site. The purpose of this meeting is to provide a forum for community interaction and to serve as a vehicle for community concerns to be expressed as advice and recommendations to CDC and ATSDR.

Matters to be Discussed: Agenda items include Status of Stanford Cohen & Associates' Draft Report; INEEL Oversight Program of Food Products Grown Near the Aquifer; Presentation on Additional Food Products Grown Near the Aquifer; Overview of the Cancer Data Registry of Idaho and Minority Data; Progress Report on the National Institute for Occupational Safety and Health INEEL Cohort Data; Presentation of the Comprehensive Environmental Response, Compensation and Liability Act and the Relationship Between Maximum Contaminant Levels and Risk; Presentation on Fish as Bioconcentrators; and a Report on Other Activities at the Radiation Studies Branch. Agenda items are subject to change as priorities dictate.

For Further Information Contact: Ms. Natasha Friday, Executive Secretary, INEELHES, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, CDC, 1600 Clifton Road, NE (E–39), Atlanta, Georgia 30333, telephone (404) 498–1800, fax (404) 498–1811.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities for both CDC and ATSDR.

Dated: December 18, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 03–31663 Filed 12–23–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9019–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July 2003 Through September 2003

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from July 2003 through September 2003, relating to the Medicare and Medicaid programs. This notice provides information on national coverage determinations affecting specific medical and health care services under Medicare. Additionally, this notice identifies certain devices with investigational device exemption numbers approved by the Food and Drug Administration that potentially may be covered under Medicare. Finally, this notice also includes listings of all approval numbers from the Office of Management and Budget for collections of information in CMS regulations.

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, and to foster more open and transparent collaboration efforts, we are also including all Medicaid issuances and Medicare and Medicaid substantive and interpretive regulations (proposed and final) published during this 3-month time frame.

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. (*See* Section III of this notice for how to obtain listed material.)

Questions concerning items in Addendum III may be addressed to Karen Bowman, Office of Strategic Operations and Regulatory Affairs, Centers for Medicare & Medicaid Services, C5–16–03, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–5252.

Questions concerning national coverage determinations in Addendum V may be addressed to Patricia Brocato-Simons, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–0261.

Questions concerning Investigational Device Exemptions items in Addendum VI may be addressed to Sharon Hippler, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C5–13–27, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–4633.

Questions concerning approval numbers for collections of information in Addendum VII may be addressed to Dawn Willinghan, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Centers for Medicare & Medicaid Services, C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–6141.

Questions concerning all other information may be addressed to Gwendolyn Johnson, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Centers for Medicare & Medicaid Services, C5–12–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–6954.

SUPPLEMENTARY INFORMATION:

I. Program Issuances

The Centers for Medicare & Medicaid Services (CMS) 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 the two programs involves (1) Furnishing information to Medicare beneficiaries and Medicaid recipients, health care providers, and the public and (2) maintaining effective communications with regional offices, State governments, State Medicaid agencies, State survey agencies, various providers of health care, all Medicare contractors 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, statements of policy, 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, and to foster more open and transparent collaboration, we are continuing our practice of including Medicare substantive and interpretive regulations (proposed and final) published during the respective 3-month time frame.

II. How To Use the Addenda

This notice is organized so that a reader may review the subjects of manual issuances, memoranda,

substantive and interpretive regulations, national coverage determinations (NCDs), and Food and Drug Administration (FDA)-approved investigational device exemptions (IDEs) published during the subject quarter to determine whether any are of particular interest. We expect this notice 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 National Coverage Determination Manual (NCDM, formerly the Medicare Coverage Issues Manual (CIM)) may wish to review the August 21, 1989, publication (54 FR 34555). Those interested in the revised process used in making NCDs under the Medicare program may review the September 26, 2003, publication (68 FR 55634).

To aid the reader, we have organized and divided this current listing into six 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 CMS Medicare and Medicaid manuals and memoranda.
- Addendum III lists a unique CMS transmittal number for each instruction in our manuals or Program Memoranda and its subject matter. A transmittal may consist of a single or multiple instruction(s). 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; and
- Title of the regulation.
- Addendum V includes completed NCDs, or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCDM (or CIM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision.
- Addendum VI includes listings of the FDA-approved IDE categorizations, using the IDE numbers the FDA 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 IDE number.
- Addendum VII includes listings of all approval numbers from the Office of Management and Budget (OMB) for collections of information in CMS regulations in title 42; title 45, subchapter C; and title 20 of the CFR.

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, most manuals are available at the following Internet address: *http://cms.hhs.gov/manuals/default.asp*.

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.gpoaccess.gov/fr/index.html*, by using local WAIS client software, or by telnet to *swais.gpoaccess.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 CMS 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 CMS Home Page. The Internet address is *http://cms.hhs.gov/rulings*.

D. CMS'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.
- CMS-related regulations.
- CMS manuals and monthly revisions.
- CMS program memoranda.

The titles of the Compilation of the Social Security Laws are current as of January 1, 1999. (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 CMS publication are shown in Addendum III, along with the CMS publication and transmittal numbers. To help FDLs locate the materials, use the Superintendent of Documents number, plus the transmittal number. For example, to find the Hospice Manual, (CMS Pub. 21) transmittal entitled ''Payment of Amounts Owed Medicare,'' use the Superintendent of Documents No. HE 22.8/18 and the transmittal number 69.

(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 2, 2003.

Jacquelyn Y. White,

Director, Office of Strategic Operations and Regulatory Affairs.

Addendum I

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

November 2, 1999 (64 FR 59185)
December 7, 1999 (64 FR 68357)
January 10, 2000 (65 FR 1400)
May 30, 2000 (65 FR 34481)
June 28, 2002 (67 FR 43762)
September 27, 2002 (67 FR 61130)
December 27, 2002 (67 FR 79109)
March 28, 2003 (68 FR 15196)
June 27, 2003 (68 FR 38359)
September 26, 2003 (69 FR 55618)

Addendum II—Description of Manuals, Memoranda, and CMS 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 former CIM (now the NCDM) 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 2003 through September 2003]

Transmittal No.	Manual/Subject/Publication No.
	Intermediary Manual
	Part 3—Audits, Reimbursement Program Administration (CMS–Pub. 13–3) (Superintendent of Documents No. HE 22.8/6)
1892	• Frequency of Billing Provider Education
1893	• Release Software
1894	• Review of Form CMS–1450 (previously Form HCFA–1450) for Inpatient and Outpatient Bills
1895	• Diabetes Outpatient Self-Management Training Services
1896	• Mammography Screening Diagnostic Mammography Diagnostic and Screening Mammography Performed With New Technologies Mammography Billing Charts for Billing for Computer Aided Detection Devices Common Working File Application of Age and Frequency Edits Hospital Outpatient Partial Hospitalization Services
1897	• 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 Definitions Retroactive Implementation Processing Claims Determining the 30-Month Coordination Period During Which Medicare May Be Secondary Payer Effect of Dual Entitlement Subsequent Periods of End-Stage Renal Disease Eligibility or Entitlement Amount of Secondary Medicare Payments Where Group Health Payments in Part for Items and Services Limitation on Right of Provider or Facility to Charge a Beneficiary Responsibility of Provider/Providers of Service and Renal Dialysis Facilities Action When Group Health Payments Erroneously Pay Primary Benefits Referral to Regional Offices of Cases Involving Taking Into Account Medicare Eligibility or Entitlement and Benefit Differentiation During Coordination Period Claimant's Right To Take Legal Action Against a Group Health Plan Medical Services Furnished to End-Stage Renal Disease Beneficiaries by Source Outside Group Health Plan Managed Care Plan Limitations on Payment for Services to Aged Beneficiaries Who are Covered by a Group Health Plan on the Basis of Current Employment Status Definitions Individuals Subject to Limitation on Payment, General Individuals Not Subject to Limitation on Payment, General Identification of Cases by Providers of Services Identification of Cases and Action Where There Is Indication of Possible Group Health Plan Coverage Action by Provider Where Medicare Is Secondary to Group Health Plan Limitation on Right of Provider or Facility to Charge a Beneficiary

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 2003 through September 2003]

Transmittal No.		Manual/Subject/Publication No.
		Employer Plan Denies Claim for Primary Benefit
		Referral of Cases to Regional Offices
		Recovery of Mistaken Primary Medicare Payments
		Advice to Providers, Physicians, and Beneficiaries
		Mistaken Group Health Plan Primary Payments
		Claimant's Right to Take Legal Action Against a Group Health Plan
		Special Rules for Services Furnished by Source Outside Group Health Plan
		Managed Care Health Plan
		Medicare as Secondary Payer for Disabled Individuals
1898	•	Payment for Services Furnished by a Critical Access Hospital
		Carriers Manual
		Part 3—Program Administration
		(CMS Pub. 14–3) (Superintendent of Documents No. HE 22.8/7)
1808	•	Mandatory Assignment and Participation Program
		Participation Program
		Limiting Charge
1809	•	Durable Medical Equipment Regional Carriers—Billing Procedures Related to Advance Beneficiary Notice Upgrades
		Providing Upgrades of Durable Medical Equipment Prosthetic, Orthotics, and Supplies Without Any Extra Charge
1810	•	Payment for Physician Services Furnished to Dialysis Inpatients
		Dialysis Services (Codes 90935–90999)
1811	•	Release Software
		Contractor Testing Requirements
1812	•	Definitions of Lines 1 through 115
		Checking Reports
		Exhibits
1813	•	Data Element Requirements
		Payment to Physician for Purchased Diagnostic Tests
		Area Carriers—Physician's Services
		Payment Jurisdiction for Services Paid Under the Physician Fee Schedule and Anesthesia Services
		Claims Processing Instructions for Payment Jurisdiction for Claims Received On or After April 1, 2004
		Payment Jurisdiction for Purchased Services
		Jurisdiction for Shipboard Services
		Exceptions to Jurisdictional Payment
		Exhibit 10
		Items 14–33 Physician or Supplier Information
1814	•	Screening Mammography Examinations
		Identifying a Screening Mammography Claim and a Diagnostic Mammography Claim
		Adjudicating the Claim
		Diagnostic and Screening Mammograms Performed With New Technologies
1815	•	Repairs, Maintenance, Replacement, and Delivery
1816	•	Correct Coding Initiative
1817	•	Medicare Secondary Payment General Provisions
		Third Party Payer Pays Charges in Full
		Physician, Supplier, or Beneficiary Bills Medicare for Primary Benefits
		Multiple Insurers
		Third Party Payer Pays Primary Benefits When Not Required
		Right of Physician or Supplier to Charge Beneficiary
		General
		Definitions
		Current Employment Status
		Employer-Sponsored Managed Care Health Plan
		Nonconforming Group Health Plan
		Recovery of Mistaken Primary Medicare Payments
		Advice to Physicians/Suppliers and Beneficiaries
		Mistaken Group Health Plan Primary Payments
		Claimant's Right to Take Legal Action Against a Group Health Plan
		Special Rules for Services Furnished by Source Outside Group Health Plan
		Managed Care Health Plan
		Medicare Secondary Payer Provisions for Working Aged Individuals
		Individual Not Subject to Medicare Secondary Payer Provision
		Exception for Small Employers in Multi-Employer and Multiple Employer Group Health Plan
		Dually Entitled Individuals
		General
		Individuals Not Subject to Medicare Secondary Payer Provision
		Items and Services Furnished On or After January 1, 1987 and Before August 10, 1993 (Date of Enactment of Omnibus Budget Reconciliation Act of 1993)
1818	•	Filing the Request for Payment
1819	•	Special Requirements for Claims for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 2003 through September 2003]

Transmittal No.		Manual/Subject/Publication No.
1820	•	Medicare Physician Fee Schedule Database 2004 File Layout Maintenance Process for the Medicare Physician Fee Schedule Database
		Carriers Manual Part 4—Professional Relations (CMS Pub. 14–4) (Superintendent of Documents No. HE 22.8/7–4)
28	•	Provider of Services or Supplier Information
		Program Memorandum Intermediaries (CMS Pub. 60A) (Superintendent of Documents No. HE 22.8/6–5)
A–03–057	•	Medicare Program-Update to the Hospice Payment Rates, Hospice Cap, Hospice Wage Index and the Hospice for Fiscal Year 2004
A–03–058	•	Change in Methodology for Determining Payment for Outliers Under the Acute Care Hospital Inpatient and Long-Term Care Hospital Prospective Payment System
A–03–059	•	Addition of Patient Status Code 43, Deletion of Patient Status Codes 71 and 72, and Information on New Patient Status Code 65
A–03–060	•	Medicare Program—Update to the Prospective Payment System for Home Health Agencies for Fiscal Year 2004
A–03–061	•	Tentative Settlement Requirements for Cost Reports from Home Health Agencies and Skilled Nursing Facilities That Have No Reimbursement Impact
A–03–062	•	Department of Veterans Affairs Claims Adjudication Services Project System Changes Needed
A–03–063	•	Installation of Version 30 of the Provider Statistical and Reimbursement Reporting System
A–03–064	•	X12N 837 Institutional Health Care Claim Companion Document
A–03–065	•	New Common Working File Edits to Ensure Accurate Coding and Payments for Discharge and/or Transfer Policies Under the Inpatient Prospective Payment System
A–03–066	•	Hospital Outpatient Prospective Payment System Implementation Instructions
A–03–067	•	The Supplemental Security Income Medicare Beneficiary Data for Fiscal Year 2002 for Inpatient Prospective Payment System Hospitals
A–03–068	•	Informing Beneficiaries About Which Local Medical Review Policy and/or National Coverage Determination Is Associated With Their Claim Denial
A–03–069	•	October Outpatient Code Editor Specification Version (V4.3)
A–03–070	•	Inclusion of the State of New York in Demonstration for Settlement of Payments for Home Health Services to Dual Eligibles and Instructions for Processing Fiscal Year 2000 Claims Under the Demonstration. Regional Home Health Intermediaries Only.
A–03–071	•	Retroactive Correction of Provider Statistical and Reimbursement System Report Data Related to Mammography and Outpatient Therapy Services
A–03–072	•	Instructions for Provider Credit Balance Reporting Related Activities
A–03–073	•	Fiscal Year 2004 Inpatient Prospective Payment System, Long Term Care Hospital, and Other Billing Changes
A–03–074	•	Inpatient Rehabilitation Facility Annual Update: Prospective Payment System Pricer Changes for Fiscal Year 2004
A–03–075	•	Medicare Part A Skilled Nursing Facility Prospective Payment System Update
A–03–076	•	October 2003 Update of the Hospital Outpatient Prospective Payment System
A–03–077	•	October Medicare Outpatient Code Editor Specification Version 19.0 for Bills From Hospitals That Are Not Paid Under the Outpatient Prospective Payment System
A–03–078	•	Reimbursement for Automated Multi-Channel Chemistry Tests for End-Stage Renal Disease Beneficiaries
A–03–079	•	Installation of Version 31 of the Provider Statistical and Reimbursement Reporting System
A–03–080	•	End-Stage Renal Disease Reimbursement for Automated Multi-Channel Chemistry Test
A–03–081	•	Conflicting Policies With Provider Reimbursement Manual 15–1, Section 2771
A–03–082	•	Clarification for Billing Under the 2300 Provider Number by Hospital-Based Renal Dialysis Facilities
		Program Memorandum Carriers (CMS Pub. 60B) (Superintendent of Documents No. HE 22.8/6–5)
B–03–050	•	Multiple Primary Payers on Part B Claims-Revision to Change Request 2050
B–03–051	•	Therapy Modifier Bypass for Ambulance Claims
B–03–052	•	Addition of Temporary ''Q'' Codes for Drugs Used in Infusion Pumps
B–03–053	•	Healthcare Provider Taxonomy Codes Crosswalk
B–03–054	•	Establishing and Maintaining Provider and Supplier Enrollment Data in Provider kEnrollment, Chain and Ownership System as Needed for Use By the Railroad Medicare Carrier to Pay Claims
B–03–055	•	Common Working File crossover Editing for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Claims During an Inpatient Stay
B–03–056	•	Durable Medical Equipment Regional Carriers—Additional Instructions for Health Insurance Portability and Accountability Act Implementatyion on National Drug Codes and the National Council of Prescription Drug Programs
B–03–057	•	Additional Guidelines for Implementing the National Council for Prescription Drug Program Format
B–03–058	•	Procedures for the Reconciliation of Total Funds Expended for Multi-Carriers Systems Medicare Contractors Used in the Preparation of Form CMS–1522, Monthly Contractor Financial Report

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 2003 through September 2003]

Transmittal No.	Manual/Subject/Publication No.
B–03–059	• Minimum Number of Pricing Files That Must Be Maintained Online for Medicare Single Drug Pricer
B–03–060	• Expansion of Beneficiary History and Claims in Process Files in the Voucher Insurance Plan Viable Medicare System. Phase 2—Adjudication Claims in Process File Expansion
B–03–061	• Durable Medical Equipment Regional Carriers National Council of Prescription of Drug Programs Crosswalk Requirements
B–03–062	• Procedures for Non-Medicare Secondary Payer Overpayments With Original Balance Less than $10
B–03–063	• Healthcare Provider Taxonomy Codes Crosswalk
B–03–064	• Clarification—ICD–9 Coding
B–03–065	• Changes to Code List for Therapy Services
B–03–066	• Durable Medical Equipment Regional Carriers—Eliminate Combined Working File Edit for Cancer Diagnosis for National Drug Codes
B–03–067	• National Council for Prescription Drug Programs Batch Transmittal Standard 1.1 Billing Request Companion Document
B–03–068	• 2004 Annual Update for Skilled Nursing Facility Consolidated Billing for the Common Working File and Medicare Carriers
B–03–069	• Schedule for Completing the Calendar Year 2004 Fee Schedule Updates and the Participating Physician Enrollment Procedures
	Program Memorandum Intermediaries/Carriers (CMS Pub. 60A/B) (Superintendent of Documents No. HE 22.8/6–5)
AB–03–094	• October 2003 Quarterly Updates for Skilled Nursing Facility Consolidated Billing
AB–03–095	• Remittance Advice Remark and Reason Code Update
AB–03–096	• Quarterly Update of Healthcare Common Procedure Coding System Codes Used for Home Health Consolidated Billing Enforcement
AB–03–097	• Delay in Implementation of Outpatient Therapy Caps to September 1, 2003
AB–03–098	• Medicare Summary Notice Implementation for Contractors Using Arkansas Part A Standard System and HCFA Part B Standard System
AB–03–099	• Instructions for Fiscal Intermediary Standard System and Multi-Carriers System Healthcare Integrated General Ledger Accounting System Changes
AB–03–100	• October Quarterly Update for 2003 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Fee Schedule
AB–03–101	• Clarification for CR 2562: Collection of Fee-for-Service Payments Made During Periods of Managed Care Enrollment
AB–03–102	• Clarifications Regarding Coverage of Hyperbaric Oxygen Therapy for the Treatment of Diabetic Wounds of the Lower Extremities
AB–03–103	• Medicare Secondary Payer Debt Referral and Write-Off Closed Instructions
AB–03–104	• Changes to the Laboratory National Coverage Determination Edit Software for October 1, 2003
AB–03–105	• Harkin Grantees: Complaint Tracking System and Aggregate Reports
AB–03–106	• Third Clarification of Medicare Policy Regarding the Implementation of the Ambulance Fee Schedule
AB–03–107	• Federal Bankruptcy/State Insurer Liquidation Actions and Medicare Secondary Payer Debt
AB–03–108	• Medicare Secondary Payer—(1) Use of Inter-Contractor Notices and the Common Working File for the Development of the Medicare Secondary Payer Conditional Payment Amount for Liability, No-Fault, Worker's Compensation, and Federal Tort Claims Act Cases; (2) Reminder Regarding Termination Updates to the Common Working File; (3) Reminder Regarding Savings Information to Non-Lead Contractors
AB–03–109	• Discontinue Use of the Healthcare Integrity and Protection Data Bank for Provider Enrollment Only
AB–03–110	• Adjustment to the Rural Mileage Payment Rate for Ground Ambulance Services
AB–03–111	• Shared System Maintainer Hours for Resolution of Problems Detected During Health Insurance Portability and Accountability Act Transaction Release Testing
AB–03–112	• Transmittal AB–03–112 Has Been Rescinded
AB–03–113	• Update of Codes in the Program Integrity Management Reporting System and the Contractor Administrative Cost and Financial Management System
AB–03–114	• Claims Processing and Payment of Incomplete Screening Colonoscopies
AB–03–115	• Payment Denial for Medicare Services Furnished to Alien Beneficiaries Who Are Not Lawfully Present in the United States
AB–03–116	• Update of Rates and Wage Index for Ambulatory Surgical Center Payment Effective October 1, 2003
AB–03–117	• Contractor Guidance for Connection to the Medicare Data Communication Network for Real-time Eligibility Inquiries (270/271) Via a Route Other Than Insurance Value-Added Network Services
AB–03–118	• Cease Further Work on the Eligibility File-Based Standard Trading Partner Agreement for the Purpose of Coordination of Benefits
AB–03–119	• Final Update to the 2003 Medicare Physician Fee Schedule Database
AB–03–120	• Medicare Secondary Payer—(1) Copy of Recovery Demand Packages Resulting From a Data Match or Non-Data Match Group Health Plan Recovery Action to Insurers/Third Party Administrators of Employers; (2) Documentation Required When an Insurer/Third Party Administrator Wishes to Resolve a Debt on Behalf of Its Client, an Employer Debtor
AB–03–121	• Requirement to Cross Claims Over to Multiple Supplemental Insurers
AB–03–122	• Notice of Interest Rate for Medicare Overpayments and Underpayments
AB–03–123	• Scheduled Release for October Updates to Software Programs and Pricing/Coding Files
AB–03–124	• Standard System Automation of the Notice of Change to Medicare Secondary Payer Auxiliary File Process
AB–03–125	• Consolidation of Claims Cross-Over Process
AB–03–126	• Change in Type of Service for L04080
AB–03–127	• Payment for Fecal Leukocyte Examination Under Clinical Laboratory Improvement Amendments of 1988 Certificate for Provider-Performed Microscopy Procedures During Calendar Year 2003

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 2003 through September 2003]

Transmittal No.	Manual/Subject/Publication No.
AB–03–128	• Clarification to Transmittal AB–03–044 (CR 2611), Addition of New Temporary ''K'' Codes
AB–03–129	• Addition of Three New International Classifications of Diseases, Ninth Revision, Clinical Modification Diagnosis Codes To Be Effective as Part of the October 1, 2003, International Classification of Diseases, Clinical Update
AB–03–130	• Levocarnitine for Use in the Treatment of Carnitine Deficiency in End-Stage Renal Disease Patients
AB–03–131	• Update to Health Care Claims Status Category Codes and Health Care Claim Status Codes for Use With the Health Care Claim Status Request and Response ASCX12N 276/277
AB–03–132	• Provider Education Article: Guidelines for Medicare Part B Laboratory Testing
AB–03–133	• Managing Medicare Appeals Workloads in Fiscal Year 2004
AB–03–134	• Modifier and Condition Code for Providers to Use When Billing for Implantable Automatic Defibrillators for Beneficiaries in Medicare+Choice Plan
AB–03–135	• Darbepoetin Alfa (Trade Name Aranesp) and Epoetin Alfa (Trade Name Epogen) for Treatment of Anemia in End-Stage Renal Disease Patients on Dialysis
AB–03–136	• Correction to Quarterly Update of Health Care Common Procedure Coding System Codes Used for Home Health Consolidated Billing Enforcement
AB–03–137	• Update of Home Care Common Procedure Coding System Codes and Payment for Ambulatory Surgical Centers and File Names, Descriptions and Instructions for Retrieving the 2004 Ambulatory Surgical Center Home Health Care Common Procedure Coding System Additions, Deletions, and Master Listing
AB–03–138	• Modification of Medicare Policy for Erythropoietin
AB–03–139	• Appeals Quality Improvement and Data Analysis Activities
AB–03–140	• 2004 Healthcare Common Procedure Coding System Annual Update Reminder
AB–03–141	• CMS Companion Document for the Accredited Standards Committee X12N276/277 Health Care Claim Status Request and Response
AB–03–142	• The Coordination of Benefits Contractor Will Post the Lead Medicare Contractor in the Group Name Field on the Common Working File and Expansion of Lead Contractor Viewing in the Electronic Correspondence Referral System
AB–03–143	• Implementation of Certain Initial Determination and Appeal Provisions Within Section 521 of the Medicare, Medicaid and State Child Health Insurance Program Benefits Improvement and Protection Act of 2000
AB–03–144	• Establishing a Uniform Process for the Preparation and Mailing of Case Files From the Contractor to the Office of Hearings and Appeals of the Social Security Administration
AB–03–145	• Instructions for Contractors Other Than the Religious Nonmedical Health Care Institution Specialty Intermediary Regarding Claims For Beneficiaries With Religious Nonmedical Health Care Institution Elections
AB–03–146	• Reminder Notice of the Implementation of the Ambulance Transition Schedule
AB–03–147	• Core Elements and Required Statements for a Valid Privacy Authorization
	State Operations Manual (CMS Pub. 7) (Superintendent of Documents No. HE 22.8/12)
31	• Regional Offices Assignment of Provider and Supplier Identification Number
	Hospice Manual (CMS Pub. 10) (Superintendent of Documents No. HE 22.8/2)
806	• Hospital Manual, Credit Balance Reporting Requirements—General Provisions Payment of Amounts Owed Medicare Medicare Credit Balance Reporting Certification Page
807	• Payment for Services Furnished by a Critical Access Hospital
	Home Health Agency Manual (CMS Pub. 11) (Superintendent of Documents No. HE 33.8/5)
305	• Diabetes Outpatient Self-Management Training
306	• Home Health Agency Manual, Credit Balance Reporting Requirements—General Provisions Completing the Centers for Medicare & Medicaid Services—838 Payment of Amounts Owed Medicare Medicare Credit Balance Report Certification Page
	Skilled Nursing Facility Manual (CMS Pub. 12) (Superintendent of Documents No. HE 22.8/3)
377	• Credit Balance Reporting Requirements—General Provisions Payment of Amounts Owed Medicare Medicare Credit Balance Report Certification Page

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 2003 through September 2003]

Transmittal No.	Manual/Subject/Publication No.
	Coverage Issues Manual (CMS Pub. 6) (Superintendent of Documents No. HE 22.8/14)
173	• Implantable Automatic Defibrillators
	Peer Review Organization (CMS Pub. 19) (Superintendent of Documents No. 22.8/8–15)
91	• Case Review and Health Care Quality Improvement Program—has been moved to Corresponding Internet-Only Manual chapter in Pub. 100–10, Medicare Quality Improvement Organizations Manual, which can be found at *http://www.cms.hhs.gov/manuals.*
92	• Denials, Reconsiderations and Appeals—has been moved to corresponding Internet-Only Manual chapters in Pub. 100–10, Medicare Quality Improvement Organization Manual, which can be found at *http://www.cms.hhs.gov/manuals.*
93	• Agreements—has been moved to Corresponding Internet-Only Manual chapter in Pub. 100–10, Medicare Quality Improvement Organization Manual, which can be found at *http://www.cms.hhs.gov/manuals.*
94	• Confidentiality and Disclosure—has been moved to the Corresponding Internet-Only Manual, which can be found at *http://www.cms.hhs.gov/manuals.*
95	• Outreach Activities—has been moved to corresponding Internet-Only Manual chapters in Pub. 100–10, Medicare Quality Improvement Organizations Manual, which can be found at *http://www.cms.hhs.gov/manuals.*
96	• Payment Error Prevention Program—has been moved to corresponding Internet-Only Manual chapter in Pub.100–10, Medicare Improvement Organizations Manual, which can be found at *http://www.cms.hhs.gov/manuals.*
97	• Beneficiary Complaint Review—has been moved to corresponding Internet-Only Manual chapter in Pub. 100–10, Medicare Quality Improvement Organizations Manual, which can be found at *http://www.cms.hhs.gov/manuals.*
98	• Data Management—has been moved to corresponding Internet-Only Manual chapter in Pub. 100–10, Medicare Quality Improvement Organizations Manual, which can be found at *http://www.cms.hhs.gov/manuals.*
	Hospice Manual (CMS Pub. 21) (Superintendent of Documents No. HE 22.8/18)
69	• Hospice Manual, Credit Balance Reporting Requirements—General Provisions Completing the Centers for Medicare & Medicaid Services—838 Payment of Amounts Owed Medicare Medicare Credit Balance Report Certification Page
	Outpatient Physical Therapy and Comprehensive Outpatient Rehabilitation Facility Manual (CMS Pub. 9) (Superintendent of Documents No. HE 22. 8/9)
18	• Outpatient Physical Therapy/Comprehensive Outpatient Rehabilitation Facility/Community Mental Health/Clinic Manual, Credit Balance Reporting Requirements General Provisions Completing the Centers for Medicare & Medicaid Services—838 Payment of Amounts Owed Medicare Medicare Credit Balance Reporting Certification Page
	Rural Health Clinic Manual & Federally Qualified Health Centers Manual (CMS Pub. 27) (Superintendent of Documents No. He 22.8/19:985)
39	• Rural Health Clinic and Federally Qualified Health Center Manual, Credit Balance Reporting—General Provisions Completing the CMS–838 Payment of Amounts Owed Medicare Medicare Credit Balance Reporting Certification Page
	Rural Dialysis Facility Manual
	(Non-Hospital Operated) CMS Pub. 29) (Superintendent of Documents No. 22.8/13)
96	• Renal Health Clinic Manual, Credit Balance Reporting Requirement—General Provisions Completing the Centers for Medicare & Medicaid Services–838 Payment of Amounts Owed Medicare Medicare Credit Balance Report Certification Page

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 2003 through September 2003]

Transmittal No.		Manual/Subject/Publication No.
		Provider Reimbursement Manual
		Part 2 Provider Cost Reporting Forms and Instructions **Chapter 11/Form CMS 22.8/4** **(CMS Pub. 15–2–11)**
5	•	Reimbursement Information
		ESRD Network Organizations Manual
		(CMS Pub. 81) **(Superintendent of Documents No. HE 22.9/4)**
15	•	Background and Responsibilities Administration Confidentiality and Disclosure Information Management Quality Improvement Community Information and Resource Sanctions and End-Stage Renal Disease Grievances Publication Policy Information Collection
		Medicare Claims Processing Manual
		(CMS Pub. 100–04)
3	•	New Effective Data for CR2112 (Revisions to the Outpatient Prospective Payment System Pricer Software and Outpatient Code Editor for Blood Deductible and Technician)
		Financial Management
		(CMS Pub. 100–06)
19	•	Intermediary Claims Accounts Receivable
		Medicare Program Integrity
		(CMS Pub. 100–08)
44	•	When to Develop New/Revised Local Medical Review Policy Coverage Provisions in Local Medical Review Policy Contractor Medical Director Local Medical Review Policy Development Process Final Local Medical Review Policy Web Site Requirements
45	•	Focused Medical Review Activity Report
46	•	Prepayment Edits
47	•	Data Analysis Centers for Medicare & Medicaid Services Mandated Edits
48	•	Written Orders Prior to Delivery
49	•	Denial Notices
50	•	Instructions for Processing Advance Determination of Medicare Coverage Request
51	•	Update of Codes in the Program Integrity Management Reporting System and the Contractor Administrative Cost and Financial Management System
		Quality Improvement Organization
		(CMS Pub. 100–10)
2	•	Introduction Referrals Quality Review Diagnostic Related Group Limitation on Liability Determinations Third-Level Physician Review Use of the Physician Reviewer Assessment Format Review Setting Requesting Medical Records/Reviewing Documentation Providing Opportunity for Discussion Adhering to Review Timeframes Monitoring Hospitals' Physician Acknowledgement Statements
3	•	Introduction Quality Improvement Project Process Developing and Conducting Interventions Documenting and Disseminating Results Centers for Medicare & Medicaid Services Project Support and Guidance Activities

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 2003 through September 2003]

Transmittal No.		Manual/Subject/Publication No.
		Related Activities Through Quality Improvement Organizations, Carrier, Intermediary, and End-Stage Renal Diseases Network Cooperation
4	•	Beneficiary Request for Review of Hospital-Issued Notice of Non-Coverage by a Quality Improvement Organization
5	•	Intermediary/Carrier Memorandum of Agreement Specifications Introduction Memorandum of Agreement With State Agencies Responsible for Licensing/Certification of Providers/Practitioners
6	•	Statutory and Regulatory Requirements General Requirements Confidential Information Disclosure of Confidential Quality Improvement Organization Information to Officials and Agencies Disclosure of Quality Improvement Organization Information for Research Purposes Disclosure of Quality Improvement Organization Sanction Information Re-disclosure of Quality Improvement Organization Information
7	•	Beneficiary Helpline Language Beneficiary Complaints Physician/Provider Meeting Activities Quality Improvement Organization/Intermediary/Carriers Coordination Activities Background Confidentiality Requirements Report Requirements Distribution Requirements Publications Policy Definition Requirements Disagreements Information Collection Policy Centers for Medicare & Medicaid Services Office of Clinical Standards and Quality Requirement Statutory and Regulatory Requirements—Office of Management & Budget Centers for Medicare & Medicaid Services, Information Collection Approval Process Additional Consideration
8	•	Introduction Review Responsibilities Monitoring Hospital Payment Patterns and Developing Collaborating With Provider and Practitioner Groups Collaborating Efforts With Federal and State Agencies and Other Medicare Contractors
9	•	Scope of Review Complaints That Do Not Meet Statutory Requirements Referral Review Process Notice of Disclosure Final Response to Complaints Disclosure of Quality Review Information to Complaints Corrective Actions Coordination With Other Entities Data Analysis and Reporting Requirements
10	•	Authority Purpose of Quality Improvement Organization Review Quality Improvement Organization Responsibilities Centers for Medicare & Medicaid Services' Role Health Care Quality Improvement Program Hospital Payment Monitoring Program
		End Stage Renal Disease (CMS Pub. 100–14)
1	•	Forward Purpose of the Network Manual Statutes and Regulations End-Stage Renal Disease Network Organization's Manual Revisions Acronyms and Glossary Purpose of End-Stage Renal Disease Network Organization Requirements for End-Stage Renal Disease Network Organization Responsibilities of End-Stage Renal Disease Network Organization Health Care Quality Improvement Program Goals Network Organization's Role in Health Care Quality Improvement Program
2	•	Forward Purpose of the Network Manual Statutes and Regulations

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 2003 through September 2003]

Transmittal No.		Manual/Subject/Publication No.
		Revision to the End-Stage Renal Disease Organizations Manual
		Purpose of End-Stage Renal Disease Network Organization
		Requirements for End-Stage Renal Disease Network Organizations
		Responsibilities of End-Stage Renal Disease Network Organizations
		Goals
		Network Organization's Role in Health Care Quality Improvement Program
3	•	Organizational Structure
		Establishing the Network Computer
		Board of Directors
		Other Committees
		Network Staff
		Required Administrative Reports/Activities
		Quarterly Progress and Status Reports
		Annual Report
		Semi-Annual Report of Network Operating Costs
		New End-Stage Renal Disease Patient Orientation Package Activities
		Internal Quality Control Program
		Internal Quality Control Program Requirements
		Managed Care Manual (CMS Pub. 100–16)
26	•	Alternate Employer Group Enrollment Election
		Optional Employer Group Medicare+Choice Enrollment Election
		Request Submitted via Internet
		Request Signature and Data
		Effective Dates
		Notice Requirements
		Optional Employer Group Medicare+Choice Disenrollment Election
		Medigap Guaranteed Issue Notification Requirements
		General Rule
		Effective Date
		Researching and Acting on a Change of Address
		Clarified the Notice Requirements for Out of Area Permanent
27	•	Noncontracted Provider Appeals
		Storage of Appeal Case Files by the Independent Review Entity
		Representative Filing on Behalf of the Enrollee
		Storage of Hearing Files
28	•	Streamlined Marketing Review Process
		Introduction
		Marketing Review Process
		Guidelines for Advertising Material
		Guidelines for Advertising (Pre-Enrollment) Material
		Guidelines for Beneficiary Notification Materials
		Model Annual Notice of Change
		General Guidance on Dual Eligibility
		Guideline for Outreach Program
		Submission Requirements
		Centers for Medicare & Medicaid Services' Review/Approval Process
		Model Direct Mail Letter
		Summary of Benefits for Medicare+Choice Organizations
		Referral Programs
		Allowable Actions for Medicare+Choice Organizations
		Specific Guidance About the Use of Independent Insurance Agents
		Answers to Frequently Asked Questions About Promotional Marketing of Multiple Lines of Business
29	•	Introduction
		Quality Assessment and Performance Improvement Program
		Administration of the Quality Assessment and Performance Improvement Program
		Medicare+Choice Organizations Using Physician Incentive Plans
		Health Information System
		Quality Assessment and Performance Improvement
		Centers for Medicare & Medicaid Services' Directed Special Projects
		Reporting Time Frames
		Communication Process
		Quality Assessment and Performance Improvement
		Process for Centers for Medicare & Medicaid Services' Multi-Year Quality Assessment and Performance Improvement Program Project Approvals
		Evaluation of Quality Assessment and Performance Improvement Program Projects
		The Medicare+Choice Deeming Program
		Terminology
		General Rule

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 2003 through September 2003]

Transmittal No.		Manual/Subject/Publication No.
		Obligations of Deemed Medicare and Medicaid Organizations
		Oversight of Accrediting Organizations
		Application Requirements
		Reporting Requirements
		Informal Hearing Procedures
30	•	Reasonable Cost-Based Payments—General
		Reasonable Cost Payments
		Bill Processing
		Principles of Payments
		Budget and Enrollment Forecast
		Interim Per Capita Rate
		Interim Payment for Health Care Prepayment Plans
		Electronic Transfer of Funds
		Payment Report
		Interim and Final Cost and Enrollment Report
		Adjustment of Payments
		Final Cost Report
		Final Settlement Process for Medicare Health Care Prepayment Plans
		Final Settlement Payment for Medicare Health Care Prepayment Plans
		Recovery of Overpayment
		Interest Charges for Medicare Overpayments/Underpayments
		The Basic Rules
		Definition of Final Determination
		Rate of Interest
		Accrual of Interest
		Waiver of Interest
		Rules Applicable to Partial Payments
		Exception to Applicability
		Nonallowable Interest Cost
		Centers for Medicare & Medicaid Services' General Payment Principles
		Medicare Payments to Health Care Prepayment Plans
		Prudent Buyer Principle
		Allowable Costs
		Costs Not Reimbursable Directly to the Health Care Prepayment Plans
		Deductible and Coinsurance
		Hospice Care Costs
		Medicare as Secondary Payer
31	•	Overview of Enrollment and Payment Process
		Purpose of the Chapter
		Medicare+Choice Organization Data Processing Responsibilities
		Centers for Medicare & Medicaid Services' Group Health Plan System
		Enrollment/Disenrollment Requirements and Effective Dates
		General
		Enrollments
		Cost-Based Medicare+Choice Organizations Only
		Medicare+Choice Organizations Only
		Disenrollments
		Cost-Based Medicare+Choice Organizations Only
		Medicare+Choice Organizations Only
		Cost-Based Medicare+Choice Organizations Only—Employer Group Health Plan
		Retroactive Enrollment
		Medicare Membership Information
		The Centers for Medicare & Medicaid Services' Medicare+Choice
		Organizations Only Interface Submitting Medicare Membership
		Information to Centers for Medicare & Medicaid Services
		Submission of Enrollment/Disenrollment Transaction Records
		Submission of Correction Transaction Records
		Health Insurance Claim Number
		Transaction Type Code and the Prior Commercial Indicator
		Transaction Type Codes
		Prior Commercial Months Field
		Special Status Beneficiaries—Medicare+Choice Organizations
		Special Status Beneficiaries
		Special Status—Hospice
		Special Status—End-Stage Renal Disease
		Special Status—Institutionalized
		Special Status—Medicaid/Medical Assistance Only
		Special Status—Working Aged
		When to Submit ''Special Status'' Information (Medicare+Choice Organizations Only)
		Other Medicare Membership Information

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 2003 through September 2003]

Transmittal No.	Manual/Subject/Publication No.
	Risk Adjustment Payment
	Bonus Payment
	Extra Payment in Recognition of Quality Congestive Heart Failure
	Outpatient Care
	Benefit Stabilization Fund
	Electronic Submission of Membership Records to Centers for Medicare & Medicaid Services
	Timeliness Requirements
	Record Submission Schedule
	Sending the Transaction File to Centers for Medicare & Medicaid Services
	Electronic Data Transfer
	Centers for Medicare & Medicaid Services' Data Center Access
	Data Processing Vendor
	Receiving Medicare Membership Information Form Centers for Medicare & Medicaid Services
	General
	Centers for Medicare & Medicaid Services' Transaction Reply/Monthly Activity Report
	Transaction Reply Field Information
	Plan Payment Report
	Demographic Report—Medicare+Choice Organizations Only
	Medicare Fee-For-Service Bill Itemization and Summary Report
	Monthly Membership Report
	Bonus Payment Report
	Working Aged Transaction Status Report
	Retroactive Payment Adjustment Policy
	Standard Operating Procedures for State and County Code Adjustments
	Standard Operating Procedures for Processing of Institutional Adjustments
	Standard Operating Procedures for Medicaid Retroactive Adjustments
	Standard Operating Procedures for End-Stage Renal Disease Retroactive Adjustments
	Processing of Working Aged Retroactive Adjustments
	Standard Operating Procedures for Retroactive Adjustment Plan Elections
	Centers for Medicare & Medicaid Services, Social Security Administration, and Customer Service Center Disenrollments
	General
	Medicare Customer Service Center Disenrollments
	Centers for Medicare & Medicaid Services' Disenrollments
	Coordination With the Medicare Fee-For-Services Program
	Pro-Rate Deductible
	Duplicate Payment Prevention by Cost-Based Medicare+Choice Organizations

Addendum IV—Regulation Documents Published in the Federal Register [July 2003 Through September 2003]

Publication date	FR Vol. 68 page No.	CFR parts affected	File code	Title of regulation
July 2, 2003	39764		CMS–1473–NC	Medicare Program; Home Health Prospective Payment System Rate Update for FY 2004.
July 15, 2003	41861		OFR Correction	Medicare Program; Prospective Payment System for Long-Term Care Hospitals: Annual Payment Rate Updates and Policy Changes.
July 25, 2003	44091		CMS–3117–N	Medicare Program; Meeting of the Medicare Coverage Advisory Committee September 9, 2003.
July 25, 2003	44089		CMS–1260–N	Medicare Program; Meeting of the Advisory Panel on Ambulatory Payment Classification Groups—August 22, 2003.
July 25, 2003	44088		CMS–3124–WN	Medicare Program; Withdrawal of Medicare Coverage of Multiple-Seizure Electroconvulsive Therapy, Electrodiagnostic Sensory Nerve Conduction Threshold Testing, and Noncontact Normothermic Wound Therapy.
July 25, 2003	44000	42 CFR Part 424	CMS–1185–P	Medicare Program; Elimination of Statement of Intent Procedures for Filing Medicare Claims.
July 25, 2003	43998	42 CFR Part 406	CMS–4018–P	Medicare Program; Continuation of Medicare Entitlement When Disability Benefit Entitlement Ends Because of Substantial Gainful Activity.

Publication date	FR Vol. 68 page No.	CFR parts affected	File code	Title of regulation
July 25, 2003	43995	42 CFR Parts 405 and 411.	CMS–6014–P	Medicare Program; Interest Calculation.
July 25, 2003	43940	42 CFR Parts 411 and 489.	CMS–1475–FC	Medicare Program; Third Party Liability Insurance Regulations.
August 1, 2003	45674	42 CFR Part 412	CMS–1474–F	Medicare Program; Changes to the Inpatient Rehabilitation Facility Prospective Payment System and Fiscal Year 2004 Rates.
August 1, 2003	45346	42 CFR Parts 412 and 413.	CMS–1470–F	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2004 Rates.
August 4, 2003	46036	42 CFR Parts 409, 411, 413, 440, 483, 488, and 489.	CMS–1469–F	Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update.
August 11, 2003	47637	42 CFR Part 412	CMS–1470–F	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2004 Rates.
August 12, 2003	47966	42 CFR Parts 410 and 419.	CMS–1471–P	Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates.
August 15, 2003	49030	42 CFR Parts 410 and 414.	CMS–1476–P	Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2004.
August 15, 2003	48805	42 CFR Part 424	CMS–0008–IFC	Medicare Program; Electronic Submission of Medicare Claims.
August 20, 2003	50428	42 CFR Part 405	CMS–1229–P	Medicare Program; Payment Reform for Part B Drugs.
August 22, 2003	50840	42 CFR Parts 409, 417, and 422.	CMS–4041–F	Medicare Program; Modifications to Managed Care Rules.
August 22, 2003	50794		CMS–1236–N	Medicare Program; September 15 and 16, 2003, Meeting of the Practicing Physicians Advisory Council and Request for Nominations.
August 22, 2003	50793		CMS–4053–N	Medicare Program: Meeting of the Advisory Panel on Medicare Education—September 18, 2003.
August 22, 2003	50790		CMS–2136–FN	Medicaid Program; State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals: Federal Fiscal Year 2002.
August 22, 2003	50784		CMS–2166–N	State Children's Health Insurance Program; Final Allotments to States, the District of Columbia, and U.S. Territories and Commonwealths for Fiscal Year 2004.
August 22, 2003	50735	42 CFR Part 414	CMS–1167–P	Medicare Program; Payment for Respiratory Assist Devices With Bi-level Capability and a Back-up Rate.
August 22, 2003	50722		CMS–2226–CN	Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications; Correction.
August 22, 2003	50717	42 CFR Part 413	CMS–1199–F	Medicare Program; Electronic Submission of Cost Reports.
August 29, 2003	51912	42 CFR Part 447	CMS–2175–FC	Medicaid Program; Time Limitation on Price Recalculations and Recordkeeping Requirements Under the Drug Rebate Program.
September 9, 2003	53266	42 CFR Part 412	CMS–1262–P	Medicare Program; Changes to the Criteria for Being Classified as an Inpatient Rehabilitation Facility.
September 9, 2003	53222	42 CFR Parts 413, 482, and 489.	CMS–1063–F	Medicare Program; Clarifying Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals With Emergency Medical Conditions.
September 26, 2003	55634		CMS–3062–N	Medicare Program; Revised Process for Making Medicare National Coverage Determinations.
September 26, 2003	55618		CMS–9018–N	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—April 2003 Through June 2003.
September 26, 2003	55616		CMS–2182–FN	Medicare and Medicaid Programs; Reapproval of the Community Health Accreditation Program (CHAP) for Deeming Authority for Hospices.

Publication date	FR Vol. 68 page No.	CFR parts affected	File code	Title of regulation
September 26, 2003	55566	42 CFR Parts 410 and 414.	CMS–1476–CN	Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2004; Correction.
September 26, 2003	55528	42 CFR Parts 483 and 488.	CMS–2131–F	Medicare and Medicaid Programs; Requirements for Paid Feeding Assistants in Long Term Care Facilities.
September 26, 2003	55527	42 CFR Part 447	CMS–2175–CN	Medicaid Program; Time Limitation on Price Recalculations and Recordkeeping Requirements Under the Drug Rebate Program; Correction
September 29, 2003	55882	42 CFR Parts 409, 411, 413, 440, 483, 488, and 489.	CMS–1469–CN	Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Correction.
September 30, 2003	56478		CMS–1233–N	Medicare Program; Hospice Wage Index for Fiscal Year 2004.
September 30, 2003	56383		CMS–1473–NC OFR Correction.	Medicare Program; Home Health Prospective Payment System Rate Update for FY 2004; Correction.

Addendum V—National Coverage Determinations [July 2003 Through September 2003]

A national coverage determination (NCD) is a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under Title XVIII of the Social Security Act, but does not include a determination of what code, if any, is assigned to a particular item or service covered under this title, or determination with respect to the amount of payment made for a particular item or service so covered. We include below all of the NCDs that were issued during the quarter covered by this notice. The entries below include information concerning completed decisions as well as sections on program and decision memoranda, which also announce pending decisions or, in some cases, explain why it was not appropriate to issue an NCD. We identify completed decisions by the section of the NCDM (or CIM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. Information on completed decisions as well as pending decisions has also been posted on the CMS Web site at *http://cms.hhs.gov/coverage*.

National Coverage Decisions [July 2003 Through September 2003]

COVERAGE ISSUES MANUAL (CIM) (CMS PUB. 06)

CIM section	Title	Issue date	Effective date
35–85.1	Implantable Automatic Defibrillators	08/22/03 09/22/03 (correction)	10/01/03 10/01/03

PROGRAM MEMORANDUM (PM)

PM No.	Title	Issue date	Effective date
AB–03–104	Changes to the Laboratory NCD Edit Software For 10/03	07/25/03	10/01/03

FEDERAL REGISTER PUBLICATIONS

Title	Publication date	Effective date
CMS–3062–N—Revised Process for Making National Coverage Determinations	09/26/03	N/A

Addendum VI—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 CMS, the Food and Drug Administration (FDA) assigns each device with an FDA-approved investigational device exemption (IDE) to one of two categories. Category A refers to experimental/investigational device exemptions, and Category B refers to nonexperimental/investigational device exemptions. 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 and category (A or B) for the second quarter, July through September 2003.

INVESTIGATIONAL DEVICE EXEMPTION NUMBERS, 3RD QUARTER 2003

IDE	Category
G020202	B
G020312	B
G020316	B
G030027	B
G030031	B

INVESTIGATIONAL DEVICE EXEMPTION NUMBERS, 3RD QUARTER 2003—Continued

IDE	Category
G030040	B
G030059	B
G030066	B
G030100	B
G030121	B
G030131	B
G030133	B
G030134	B
G030135	B
G030136	B

INVESTIGATIONAL DEVICE EXEMPTION NUMBERS, 3RD QUARTER 2003—Continued

IDE	Category
G030137	B
G030138	B
G030141	B
G030143	B
G030144	B
G030145	B
G030146	B
G030147	B
G030151	B
G030159	B

INVESTIGATIONAL DEVICE EXEMPTION NUMBERS, 3RD QUARTER 2003—Continued

IDE	Category
G030162	B
G030165	B
G030167	B
G030169	B
G030170	B
G030172	B
G030173	B
G030174	B
G030177	B

Addendum VII—Approval Numbers for Collections of Information

Below we list all approval numbers for collections of information in the referenced sections of CMS regulations in Title 42; Title 45, Subchapter C; and Title 20 of the Code of Federal Regulations, which have been approved by the Office of Management and Budget:

OMB control Nos.	Approved CFR sections in Title 42, Title 45, and Title 20 (**Note:** sections in Title 45 are preceded by ''45 CFR,'' and sections in Title 20 are preceded by ''20 CFR'')
0938–0008	414.40, 424.32, 424.44
0938–0022	413.20, 413.24, 413.106
0938–0023	424.103
0938–0025	406.28, 407.27
0938–0027	486.100–486.110
0938–0033	405.807
0938–0034	405.821
0938–0035	407.40
0938–0037	413.20, 413.24
0938–0041	408.6
0938–0042	410.40, 424.124
0938–0045	405.711
0938–0046	405.2133
0938–0050	413.20, 413.24
0938–0062	431.151, 435.1009, 440.220, 440.250, 442.1, 442.10–442.16, 442.30, 442.40, 442.42, 442.100–442.119, 483.400–483.480, 488.332, 488.400, 498.3–498.5
0938–0065	485.701–485.729
0938–0074	491.1–491.11
0938–0080	406.7, 406.13
0938–0086	420.200–420.206, 455.100–455.106
0938–0101	430.30
0938–0102	413.20, 413.24
0938–0107	413.20, 413.24
0938–0146	431.800–431.865
0938–0147	431.800–431.865
0938–0151	493.1405, 493.1411, 493.1417, 493.1423, 493.1443, 493.1449, 493.1455, 493.1461, 493.1469, 493.1483, 493.1489
0938–0155	405.2470
0938–0170	493.1269–493.1285
0938–0193	430.10–430.20, 440.167
0938–0202	413.17, 413.20
0938–0214	411.25, 489.2, 489.20
0938–0236	413.20, 413.24
0938–0242	416.44, 418.100, 482.41, 483.270, 483.470
0938–0245	407.10, 407.11
0938–0246	431.800–431.865
0938–0251	406.7
0938–0266	416.41, 416.47, 416.48, 416.83
0938–0267	410.65, 485.56, 485.58, 485.60, 485.64, 485.66
0938–0269	412.116, 412.632, 413.64, 413.350, 484.245
0938–0270	405.376
0938–0272	440.180, 441.300–441.305
0938–0273	485.701–485.729
0938–0279	424.5
0938–0287	447.31
0938–0296	413.170
0938–0300	431.800
0938–0301	413.20, 413.24
0938–0302	418.22, 418.24, 418.28, 418.56, 418.58, 418.70, 418.74, 418.83, 418.96, 418.100
0938–0313	418.1–418.405
0938–0328	482.12, 482.22, 482.27, 482.30, 482.41, 482.43, 482.53, 482.56, 482.57, 482.60, 482.61, 482.62, 482.66
0938–0334	491.9
0938–0338	486.104, 486.106, 486.110
0938–0354	441.60
0938–0355	484.10–484.52
0938–0357	409.40–409.50, 410.36, 410.170, 411.4–411.15, 421.100, 424.22, 484.18, 489.21
0938–0358	412.20–412.30

OMB control Nos.	Approved CFR sections in Title 42, Title 45, and Title 20 (**Note:** sections in Title 45 are preceded by ''45 CFR,'' and sections in Title 20 are preceded by ''20 CFR'')
0938–0359	412.40–412.52
0938–0360	405.2100–405.2184
0938–0365	484.10, 484.11, 484.12, 484.14, 484.16, 484.18, 484.20, 484.36, 484.48, 484.52
0938–0372	414.330
0938–0378	482.60–482.62
0938–0379	442.30, 488.26
0938–0386	405.2100–405.2171
0938–0391	488.18, 488.26, 488.28
0938–0426	476.104, 476.105, 476.116, 476.134
0938–0429	447.53
0938–0443	473.18, 473.34, 473.36, 473.42
0938–0444	1004.40, 1004.50, 1004.60, 1004.70
0938–0445	412.44, 412.46, 431.630, 456.654, 466.71, 466.73, 466.74, 466.78
0938–0447	405.2133
0938–0449	440.180, 441.300–441.310
0938–0454	424.20
0938–0456	412.105
0938–0463	413.20, 413.24
0938–0465	411.404, 411.406, 411.408
0938–0467	431.17, 431.306, 435.910, 435.920, 435.940–435.960
0938–0469	417.107, 417.478
0938–0470	417.143, 417.408
0938–0477	412.92
0938–0484	424.123
0938–0486	498.40–498.95
0938–0501	406.15
0938–0502	433.138
0938–0512	486.301–486.325
0938–0526	462.102, 462.103. 475.100, 475.106, 475.107
0938–0534	410.38, 424.5
0938–0544	493.1–493.2001
0938–0565	411.20–411.206
0938–0566	411.404, 411.406, 411.408
0938–0567	Part 498 Subparts D and E, and 20 CFR 404.933
0938–0573	412.230, 412.256
0938–0581	493.1–493.2001
0938–0599	493.1–493.2001
0938–0600	405.371, 405.378, 413.20
0938–0610	417.436, 417.801, 422.128, 430.12, 431.20, 431.107, 434.28, 483.10, 484.10, 489.102
0938–0612	493.1–493.2001
0938–0618	433.68, 433.74, 447.272
0938–0653	493.1771, 493.1773, 493.1777
0938–0655	493.1840
0938–0657	405.2110, 405.2112
0938–0658	405.2110, 405.2112
0938–0667	482.12, 488.18, 489.20, 489.24
0938–0673	430.10
0938–0679	410.38
0938–0685	410.32, 410.71, 413.17, 424.57, 424.73, 424.80, 440.30, 484.12
0938–0686	493.551–493.557
0938–0688	486.301–486.325
0938–0690	488.4–488.9, 488.201
0938–0691	412.106
0938–0692	466.78, 489.20, 489.27
0938–0700	417.479, 417.500; 422.208, 422.210; 434.44, 434.67, 434.70; 1003.100, 1003.101, 1003.103, 1003.106
0938–0701	422.152
0938–0702	45 CFR 146.111, 146.115, 146.117, 146.150, 146.152, 146.160, 146.180
0938–0703	45 CFR 148.120, 148.124, 148.126, and 148.128
0938–0714	411.370–411.389
0938–0717	424.57
0938–0721	410.33
0938–0722	422.370–422.378
0938–0723	421.300–421.318
0938–0730	405.410, 405.430, 405.435, 405.440, 405.445, 405.455, 410.61, 415.110, 424.24
0938–0732	417.126, 417.470
0938–0734	45 CFR 5b
0938–0739	413.337, 413.343, 424.32, 483.20
0938–0742	422.300–422.312
0938–0749	424.57
0938–0753	422.000–422.700
0938–0754	441.152
0938–0758	413.20, 413.24
0938–0760	Part 484 Subpart E, 484.55

OMB control Nos.	Approved CFR sections in Title 42, Title 45, and Title 20 (**Note:** sections in Title 45 are preceded by ''45 CFR,'' and sections in Title 20 are preceded by ''20 CFR'')
0938–0761	484.11, 484.20
0938–0763	422.1–422.10, 422.50–422.80, 422.100–422.132, 422.300–422.312, 422.400–422.404, 422.560–422.622
0938–0768	417.800–417.840
0938–0770	410.2
0938–0778	422.64, 422.111, 422.560–422.622
0938–0779	417.126, 417.470, 422.64, 422.210
0938–0781	411.404–411.406, 484.10
0938–0786	438.352, 438.360, 438.362, 438.364
0938–0787	406.28, 407.27
0938–0790	460.12, 460.22, 460.26, 460.30, 460.32, 460.52, 460.60, 460.70, 460.71, 460.72, 460.74, 460.80, 460.82, 460.98, 460.100, 460.102, 460.104, 460.106, 460.110, 460.112, 460.116, 460.118, 460.120, 460.122, 460.124, 460.132, 460.152, 460.154, 460.156, 460.160, 460.164, 460.168, 460.172, 460.190, 460.196, 460.200, 460.202, 460.204, 460.208, 460.210
0938–0792	491.3, 491.8, 491.11
0938–0798	413.24, 413.65, 419.42
0938–0802	419.43
0938–0810	482.45
0938–0819	45 CFR 146.121
0938–0823	420.410
0938–0824	440.10, 482.13
0938–0827	45 CFR 146.141
0938–0829	422.568
0938–0832	Part 489
0938–0833	483.350–483.376
0938–0841	431.636, 457.50, 457.60, 457.70, 457.340, 457.350, 457.431, 457.440, 457.525, 457.560, 457.570, 457.740, 457.750, 457.810, 457.940, 457.945, 457.965, 457.985, 457.1005, 457.1015, 457.1180
0938–0842	412, 413
0938–0846	411.1, 411.350–411.357, 424.22
0938–0857	Part 419
0938–0860	Part 419
0938–0866	45 CFR Part 162
0938–0872	413.337, 483.20
0938–0873	422.152
0938–0874	45 CFR Parts 160 and 162
0938–0878	Part 422 Subparts F and G
0938–0883	45 CFR Parts 160 and 164
0938–0887	45 CFR 148.316, 148.318, 148.320
0938–0897	412.22, 412.533

[FR Doc. 03–30756 Filed 12–23–03; 8:45 am]
BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3119–PN]

RIN 0938–AM36

Medicare Program; Procedures for Maintaining Code Lists in the Negotiated National Coverage Determinations for Clinical Diagnostic Laboratory Services

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of proposed procedures for code maintenance.

SUMMARY: This proposed notice would establish the procedures for maintaining the lists of codes that were included in the national coverage determinations (NCDs) that were announced in the final rule published in the **Federal Register** on November 23, 2001 (66 FR 58788). It also sets forth the circumstances in which a laboratory is permitted to use the date the specimen was retrieved from storage for testing as the date of service instead of the date of collection. The proposed notice clarifies the meaning of the ''date of collection.'' In this proposed notice, we propose a standard time frame that would define when a specimen has been ''archived'' for undetermined later use.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on February 23, 2004.

ADDRESSES: In commenting, please refer to file code CMS–3119–PN. Because staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission or e-mail.

Mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3119–PN, P.O. Box 8011, Baltimore, MD 21244–8011. Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to one of the following addresses: Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.