reviewing the plan, CHAP added to its standard the wording, ''by the attending physician, the medical director or physician designee and the IDT/IDG.''

- In order to meet the requirements of § 418.22(d)(2), CHAP added certification and recertification of the terminal illness with a six-month prognosis, signed by a physician, as necessary elements that needed to be maintained in the medical record.
- The word ''paraprofessional'' was removed and replaced with the term ''Home Health Aide'' in the CHAP standard.
- CHAP agreed to change homemaker supervision from every 6 months to 1 month.
- To meet the requirements of the 2000 edition of the Life Safety Code and to comply with § 418.100, CHAP has agreed to add an additional standard that states that roller latches are not used on corridor doors.

B. Term of Approval

Based on the review and observations described in section III of this final notice, we have determined that CHAP's requirements for hospices meet or exceed our requirements. Therefore, we recognize CHAP as a national accreditation organization for hospices that request participation in the Medicare program, effective November 21, 2003 through November 21, 2009.

IV. Collection of Information Requirements

This final notice does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. The requirements associated with granting and withdrawal of deeming authority to national accreditation organizations, codified in 42 CFR part 488, ''Survey, Certification, and Enforcement Procedures,'' are currently approved by OMB under OMB approval number 0938–0690.

V. Regulatory Impact Statement

We have examined the impact of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). This final notice recognizes CHAP as a national accreditation organization for hospices that request participation in the Medicare and Medicaid programs. There are neither significant costs nor savings for the program and administrative budgets of Medicare. Therefore, this notice is not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any one year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

In an effort to better ensure the health, safety, and services of beneficiaries in hospices already certified as well as provide relief to State budgets in this time of tight fiscal restraints, we deem hospices accredited by CHAP as meeting our Medicare requirements. Thus, we continue our focus on ensuring the health and safety of services by providers and suppliers already certified for participation in a cost-effective manner.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This notice will have no consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this notice does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplemental Medical Insurance Program)

Dated: August 7, 2003.

Thomas Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03–24547 Filed 9–25–03; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9018–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—April 2003 Through June 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 April 2003 through June 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 Margie Teeters, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Centers for Medicare & Medicaid Services, C5–13–18, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–4678.

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 Coverage Issues Manual (CIM) may wish to review the August 21, 1989 publication (54 FR 34555). Those interested in the procedures used in making NCDs under the Medicare program may review the April 27, 1999 publication (64 FR 22619).

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 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, 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, 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 Carriers Manual, Part 3—Program Administration (CMS Pub. 14–3) transmittal entitled ''Incident to Physician's Professional Services (Subsection A—Commonly Furnished in Physicians' Offices),'' use the Superintendent of Documents No. HE 22.8/7 and the transmittal number 1793.

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

Dated: September 8, 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.

May 11, 1999 (64 FR 25351)
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)

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 Medicare Coverage Issues Manual (CIM) 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

[April 2003 Through June 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)**
1879	• Clinical Diagnostic Laboratory Services Other Than To Inpatients Screening Pap Smears and Pelvic Examinations
1880	• Autologous Stem Cell Transplantation
1881	• Review of Form HCFA–1450 for Inpatient and Outpatient Bills
1882	• Frequency of Billing
1883	• Magnetic Resonance Angiography
1884	• Telehealth Services
1885	• Medicare Payment for Telehealth Services
1886	• Payment Without Common Working File Approval
1887	• Filing a Request for Payment Request for Payment Filing Claims for Payment Time Limits for Requests and Claims for Payment for Services Reimbursed Effects on Beneficiary and Provider of Beneficiary's Refusal to File a Request for Payment Filing Claims Where Usual Time Limit Has Expired Claims for Payment for Emergency Hospital Services and Services Outside the United States Appeals Time Limits for Filing Part B Reasonable Charge Claims Claims Processing Timeliness Time Limitations for Filing Provider Claims Incomplete or Invalid Claims Addendum L Paper and Electronic Data Element Requirements Bill Type Codes and Allowable Provider Numbers
1888	• Screening Pap Smears and Screening Pelvic Examinations
1889	• Billing of the Diagnosis and Treatment of Peripheral Neuropathy With Loss of Protective Sensation in People With Diabetes
1890	• Coverage and Billing of Sacral Nerve Stimulation Deep Brain Stimulation for Essential Tremor and Parkinson's Disease
1891	• International Classification of Diseases 9th Edition Clinical Modification Coding for Diagnostic Tests
	Carriers Manual **Part 3—Program Administration** **(CMS Pub. 14–3)** **(Superintendent of Documents No. HE 22.8/7)**
1793	• Incident to Physician's Professional Services (Subsection A—Commonly Furnished in Physicians' Offices)
1794	• The ''Do Not Forward'' Initiative (Subsection C—Internal Revenue Services—1099 Reporting)
1795	• Magnetic Resonance Angiography Coverage Summary Coding Requirements
1796	• Skilled Nursing Facility Consolidated Billing Determining the End of a Skilled Nursing Facility Stay Types of Facilities Included in and Excluded From Consolidated Billing Types of Services Included in and Excluded From Consolidated Billing Risk-Based Health Maintenance Organization Beneficiaries Clarification of Ambulance Services Information on a Skilled Nursing Facility Contracting With Outside Entities for Services Carrier Claims Processing Special Requirements for Claims for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Revisions to Common Working File Edits To Permit Payment for Certain Diagnostic Services Furnished To Beneficiaries Receiving Treatment for End-Stage Renal Disease at an Independent or Provider-Based Dialysis Facility
1797	• Telehealth Claims
1798	• Medicare Payment for Telehealth Services
1799	• Payment Limit for Certain Drugs and Biologicals Procedures for Determining Payment Limit Injection Services Mandatory Assignment for Drugs and Biologicals
1800	• Drugs and Biologicals Definition of Drug or Biological Determining Self-Administration of Drugs or Biologicals Incident-To Requirements
1801	• Healthcare Common Procedure Coding System Coding Common Working File Edits for Flu and Pneumonia Claims Administrative Bulletin Crossover Edit Payment Requirements No Legal Obligation To Pay Roster Billing Health Maintenance Organization Processing

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April 2003 Through June 2003]

Transmittal No.		Manual/Subject/Publication No.
		Specialty Code/Place of Service Processing
1802	•	Foot Care and Supportive Devices for Feet Foot Care Peripheral Neuropathy With Loss of Protective Sensation in People With Diabetes Coverage Applicable Codes Payment Requirements Standard System Edits Common Working File Edits
1803	•	End-Stage Renal Disease Bill Procedures 1804
1804	•	Durable Medical Equipment Regional Carriers—Pre-Discharge Delivery of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies for Fitting and Training
1805	•	Necessity for Treatment
1806	•	Intestinal and Multi-Visceral Transplantation Approved Transplant Facilities Payment Procedures for Intestinal and Multi-Visceral Transplants
1807	•	International Classification of Diseases 9th Edition Clinical Modification Coding for Diagnostic Tests
		Program Memorandum Intermediaries (CMS Pub. 60A) (Superintendent of Documents No. HE 22.8/6–5)
A–03–020	•	April 2003 Update of the Hospital Outpatient Prospective Payment System
A–03–021	•	Announcement of Medicare Rural Health Clinics and Federally Qualified Health Centers Payment Rate Increases, Clarification on Coverage and Payment of Diabetes Self-Management Training Services and Medical Nutrition Therapy Services
A–03–022	•	Installation of Version 29.0 of the Provider Statistical and Reimbursement Reporting System—Modification A–03–023
A–03–023	•	Implementation of the Temporary Equalization of Urban and Rural Standardized Payment Amounts Under the Medicare Inpatient Hospital Prospective Payment System as Required By Section 402(b) of Public Law 108–7
A–03–024	•	Advance Beneficiary Notices Must Be Given To Beneficiaries and Demands Bills Must Be Submitted By Home Health Agencies
A–03–025	•	Advance Beneficiary Notices Must Be Given To Beneficiaries and Demands Bills Must Be Submitted By Home Health Agencies
A–03–026	•	April Outpatient Code Editor Specifications Version (V4.1)
A–03–027	•	Updated Outpatient Prospective Payment System: Requirements for Provider Education and Training
A–03–028	•	January Medicare Outpatient Code Editor Specifications Version 18.1R1 for Bills From Hospitals That Are Not Paid Under the Outpatient Prospective Payment System
A–03–029	•	Corrections to: Changes to the Hospital Inpatient Prospective Payment Systems and Rates and Costs of Graduate Medical Education, etc., as Published in the **Federal Register**, Fiscal Year 2003 (67 FR 49982, August 1, 2002)
A–03–030	•	Provider-Based Status On or After October 1, 2002
A–03–031	•	Medicare Secondary Payer Information Collection Policies Changed for Hospitals
A–03–032	•	Addition of Patient Status Code 43, Deletion of Patient Status Codes 71 and 72, and Information on New Patient Status Code 65
A–03–033	•	End-Stage Renal Disease Reimbursement for Automated Multi-Channel Chemistry Tests
A–03–034	•	Modification to Medicare Timely Filing Edit for Claims Paid Under Certain Prospective Payment Systems
A–03–035	•	Reporting of Revenue Codes Under the Outpatient Prospective Payment System
A–03–036	•	Installation of Version 30.0 of the Provider Statistical and Reimbursement Reporting System—Modification
A–03–037	•	Contractor Reporting of Operational and Workload Data for Electronic Data Interchange and Manual Transactions
A–03–038	•	Program Integrity Management Reporting System for Part A Phase 2
A–03–039	•	Clarification to Corrections to Updated Instruction on Receipt and Processing of Non-Covered Changes on Other Than Part A Inpatient Claims (Transmittals A–02–071, A–02–117)—Change In Effective and Implementation Date Only
A–03–040	•	Clarification of Bill Types 22x and 23x Submitted by Skilled Nursing Facilities
A–03–041	•	Health Insurance Portability and Accountability Act Version 4010A1 Institutional 837 Health Care Claim Additional Implementation Direction
A–03–042	•	Updated Revision to Change Request 2508, Suspension, Offset, and Recoupment of Medicare Payment to Providers and Suppliers of Services
A–03–043	•	Changes to Fiscal Year 2001 Nursing and Allied Health Education Payment Policies
A–03–044	•	Audit Guidance Pertaining To Write-Offs of Small Debit Balances in Patients' Accounts Receivable
A–03–045	•	Payment to Hospitals and Units Excluded From the Acute Inpatient Prospective Payment System for Direct Graduate Medical Education and Nursing and Allied Health Education for Medicare+Choice Enrollees
A–03–046	•	Demonstration—Settlement of Payment for Home Health Services to Beneficiaries Eligible for Both Medicare and Medicaid in Connecticut, and Massachusetts. Regional Home Health Intermediaries Only.
A–03–047	•	Medicare's Coordination of Benefits Contractor Shall Discontinue the Dissemination of the Right of Recovery Letter to Intermediaries
A–03–048	•	July Outpatient Code Editor Specifications Version (V4.2)
A–03–049	•	Fiscal Intermediaries Must Install and Use Super Op With the Fiscal Intermediary Standard System
A–03–050	•	July Medicare Outpatient Code Editor Specifications Version 18.2 for Bills From Hospitals That Are Not Paid Under the Outpatient Prospective Payment System
A–03–051	•	July 2003 Update of the Hospital Outpatient Prospective System
A–03–052	•	Revision to Billing for Swing-Bed Services Under the Skilled Nursing Facility Prospective Payment System

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April 2003 Through June 2003]

Transmittal No.	Manual/Subject/Publication No.
A–03–053	• Nurse Practitioner Services Under Medicare Hospice
A–03–054	• Revision to Change Request 2573, Transmittal A–03–013, dated February 14, 2003: 3-Day Payment Window Refinements Under the Short-Term Hospital Inpatient Prospective Payment System
A–03–055	• Disclosure of Information Requirements Related to Hospice Claims
A–03–056	• Payment Update for Long-Term Care Hospital Prospective Payment System Rate Year 2004
	Program Memorandum Carriers (CMS Pub. 60B) (Superintendent of Documents No. HE 22.8/6–5)
B–03–023	• Correct Payment of January and February 2003 Physician Services
B–03–024	• Follow-Up to Implementation of the National Council for Prescription Drug Programs Telecommunications Standard Version 5.1 and the Equivalents Batch Standard Version 1.1 for Retail Pharmacy Drug Transactions
B–03–025	• Durable Medical Equipment Regional Carriers—DeWall Posture Protector Orthotic Body Jacket (L0430)
B–03–026	• Standard System Acceptance of Primary Payer Information at the Line Level
B–03–027	• Implementation of Carriers Jurisdiction Manual Instructions Based on the Medicare Carriers Manual Part 3, Section 3101 for the Multi-Carrier System Standard System and Associated Medicare Carriers
B–03–028	• Durable Medical Equipment Regional Carriers—Internal Classification of Diseases—9—Classification of Diseases Coding
B–03–029	• Manager Care Reasonable Charge Data Disclosure Requirements for Ambulance Services
B–03–030	• Types of Services Corrections
B–03–031	• Multi-Carriers System Reporting of 2003 Participating Data to the Contractor Reporting of Operational and Workload Data System
B–03–032	• Continuation of April and July 2003 Change Requests (2423 and 2524): Create Import/Export Functionality Between the Unique Provider Identification Number System and the Provider Enrollment Chain Ownership System
B–03–033	• Continuation of April and July 2003 Change Requests (2425 and 2525): Create Import/Export Functionality Between the Medicare Claims System and the Provider Enrollment Chain Ownership System
B–03–034	• Continuation of April and July 2003 Change Requests (2426 and 2526): Process All Medicare Part B Provider Enrollments in the Provider Enrollment Chain Ownership System. Modify the Medicare Claims System To Incorporate All Claim Payment and Provider Correspondence Functionality That Is Included in the Provider Enrollment System But Will Not Be a Part of Provider Enrollment Chain Ownership System
B–03–035	• Continuation of April and July 2003 Change Requests (2427 and 2527): Process All Medicare Part B Provider Enrollments in the Provider Enrollment Chain Ownership System. Create Import/Export Functionality Between the Viable Information Processing Systems Medicare System and Provider Enrollment Chain Ownership System
B–03–036	• Expansion of Beneficiary History and Claims In Process Files in the Viable Information Processing System Phase 1—Beneficiary History File Expansion
B–03–037	• Excluding From Home Health Consolidated Billing Edits Claims for Therapy Services Rendered by Physicians
B–03–038	• Oral Anti-Cancer Drugs
B–03–039	• Common Working File Skilled Nursing Facility Consolidated Billing Bypass To Allow Separate Payment for Drugs
B–03–040	• Update of the Place of Services Code Set
B–03–041	• National Council for Prescription Drug Program Batch Transaction Standard 1.1 Billing Request Companion Document
B–03–042	• Bi-Annual Updates to the Health Care Provider Taxonomy Code
B–03–043	• Diabetes Outpatient Self-Management Training and the ''Incident To'' Provision
B–03–044	• Correction to Business Requirements 2
B–03–045	• International Classification of Diseases 9th Edition Clinical Modification Coding Requirements for Claims Submitted to Medicare Carriers
B–03–046	• Provider Education: Establishing New Requirements for ICD–9–CM Coding on Claims Submitted to Medicare Carriers—Increased Role for Physicians/Practitioners
B–03–047	• Changes To Correct Coding Edits, Version 9.3, Effective October 1, 2003
B–03–048	• Addition of Temporary Codes Q4052 and Q4053
B–03–049	• Additional Instructions To Assist in the Implementation of Program Memorandum B–02–075—Carrier Review of Payment Amounts for Portable X-Ray Transportation Services Health Care Procedure Coding System
	Program Memorandum Intermediaries/Carriers (CMS Pub. 60A/B) (Superintendent of Documents No. HE 22.8/6–5)
AB–03–041	• Common Working File Reject and Utilization Edits and Carriers Resolution for Consolidated Billing for Skilled Nursing Facility Residents
AB–03–042	• Coverage and Billing for Percutaneous Image-Guided Breast Biopsy
AB–03–043	• Addition of ''K'' Codes for Surgical Dressings
AB–03–044	• Addition of Temporary ''K'' Codes
AB–03–045	• Addition of Temporary ''K'' Codes
AB–03–046	• Expanding the Number of Source Identifiers for Common Working File Medicare Secondary Payor
AB–03–047	• Single Drug Pricer Clarifications
AB–03–048	• End-Stage Renal Disease Coordination Period
AB–03–049	• Clarification of Payment Responsibilities of Fee-for-Service Contractors as They Relate to Hospice Members Enrolled in Managed Care Organizations and Claims Processing Instructions for Processing Rejected Claims

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April 2003 Through June 2003]

Transmittal No.	Manual/Subject/Publication No.
AB–03–050	• Data Center Testing and Production—Electronic Correspondence Referral System User Manual 5.1 and Quick Reference Guide Replacement
AB–03–051	• Notice of Interest Rate for Medicare Overpayments and Underpayments
AB–03–052	• Managing Medicare Appeals Workloads in Fiscal Year 2003
AB–03–053	• Availability of Online Screens for the Laboratory National Coverage Determinations
AB–03–054	• Diagnosis Code for Screening Pap Smear and Pelvic Examination Services
AB–03–055	• Shared System Maintainer Hours for Resolution of Problems Detected During Health Insurance Portability and Accountability Act Transaction Release Testing
AB–03–056	• New Waived Test—March 21, 2003
AB–03–057	• Implementation of the Financial Limitation for Outpatient Rehabilitation Services
AB–03–058	• Collection of Fee-for-Service Payments Made During Periods of Managed Care Enrollment
AB–03–059	• Shared Systems Changes for Name Change From Health Care Financing Administration to Centers for Medicare & Medicaid Services (Fiscal Intermediary Standard and VIPS Medicare System External Changes Only)
AB–03–060	• Flat File Changes in the Health Care Claim Professional (837 Professional) Version 4010A1, Health Care Claim Payment/Advice (835) Version 4010 and 4010A1 and 3051.4A, and Health Care Claim Status Inquiry and Response (276/277) Version 4010A1 Transactions
AB–03–061	• Program Memorandum on Written Statements of Intent To Claim Medicare Benefits
AB–03–062	• New Common Working File Edits and Standard System Responses on Skilled Nursing Facility Claims
AB–03–063	• New Common Working File Medicare Secondary Payer Edit to Reject Medicare Secondary Edit Records for Medicare Beneficiaries Who Are Only Entitled To Medicare Part B, and Are Covered by a Group Health Plan
AB–03–064	• System Networking Electronic Correspondence Referral System User Guide
AB–03–065	• Schedule Release for July Updates to Software Programs and Pricing/Coding Files
AB–03–066	• Issuance of the Eligibility File-Based Standard Trading Partner Agreement for the Purpose of Coordination of Benefits
AB–03–067	• Revision to Change Request 2170: Appeals Quality Improvement and Data Analysis Activities
AB–03–068	• Common Working File Change for the 270/271 Eligibility Transaction
AB–03–069	• Clarification of the Criteria for a Valid Written Statement of Intent To File a Medicare Claim
AB–03–070	• Second Update to the 2003 Medicare Physician Fee Schedule Database
AB–03–071	• July Quarterly Update for 2003 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Fee Schedule
AB–03–072	• Mammography Computer-Aided Detection Equipment
AB–03–073	• Provider Education Article: Financial Limitation of Claims for Outpatient Rehabilitation Services
AB–03–074	• Instructions for Fiscal Intermediary Standard System and Multi-Carrier System Healthcare Integrated General Ledger Accounting System Changes
AB–03–075	• Provider Education Article: Quarterly Provider Update
AB–03–076	• Remittance Advice Message for Denial of Clinical Diagnostic Laboratory Services Denied Due to Frequency Edits
AB–03–077	• Revised Disclosure Desk Reference for Call Centers
AB–03–078	• Medicare Fee-for-Service Contractor Guidance of the Health Insurance Portability and Accountability Act Privacy Rule Business Associate Provisions
AB–03–079	• Claims Processing Instructions for the Utah Graduate Medical Education Demonstration
AB–03–080	• Single Drug Pricer Clarification for Code J7342
AB–03–081	• Data Center Testing and Production—Electronic Correspondence Referral System User Manual 6.0
AB–03–082	• Medicare Secondary Payer Prepayment and Postpayment Workload Reporting—Activity Code Definitions
AB–03–083	• Screening of Complaints Alleging Fraud and Abuse
AB–03–084	• Changes to the Laboratory National Coverage Determination Edit Software for July 1, 2003
AB–03–085	• Beneficiary Notice of Implementation of Outpatient Therapy Service Limitations
AB–03–086	• New Automatic Notice of Change to Medicare Secondary Payer Auxiliary File
AB–03–087	• Common Working File Edits With Unsolicited Responses for Skilled Nursing Facility Consolidated Billing
AB–03–088	• Prohibition on New Trading Partner Agreements With Certain Entities for the Purpose of Coordination of Benefits
AB–03–089	• Coverage and Billing for Home Prothrombin Time International Normalized Ratio Monitoring for Anticoagulation Management
AB–03–090	• Coverage of Compression Garments in the Treatment of Venous Stasis Ulcers
AB–03–091	• Medicare Contractor Annual Update of the International Classification of Diseases, Ninth Revision, Clinical Modification
AB–03–092	• Expanded Coverage of Positron Emission Tomography Scans and Related Claims Processing Requirements for Thyroid Cancer and Perfusion of the Heart Using Ammonia N–13
AB–03–093	• Correction: Coverage and Billing Requirements for Electrical Stimulation for the Treatment of Wounds
	Hospice Manual (CMS Pub. 10) (Superintendent of Documents No. HE 22.8/2)
800	• Screening Pap Smears and Screening Pelvic Examinations
801	• Notice to Beneficiaries Peer Review Organization Monitoring of Hospital Admission Notice to Beneficiaries
802	• Frequency of Billing
803	• Magnetic Resonance Angiography
804	• Screening Pap Smears and Screening Pelvic Examinations
805	• International Classification of Diseases 9th Edition Clinical Modification

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April 2003 Through June 2003]

Transmittal No.	Manual/Subject/Publication No.
	Home Health Agency Manual (CMS Pub. 11) (Superintendent of Documents No. HE 22.8/5)
304	• Frequency of Billing
	Coverage Issues Manual (CMS Pub. 6) (Superintendent of Documents No. HE 22.8/14)
169	• Stem Cell Transplantation
170	• Magnetic Resonance Angiography
171	• Positron Emission Tomography Scans
172	• Intestinal and Multi-Visceral Transplantation
	Peer Review Organization (CMS Pub. 19) (Superintendent of Documents No. 22.8/8–15)
90	• Eligibility—has been moved to the Pub. 100–10, Medicare Quality Improvement Organizations Manual, Chapter 2, which can be found at *http://www.cms.hhs.gov/manuals.* Data Management—has been moved to the Pub. 100–10, Medicare Quality Improvement Organizations Manual, Chapter 8, which can be found at *http://www.cms.hhs.gov/manuals.* Management—has been moved to the Pub. 100–10, Medicare Quality Improvement Organizations Manual, Chapter 13, which can be found at *http://www.cms.hhs.gov/manuals.* Performance Evaluation—has been moved to the Pub. 100–10, Medicare Quality Improvement Organizations Manual, Chapter 15, which can be found at *http://www.cms.hhs.gov/manuals.*
	Hospice Manual (CMS Pub. 21) (Superintendent of Documents No. HE 22. 8/18)
67	• Frequency of Billing
	Rural Health Clinic Manual & Federally Qualified Health Centers Manual (CMS Pub. 27) (Superintendent of Documents No. He 22. 8/19:985)
38	• Magnetic Resonance Angiography
	Rural Dialysis Facility Manual (Non-Hospital Operated) (CMS Pub. 29) (Superintendent of Documents No. 22.8/13)
95	• Frequency of Billing
	Provider Cost Reporting Forms and Instructions Provider Reimbursement Manual—Part 2
	Chapter 36/Form CMS–2552–96 (CMS Pub. 15–2–36) (Superintendent of Documents No. HE 22.8/4)
10	• Hospital Healthcare Complex Cost Report
	Program Integrity Manual (CMS Pub. 100–08)
40	• Local Provider Education and Training Program
41	• Definitions Related To Enrollment Benefit Integrity/Payment Safeguard Contractor vs. Provider Enrollment Contractors Forms Disposition Processing the Application Identification Adverse Legal Actions Practice Location Ownership and Managing Control Information (Organizations) Ownership and Managing Control Information (Individuals) Delegated Official Ambulance Services Suppliers Certified Basic Life Support Independent Diagnostic Testing Facilities—Attachment 1 Entities That Must Enroll as Independent Diagnostic Testing Facilities

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April 2003 Through June 2003]

Transmittal No.		Manual/Subject/Publication No.
		Review of Attachment 2, Independent Diagnostic Testing Facility
		Enrollment Checks
		Special Consideration
		Reassignment of Benefits—Form CMS–855R
		Reassignment of Benefits Statement
		Attestation Statement
		Enrolling Certified Suppliers Who Enroll With Carrier
		Managed Care Organization
		Application Sectional Instructions for Intermediaries
		Processing the Application
		Provider Identification
		Adverse Legal Actions
		Practice Location
		Ownership and Managing Control Information (Organizations)
		Chain Home Office Information
		Billing Agency
		Staffing Company
		Capitalization Requirements for Home Health Agencies
		Contact Person
		Certification Statement
		Delegated Official
		Special Processing Situation
		Community Mental Health Centers
		Benefit Improvement and Protection Act of 2000 Provisions
		Community Mental Health Centers Enrollment and Change of Ownership
		Site Visit
		Process
		Deactivation of Billing Numbers for Inactive Community Mental Health Centers
		State Survey Regional Office Process
		Changes of Information—New Form CMS–855 Data
		Change Requirement
		Procedures for Request for Additional Information, Approval, Denial or Transmission of Recommendations
		Request for Additional Information
		Approval and Recommendations for Approval
		Denials
		Failure to Sign and/or Date the Application
		Revocations
		Time Frame for Application Processing
		Matrix
		Verification and Validation of Information
		Fraud Investigation Database
		Healthcare Integrity and Protection Data Bank
		Excluded Parties List System
		Enrollment of Hospitals, Assignment of Billing Numbers
		Provider-Based Processing and Changes in Status
		Web Site
		File Maintenance and Review
42	•	Effectuating Favorable Final Appellate Decisions That a Beneficiary Is Confined To Home
43	•	Medical Records Information Reported Electronically
		Electronic Media Claim Flat File Record for End-Stage Renal Disease
		Argus Filed Descriptions and Formats
		Managed Care Manual (Pub. 100–16)
23	•	Introduction
		General Requirements
		Basic Rule
		Services of Noncontracting Providers and Suppliers
		Types of Benefits
		Availability and Structure of Plans
		Terms of Medicare+Choice Plans
		Multiple Plans in One Service Area
		Centers for Medicare & Medicaid Services Review and Approval of Medicare+Choice Benefits
		Requirements Relating To Medicare Conditions of Participation
		Provider Networks
		Requirements Relating To Benefits
		Basic Benefits
		Additional Benefits
		Supplemental Benefits—Mandatory Supplemental and Optional Supplemental

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April 2003 Through June 2003]

Transmittal No.	Manual/Subject/Publication No.
	Basic Versus Supplemental Benefits
	Medicare Covered Benefits
	Medicare+Choice Medical Savings Account Plan Benefits
	General Rule
	Countable Expenses
	Services After the Deductible
	Balance Billing
	The Annual Deductible
	Special Rules on Supplemental Benefits for Medicare+Choice Medical Savings Account Plans
	Point of Service Option
	General Rule
	Accessing Plan Contracting Providers
	Financial Cap
	Enrollee Information and Disclosure
	Prompt Payment
	Point of Services Related Data
	Services Area
	Definition
	Factors That Influence Service Area Approvals
	The ''County Integrity Rule''
	Coordination of Benefits With Employer Group Health Plans and Medicaid
	General Rule
	Requirements, Rights, and Beneficiary Protection
	Medicare Secondary Payer Procedures
	Basic Rule
	Responsibilities of the Medicare+Choice Organization
	Medicare Benefits Secondary to Group Health Plans and Large Group Health Plans
	Collecting From Other Entities
	Collecting From Other Insurers or the Enrollee
	Collecting From Group Health Plans and Large Group Health Plans
	Medicare Secondary Payor
	National Coverage Determinations and Legislative Changes in Benefits
	Definitions
	General Rules
	Sources for Obtaining Information
	Discrimination Against Beneficiaries Prohibited
	General Prohibition
	Additional Requirements
	A Medicare+Choice Organization's Responsibility
	Disclosure Requirements
	Introduction
	Disclosure Requirements at Enrollment (and Annually Thereafter)
	Disclosure Upon Request
	Information Pertaining to a Medicare+Choice Organization Changing Its Rules or Provider Network
	Other Information That Is Disclosable
	Access to (and Availability of) Service
	Introduction
	Access and Availability Rule for Coordinated Care Plans
	Rules for All Medicare+Choice Organizations to Ensure Continuity of Care
	Ambulance, Emergency, and Urgently Needed, and Post-Stabilization Care Services Ambulance
	Emergency and Urgently Needed Services
	Post-Stabilization Care Services
	Confidentiality and Accuracy of Enrollee Records
	General Rule
	Private Fee-for-Service Plans
	Information on Advance Directives
	Definition
	Basic Rule
	State Law Primary
	Content of Enrollee Information and Other Medicare+Choice Obligations
	Incapacitated Enrollees
	Community Education Requirements
	Medicare+Choice Organization Rights
	Appeal and Anti-Discrimination Rights

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April 2003 Through June 2003]

Transmittal No.	Manual/Subject/Publication No.
24	• Introduction Provider Involvement in Policy-Making Physician Consultation in Medical Policies Consultation in Development of Credentialing Policies Written Information on Physician Participation Interference With Health Care Professionals' Advice to Enrollees Prohibited Provider Anti-Discrimination Provider Participation Notice of Reason for Not Granting Participation Confirmation of Eligibility for Participation in Medicare Excluded and Outpatient Physical Therapy and Opt-Out Provider Checks Credentialing, Monitoring, and Recredentialing Suspension, Termination, or Nonrenewal of Physician Contract Institutional Provider and Supplier Certification Physician Incentive Plans Requirements and Limitations Disclosure of Physician Incentive Plans Provider Indemnification of Medicare+Choice Organization Prohibited Special Rules for Services Furnished by Non-Contract Provider
25	• Introduction Terminology Rules Governing Premiums and Cost Sharing Monthly Premiums Uniformity of Premiums Segmented Services Area Option Timing of Payments Monetary Inducements Prohibited Submission of Proposed Premiums and Related Information General Rule Information Required for Coordinated Care Plans and Private Fee-For-Service Plans Average Payment Rate Centers for Medicare & Medicaid Services Review Limits on Premiums and Cost-Sharing Amounts Rules for Coordinated Care Plans Rules for Medicare+Choice Private Fee-for-Service Plans Special Rules for Mid-Year (Benefit) Enhancement General Rule Incorrect Collections of Premiums and Cost Sharing Definitions Refund Methods Reduction by Centers for Medicare & Medicaid Services Adjusted Community Rate Process General Information Standard Method Initial Rate Calculation Initial Rate Adjustment by Medicare+Choice Organization Initial Rate Adjustment by Centers for Medicare & Medicaid Services Other Methods for Computing Adjusted Community Rate Special Rule for Centers for Medicare & Medicaid Services Average Payment Rate or Adjusted Community Rate Calculation Centers for Medicare and Medicaid Services Review Sufficiency of Documentation and Periodic Audits Requirement for Additional Benefits—42 Code of Federal Regulations 422.312 Definitions General Information Stabilization Fund Establishment of a Stabilization Fund Limit Per Contract Period Exception to the Limit Per Contract Period Cumulative Limit Interest on and Accounting of Reserved Funds Withdrawal From a Stabilization Fund Criteria for Centers for Medicare & Medicaid Services Approval Basis for Denial Form of Payment Additional Benefits Part B Premium Reduction As an Additional Benefit Additional Health Care Benefits Reduction of Charges to Enrollees for Basic Benefits Additional Supplemental Health Care Benefits and Related Premiums

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[April 2003 Through June 2003]

Transmittal No.	Manual/Subject/Publication No.
	Detailed Instructions
	Enrollees Who Elect Hospice While Remaining Enrolled in a Medicare+Choice Plan
	Hospice Benefits
	Medicare+Choice Non-Medicare-Covered Benefits
	Medicare+Choice Medicare-Covered Benefits (Except Hospice)
	Medicare+Choice Non-Medicare-Covered Benefits
	Enrollees with End-Stage Renal Stage Disease User Fees
	End-Stage Renal Disease Network Fee
	Information Campaign User Fee
	Waivers for Medicare+Choice Organization Contracts With Employer or Union Groups
	Background
	Section 617 Waiver Categories Approved
	Service Areas
	Adjusted Community Rate Filings
	Coordination of Benefits
	Effect on Medicare+Choice Plan Cash Flow
	Effect on Adjusted Community Rate Calculations

Addendum IV.—Regulation Documents Published in the Federal Register

[April 2003 Through June 2003]

Publication date	FR vol. 68 page No.	CFR parts affected	File code	Title of regulation
April 2, 2003	15973	42 CFR Part 440	CMS–2132–P	Medicaid Program; Provider Qualifications for Audiologists.
April 4, 2003	16652	42 CFR Parts 422 and 489.	CMS–4024–FC	Medicare Program; Improvements to the Medicare+Choice Appeal and Grievance Procedures.
April 16, 2003	18654		CMS–1256–N	Medicare Program; Notice of Ambulance Fee Schedule in Accordance With Federal District Court Order.
April 17, 2003	18895	45 CFR Part 160	CMS–0010–IFC	Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings.
April 25, 2003	22268	42 CFR Parts 405, 412, 413, and 485.	CMS–1203–CN	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2003 Rates; Correction.
April 25, 2003	22064	42 CFR Parts 420, 424, 489, and 498.	CMS–6002–P	Medicare Program; Requirements for Establishing and Maintaining Medicare Billing Privileges.
April 25, 2003	20394		CMS–1251–N	Medicare Program; Meeting of the Practicing Physicians Advisory Council—May 19, 2003.
April 25, 2003	20393		CMS–4052–N	Medicare Program: Meeting of the Advisory Panel on Medicare Education—May 21, 2003.
April 25, 2003	20391		CMS–2182–PN	Medicare and Medicaid Programs; Application by the Community Health Accreditation Program (CHAP) for Continued Approval of Deeming Authority for Hospices.
April 25, 2003	20349	42 CFR Parts 422 and 489.	CMS–4024–CN	Medicare Program; Improvements to the Medicare+Choice Appeal and Grievance Procedures; Correction.
April 25, 2003	20347	42 CFR Part 411	CMS–1809–F3	Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Extension of Partial Delay of Effective Date.
April 28, 2003	22453	45 CFR Part 160	CMS–0010–IFC (OFR) Correction).	Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings; Correction.
May 2, 2003	23410	45 CFR Part 148	CMS–2179–FC	Grants to States for Operation of Qualified High Risk Pools.
May 16, 2003	26786	42 CFR Part 412	CMS–1474–P	Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for FY 2004.
May 16, 2003	26758	42 CFR Parts 409, 413, 440, and 483.	CMS–1469–P	Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update.
May 16, 2003	26621		CMS–4060–N	Medicare Program; Town Hall Meeting on the Refinement of the Minimum Data Set (MDS), Version 3.0.
May 19, 2003	27154	42 CFR Parts 412 and 413.	CMS–1470–P	Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2004 Rates.
May 29, 2003	32053		CMS–2185–N	Fiscal Year 2003 Program Announcement; Availability of Funds and Notice Regarding Applications.
May 30, 2003	32528		CMS–2177–FN	Medicare and Medicaid Programs; Approval of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for Deeming Authority for Hospices.
May 30, 2003	32527		CMS–3116–N	Medicare Program; Request for Nominations for Members for the Medicare Coverage Advisory Committee.

Addendum IV.—Regulation Documents Published in the Federal Register—Continued

[April 2003 Through June 2003]

Publication date	FR vol. 68 page No.	CFR parts affected	File code	Title of regulation
May 30, 2003	32406	42 CFR Part 416	CMS–1885–CN	Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures Effective July 1, 2003.
May 30, 2003	32400	42 CFR Parts 410, 414, and 485.	CMS–1204–CN	Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2003 and Inclusion of Registered Nurses in the Personnel Provision of the Critical Access Hospital Emergency Services Requirement for Frontier Areas and Remote Locations.
June 4, 2003	33579	42 CFR Parts 412 and 413.	CMS–1470–P (OFR Correction).	Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2004 Rates.
June 4, 2003	33495		CMS–5003–N	Medicare Program; Demonstration: End-Stage Renal Disease—Disease Management.
June 6, 2003	34122	42 CFR Part 412	CMS–1472–F	Medicare Program; Prospective Payment System for Long-Term Care Hospitals: Annual Payment Rate Updates and Policy Changes.
June 9, 2003	34494	42 CFR Part 412	CMS–1243–F	Medicare Program; Change in Methodology for Determining Payment for Extraordinarily High-Cost Cases (Cost Outliers) Under the Acute Care Hospital Inpatient and Long-Term Care Hospital Prospective Payment Systems.
June 9, 2003	34492	42 CFR Parts 412 and 413.	CMS–1470–P (OFR Correction).	Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2004 Rates; Correction.
June 10, 2003	34768	42 CFR Part 413	CMS–1469–P2	Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update.
June 27, 2003	38370		CMS–1259–N	Medicare Program; Public Meeting in Calendar Year 2003 for New Clinical Laboratory Tests Payment Determinations.
June 27, 2003	38370		CMS–5003–N2	Medicare Program; Extension of Date of Submissions and Informational Meeting on the Application Process for the End-Stage Renal Disease—Disease Management Demonstration.
June 27, 2003	38359		CMS–9017–N	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—January 2003 Through March 2003.
June 27, 2003	38346		CMS–4062–N	Medicare and Medicaid Programs; Solicitation for Information on the Hospital CAHPS.
June 27, 2003	38345		CMS–1257–N	Medicare Program: Notice of the Practicing Physicians Advisory Council Rechartering.
June 27, 2003	38269		CMS–6012–N6	Medicare Program; Negotiated Rulemaking Committee on Special Payment Provisions and Requirements for Prosthetics and Certain Custom-Fabricated Orthotics; Meeting Announcement.
June 27, 2003	38206	45 CFR Part 146	CMS–2152–F	Amendment to the Interim Final Regulation for Mental Health Parity.

Addendum V.—National Coverage Determinations, April 2003 Through June 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 became effective 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 impending decisions or, in some cases, explain why it was not appropriate to issue an NCD. We identify completed decisions by section of the Coverage Issues Manual (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

[April 2003 Through June 2003]

CIM section	Title	Issue date	Effective date
	Coverage Issues Manual (CIM) (CMS Pub. 06)		
50–14	Magnetic Resonance Angiography of the Abdomen and Pelvis	05/09/03	07/01/03
35.85.1	Implantable Automatic Defibrillators	06/06/03	10/01/03
50–36	PET for Thyroid Cancer	06/20/03	10/01/03
50–36	PET for Soft Tissue Sarcoma	06/20/03	10/01/03
50–36	PET for Alzheimer's Disease/Dementia	06/20/03	10/01/03

NATIONAL COVERAGE DECISIONS—Continued

[April 2003 Through June 2003]

CIM section	Title	Issue date	Effective date
50–36	PET for Myocardial Perfusion of the Heart Using Ammonia N–13	06/20/03	10/01/03

PM No.	Title	Issue date	Effective date
	Program Memorandum (PM)		
AB–03–084	Changes to the Laboratory NCD Edit Software For 07/03 (Blood Counts, Blood Glucose Testing, HIV Testing).	06/06/03	07/01/03

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, April through June 2003.

INVESTIGATIONAL DEVICE EXEMPTION NUMBERS, 2ND QUARTER 2003

IDE	Category
G010175	B
G010354	B
G020083	B
G020115	A
G020230	B
G020231	B
G020244	B
G020273	B
G020307	B
G020319	B
G020323	B
G030001	B
G030007	B
G030034	B
G030044	B
G030045	B
G030051	B
G030054	B
G030055	B
G030056	B
G030058	B
G030061	B
G030062	B
G030063	B
G030064	B
G030065	B
G030073	B
G030074	B
G030075	B
G030078	B
G030080	B
G030082	B
G030088	B
G030089	B
G030090	B
G030091	B
G030095	B
G030096	B
G030097	B
G030101	B
G030103	B
G030104	B
G030105	A
G030106	B
G030108	B
G030109	B
G030110	B
G030113	B
G030114	B
G030115	B
G030117	B
G030118	B
G030120	B
G030122	B
G030124	B
G030126	B
G030128	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.
0938–0034	405.821.
0938–0035	407.4.
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, 440.250, 440.220, 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 and 455.100–455.106.

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'')
0938–0101	430.3.
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	405.247.
0938–0170	493.1269–493.1285.
0938–0193	430.10–430.20 and 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.
0938–0251	406.7.
0938–0266	416.41, 416.83, 416.47, 416.48.
0938–0267	485.56, 485.58, 485.60, 485.64, 485.66, 410.65.
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	413.17.
0938–0300	431.8.
0938–0301	413.20, 413.24.
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 Subpart A.
0938–0338	486.104, 486.106, 486.110.
0938–0354	441.6.
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 and 489.21.
0938–0358	412.20–412.30.
0938–0359	412.40–412.52.
0938–0360	405.2100–405.2184.
0938–0365	484.10, .11, .12, .14, .16, .18, .20, .36, .48, .52.
0938–0372	414.33.
0938–0378	482.60–482.62.
0938–0379	418.1–418.405.
0938–0380	482.1–482.66.
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	424.2.
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 and 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	475.100 Subpart C, 475.106 and 475.107, 462.102, 462.103.
0938–0534	410.38, 424.5.
0938–0544	493.1–493.2001.
0938–0565	411.20–411.206.
0938–0566	411.404(b)(c), 411.406(d), 411.408(d)(2) and (f).
0938–0567	Part 498 Subpart H, Part 498 Subparts D and E, and 20 CFR 404.933.
0938–0573	412.256 and 412.230.
0938–0581	493.1–493.2001.
0938–0599	493.1–493.2001.
0938–0600	405.371, 405.378 and 413.20.

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0938–0610	417.436, 417.801, 417.436(d), 422.128, 430.12(c)(1)(ii), 431.20, 31.107, 434.28, 483.10, 484.10(c)(ii), 489.102.
0938–0612	493.1–493.2001.
0938–0618	433.68, 433.74, 447.272.
0938–0653	493.
0938–0655	493.184.
0938–0657	405.2110, 405.2112.
0938–0658	405.2110, 405.2112.
0938–0667	482.12, 488.18, 489.20 and 489.24.
0938–0673	430.1.
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, and 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.
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, and 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	417.470, 417.126(a), 422.210(h), 422.64(10).
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	413.65, 419.42.
0938–0802	419.43.
0938–0810	482.45.
0938–0819	45 CFR 146.121.
0938–0823	420.41.
0938–0824	482.13(f)(7), 440.10(1)(3)(iii).
0938–0827	45 CFR 146.141.
0938–0829	422.568.
0938–0832	489.
0938–0833	483.350–483.376.
0938–0840	422.152(b)(2).
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, and 457.1180.
0938–0842	412 and 413.
0938–0846	411.1, 411.350–411.357 and 424.22.
0938–0857	419.
0938–0860	419.
0938–0866	45 CFR Part 162.
0938–0872	483.20, 413.337.
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.

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'')
0938–0897	412.22, 412.533.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3062–N]

RIN 0938–AK61

Medicare Program; Revised Process for Making Medicare National Coverage Determinations

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

ACTION: Notice.

SUMMARY: This notice revises the process we will use to make a national coverage determination for a specific item or service under sections 1812, 1832, 1861, 1862, 1869, and 1871 of the Social Security Act, as revised by sections of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000. This notice further clarifies our decision-making process and increases the opportunities for public participation.

EFFECTIVE DATE: This notice is effective on October 27, 2003.

FOR FURTHER INFORMATION CONTACT: Vadim Lubarsky, (410) 786–0840.

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I. Background

In the April 27, 1999 **Federal Register** (64 FR 22619), we published a notice that announced changes to our internal procedures for developing a national coverage determination (NCD) and making the NCD process more open and understandable to the public. As we strive for continuous improvement of our processes, and in recognition of the changes that section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) requires, we are revising our process for developing an NCD in order to make the process more efficient and ensure that we have access to all relevant information to make fully informed decisions. (BIPA, Pub. L. 106–554, was enacted on December 21, 2000.) The processes described in this notice apply to both scope of benefit and section 1862(a)(1) determinations as defined in the Social Security Act (the Act). This notice replaces the April 27, 1999 notice and will be effective on October 27, 2003. Improvements include the following:

- Updating and organizing the reconsideration process into one section, and distinguishing it from an initial request to make an NCD.
- Defining, streamlining, and organizing the contact/inquiry information into one section.
- Revising, formalizing, and updating the elements that constitute a complete, formal request to reflect best practices.
- Adding a section on information that does *not* constitute a complete, formal request.
- Updating and clarifying the conditions for acceptance of a complete, formal request.
- Making it clear that all evidence currently available must be adequate for us to conclude that the item or service is reasonable and necessary.
- Establishing two main tracks for the initial NCD request. One track is a highly time-structured track only available to aggrieved parties (section IV.E track #2), as defined in section 522 of BIPA. The other track is open to anyone, including aggrieved parties, beneficiaries, and manufacturers, and offers a more collaborative and less time-stringent process (section IV.E track #1).

Historically, we have based our coverage determinations on descriptive information, and scientific and clinical evidence. Under the revised BIPA coverage process, we will continue to use descriptive information, and scientific and clinical evidence as a basis for our coverage determinations.

II. Purpose of This Notice

This notice outlines the process we will use to make an NCD under the Medicare program. It sets forth the steps we are taking to make the NCD process more efficient, while maintaining as open and transparent a process as appropriate. It describes the following:

- A tracking system that provides public notice of our acceptance of a complete, formal request and subsequent actions in a web-based format.
- The process we will institute to afford notice and opportunity to comment before implementation of an NCD.
- Information that does and does *not* constitute a complete, formal request.
- The process for asking us to reconsider an existing NCD based on new information, including new medical or scientific evidence.
- The basis and purpose of a decision memorandum and where it can be accessed on our Web site.
- The revisions made to the NCD process under BIPA, including a response to public comments, and how these revisions affect the current NCD process and any subsequent challenges to an NCD.

In addition, we will continue to pursue an ongoing effort to work with various sectors of the scientific and medical community to develop and publish on the CMS Web site documents that describe our approach when analyzing scientific and clinical evidence to develop an NCD. Interested parties will be able to offer comments. Accordingly, these documents will make our coverage process more open and offer the public a better understanding into our NCD process.

In our April 1999 notice, we announced that we anticipated publishing a final coverage criteria rule that would be followed by sector-specific guidance documents (64 FR 22620). Since then, we published a notice of intent to engage in rulemaking for coverage criteria (May 16, 2000, 65 FR 31124) and had a subsequent town