS) for Home Health Agencies.	07/19/99

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

Publication Date	FR Vol. 64 Page	CFR ¹ Part(s)	File Code ²	Regulation title	End of comment period	Effective date
06/18/99	32992–32998	Privacy Act of 1974; Report of New System.	06/18/99 or 07/28/99
06/22/99	33314–33315	HCFA–1081–2N	Medicare Program; Cancellation of the June 24, 1999, Meeting of the Competitive Pricing Advisory Committee and the Area Advisory Committee for the Kansas City Metropolitan Area.		
06/30/99	35257–35513	409, 410, 411, 412, 413, 419, 489, 498, and 1003.	HCFA–1005–CN	Medicare Program; Prospective Payment for Hospital Outpatient Services; Correction; Proposed Rule.		

¹ 42 CFR except where noted.

² 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; GNC—General Notice 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.

G940094 A1
G940156 A1
G970104 A1
G970204 A1
G980179 A2
G980283 A1
G990056 A1
G990062 A2
G990071 A1

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

G980237 B2
G980258 B2
G980317 B1
G980329 B2
G990002 B2
G990013 B2
G990018 B2
G990027 B3
G990059 B3
G990063 B4
G990065 B4
G990072 B1

G990073 B
G990079 B2
G990081 B3
G990082 B2
G990086 B4
G990087 B4
G990088 B2
G990090 B4
G990091 B4
G990093 B2
G990095 B4
G990096 B3
G990098 B4
G990099 B2
G990106 B2
G990109 B4
G990115 B3
G990117 B1
G990119 B4
G990136 B3

[FR Doc. 00–505 Filed 1–7–00; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4565–N–04]

Notice of Proposed Information Collection: Comment Request; Request for Occupied Conveyance

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

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

DATES: *Comments Due Date:* March 10, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to; Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW, L'Enfant Plaza Building, Room 8202, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Joseph McCloskey, Director, Single Family Asset Management, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410, telephone (202) 708–1672 (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.