before they will be allowed to enter the building. Persons who are not registered in advance will not be permitted into the building and will not be permitted to attend the meeting.

A member of our staff will be stationed at the Central Building first-floor lobby to provide assistance to attendees. Please remember that all visitors must be escorted if they have business in areas other than the lower- and first-floor levels in the Central Building. Parking permits and instructions are issued upon arrival by the guards at the main entrance.

Individuals requiring sign-language interpretation for the hearing impaired or other special accommodations should send a request for these services to the meeting coordinator by Monday, January 6, 2003.

Authority: Section 1833(t) of the Social Security Act (42 U.S.C. 1395(t), as amended by section 201(h) of the BBRA of 1999 (Pub. L. 106–113). The Panel is governed by the provisions of Pub. L. 92–463, as amended (5 U.S.C. Appendix 2).

Dated: December 4, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02–31409 Filed 12–26–02; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3104–N]

Medicare Program; Renewal and Amendment of the Charter of the Medicare Coverage Advisory Committee (MCAC)

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

ACTION: Notice.

SUMMARY: This notice announces the renewal and amendment of the Charter of the Medicare Coverage Advisory Committee (the Committee). The Committee advises the Secretary of the Department of Health and Human Services (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services on whether adequate evidence exists to determine whether specific medical items and services are reasonable and necessary under Title XVIII of the Social Security Act.

FOR FURTHER INFORMATION CONTACT: Michelle Atkinson, Office of Clinical Standards and Quality, CMS, 7500 Security Boulevard, Mail Stop C1–09–06, Baltimore, MD 21244, (410) 786–2881, or e-mail *matkinson@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) announcing establishment of the Medicare Coverage Advisory Committee (MCAC). The Secretary signed the initial charter for the MCAC on November 24, 1998.

The MCAC, chartered under 42 U.S.C. 217(a), section 222 of the Public Health Service Act, as amended, is governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463 as amended (5 U.S.C. Appendix 2)), which sets forth standards for the formulation and use of advisory committees.

The Committee consists of a maximum of 100 appointed members from authorities in clinical and administrative medicine, biologic and physical sciences, public health administration, health care data and information management and analysis, the economics of health care, medical ethics, and other related professions. Each Committee meeting will deal with one or more specific clinical topics, and will generally include 13 to 15 Committee members. A roster will be developed and published in advance for each Committee meeting. Members will be chosen to serve on the roster for each Committee meeting as to their expertise and topic to be discussed.

The Committee reviews and evaluates medical literature, reviews technical assessments, and examines data and information on the effectiveness and appropriateness of medical items and services that are covered or eligible for coverage under Medicare. The Committee works from an agenda provided by the Designated Federal Official that lists specific issues, and develops technical advice in order to assist us in determining reasonable and necessary applications of medical services and technology.

II. Provision of This Notice

This notice announces the signing of the MCAC Charter Amendment on October 30, 2002 and the renewal by the Secretary on November 22, 2002. The Charter will terminate on November 22, 2004, unless renewed by the Secretary.

III. Copies of the Charter

You may obtain a copy of the Secretary's Charter for the MCAC by submitting a request to Maria Ellis, Office of Clinical Standards and Quality, CMS, 7500 Security Blvd., Mail Stop S3–02–01, Baltimore, MD 21244, 410–786–0309, or e-mail the request to *mellis@cms.hhs.gov.*

Authority: 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

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

Dated: December 17, 2002.

Robert A. Streimer,

Acting Director, Office of Clinical Standards and , Quality, Centers for Medicare & Medicaid Services.

[FR Doc. 02–32653 Filed 12–26–02; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–9015–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July 2002 Through September 2002

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 2002, through September 2002, relating to the Medicare and Medicaid programs. This notice also 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.

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

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may have a specific information need and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing information contact persons to answer

general questions concerning these items. Copies are not available through the contact persons. (*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, (410) 786–5252.

Questions concerning national coverage determinations should be directed to Shana Olshan, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244–1850, (410) 786–3122.

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

Questions concerning all other information may be addressed to Misty Whitaker, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Centers for Medicare & Medicaid Services, C5–10–24, 7500 Security Boulevard, Baltimore, MD 21244–1850, (410) 786–3087.

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 these 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, fiscal intermediaries and carriers that process claims and pay bills, and others. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act). We also issue various manuals, memoranda, and statements necessary to administer the programs efficiently.

Section 1871(c)(1) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, 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, we are continuing our practice of including Medicare substantive and interpretive regulations (proposed and final) published during the 3-month timeframe.

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, and Food and Drug Administration-approved investigational device exemptions published during the timeframe 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 may wish to review the August 21, 1989, publication (54 FR 34555). Those interested in the procedures used in making national coverage determinations may review the April 27, 1999, publication (64 FR 22619). In this publication, the 1989 proposed rule affecting national coverage procedures and decisions (54 FR 4302) was withdrawn, and the procedures for national coverage determinations established.

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 instruction or many. Often, it is necessary to use information in a transmittal in conjunction with information currently in the manuals.
- Addendum IV lists all substantive and interpretive Medicare and Medicaid regulations and general notices published in the **Federal Register** during the quarters 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 national coverage determinations from the quarter covered by this notice. Completed decisions are identified by title, a brief description, effective date, and section in the appropriate Federal publication.
- Addendum VI includes listings of the Food and Drug Administration-approved investigational device exemption categorizations, using the investigational device exemption numbers the Food and Drug Administration assigns. The listings are organized according to the categories to which the device numbers are assigned (that is, Category A or Category B), and identified by the investigational device exemption number.)

III. How To Obtain Listed Material

A. Manuals

Those wishing to subscribe to program manuals should contact either the Government Printing Office (GPO) or the National Technical Information Service (NTIS) at the following addresses: Superintendent of Documents, Government Printing Office, Attn: New Orders, P.O. Box 371954, Pittsburgh, PA 15250–7954, Telephone (202) 512–1800, Fax number (202) 512–2250 (for credit card orders); or National Technical Information Service, Department of Commerce, 5825 Port Royal Road, Springfield. VA 22161, Telephone (703) 487–4630.

In addition, individual manual transmittals and Program Memoranda listed in this notice can be purchased from NTIS. Interested parties should identify the transmittal(s) they want. GPO or NTIS can give complete details on how to obtain the publications they sell. Additionally, 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.access.gpo.gov/nara/index.html,* by using local WAIS client software, or by telnet to *swais.access.gpo.gov,* then log in as guest (no password required). Dial-in users should use communications software and modem to call (202) 512–1661; type swais, then log in as guest (no password required).

C. Rulings

We publish rulings on an infrequent basis. Interested individuals can obtain copies from the nearest 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, as the stock number is: 717–319–00000–3. 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 reports 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

Transmittal 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 Part 3—Program Administration, (CMS Pub. 14–3) transmittal entitled ''Payment Requirements,'' use the Superintendent of Documents No. HE 22.8/7 and the transmittal number 1758.

(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 16, 2002.

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.

August 11, 1998 (63 FR 42857)
September 16, 1998 (63 FR 49598)
December 9, 1998 (63 FR 67899)
May 11, 1999 (64 FR 25351)
November 2, 1999 (64 FR 59185)
December 7, 1999 (64 FR 68357)
January 10, 2000 (65 FR 1400)
May 30, 2000 (65 FR 34481)
June 28, 2002 (67 FR 43762)
September 27, 2002 (67 FR 61130)

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

An extensive descriptive listing of Medicare manuals and memoranda was published on June 9, 1988, at 53 FR 21730 and supplemented on September 22, 1988, at 53 FR 36891 and December 16, 1988, at 53 FR 50577. Also, a complete description of the Medicare Coverage Issues Manual was published on August 21, 1989, at 54 FR 34555. (Please note that in this publication the 1989 proposed rule referred to, concerning the criteria for national coverage determinations, was withdrawn (64 FR 22619)). A brief description of the various Medicaid manuals and memoranda that we maintain was published on October 6, 1992 (57 FR 47468).

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS

[July 2002 Through September 2002]

Transmittal No.	Manual/Subject/Publication No.
	Intermediary Manual Part 2—Audits, Reimbursement Program Administration (CMS Pub. 13–2) (Superintendent of Documents No. HE 22.8/6–2)
420	• Provider Services

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 2002 Through September 2002]

Transmittal No.		Manual/Subject/Publication No.
		Intermediary Manual Part 3—Claims Process (CMS Pub. 13–3) (Superintendent of Documents No. HE 22.8/6)
1858	•	Claims Processing Timeliness
1859	•	Coding for Adequacy of Hemodialysis
1860	•	Payment for Services Furnished by a Critical Access Hospital
1861	•	Definitions
1862	•	ICD–9–CM Coding for Diagnostic Tests
		Carriers Manual Part 3—Program Administration (CMS Pub. 14–2) (Superintendent of Documents No. HE 22.8/7–3)
145	•	Provider Services
		Carriers Manual Part 3—Program Administration (CMS Pub. 14–3) (Superintendent of Documents No. HE 22.8/7)
1757	•	Durable Medical Equipment Regional Carriers Mandatory Assignment for Drug Claims
1758	•	Payment Requirements Roster Claim Form
1759	•	Splitting Claims for Processing
1760	•	Participating Physician/Supplier Report Purpose and Scope Definitions of Columns One Through Eight Definitions of Lines One Through One Hundred Fifteen Checking Reports Exhibits
1761	•	Completing Quarterly Report on Provider Enrollment Checking Reports Type of Provider Completing Lines Twelve Through Seventeen—Reason for Denial Completing Lines Eighteen Through Twenty-Two-Reason for Return Exhibits
1762	•	Diabetes Outpatient Self-Management Training Services General Conditions of Coverage and Diabetes Training Hours Beneficiaries Eligible for Coverage Provider/Supplier Eligibility to Provide the Training Quality Standards Enrollment of Entities Other Than Durable Medical Equipment Prosthetic, Orthotics & Supplies Health Common Procedure Coding System Coding General Payment Conditions
1763	•	The "Do Not Forward" Initiative
1764	•	Services and Supplies Incident to Physician's Professional Services Services of Nonphysician Personnel Furnished Incident to Physicians Services
1765	•	Medicare Physician Fee Schedule Database 2003 File Layout Medicare Physician Fee Schedule Database Status Indicators Maintenance Process for the Medicare Physician Fee Schedule Database
1766	•	Anesthesia Services and Teaching Certified Registered Nurse Anesthetist
1767	•	Entitlement and Enrollment
1768	•	Identifying a Screening Mammography Claim and a Diagnostic Mammography Claim
1769	•	Method for Computing Fee Schedule Amounts Coding for Diagnostic Tests
1770	•	General Resolution of Common Working File 5232 Rejects
1771	•	Mandatory Assignment and Other Requirements for Home Dialysis Supplies and Equipment Paid Under Method II
		Program Memorandum Intermediaries (CMS Pub. 60A) Superintendent of Documents No. HE 22.8/6–5)
A–02–057	•	Medicare Part A Skilled Nursing Facility Prospective Payment System Update
A–02–058	•	Inpatient Rehabilitation Facility Annual Update: Prospective Payment System Pricer Changes for FY 2003
A–02–059	•	Medicare Program—Update to the Hospice Payment Rates, Hospice Cap, Hospice Wage Index and the Hospice Pricer for FY 2003

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued
[July 2002 Through September 2002]

Transmittal No.		Manual/Subject/Publication No.
A–02–060	•	Revision to Billing for Swing Bed Services Under Skilled Nursing Facility Prospective Payment System
A–02–061	•	Medicare Program—Update to the Prospective Payment System for Home Health Agencies for Fiscal Year 2003
A–02–062	•	Applicable Bill Type for Ambulance Services (Revenue Code 540)
A–02–063	•	Scheduled Release for October Updates to Software Programs and Pricing/Coding Files
A–02–064	•	Excluding Hospitals that Provide Part B Only Services to Their Inpatients from the Outpatient Prospective Payment System
A–02–065–	•	Implementation of the Transmission Control Protocol/Internet Protocol for the Health Insurance Portability and Accountability Act Health Care Eligibility Benefit Inquiry And Response Transaction (270/271) Standard
A–02–066–	•	Department of Veterans Affairs Claims Adjudication Services Project: Systems Changes Needed
A–02–067	•	Production of Flat Files to Enable Centers for Medicare and Medicaid Services to Populate the Online Survey, Certification and Reporting Online Survey, Certification and Reporting System with the Provider Taxpayer Identification Number
A–02–068	•	Enhancements to Home Health Prospective Payment System Claims Processing
A–02–069–	•	Health Insurance Protability and Accountability Act Institutional 837 Health Care Claim Additional Implementation Direction
A–02–070	•	Health Insurance Portability and Accountability Act Transaction 835v4010 Completion Update
A–02–071	•	Updated Instruction on Receipt and Processing of Non-Covered Charges on Other Than Part A Inpatient Claims
A–02–072	•	Implementation of the Provider Enrollment, Chain and Ownership System
A–02–073	•	Financial Report Instructions for the Fiscal Intermediary Shared System Recovery Tracking System
A–02–074	•	Hospital Outpatient Prospective Payment System Implementation Instructions
A–02–075	•	Admitting Diagnosis for Observation for the Outpatient Prospective Payment System
A–02–076	•	October 2002 Update to the Hospital Outpatient Prospective Payment System
A–02–077	•	Intermediaries Must Adjust Their Translators for Reporting Line Item Dates, and Healthcare Common Procedure Coding System Codes for Part A Outpatient Claims
A–02–078	•	Health Insurance Portability and Accountability Act Institutional 837 Health Care Claim—Direct Data Entry Updates
A–02–079	•	Data Fields that the Fiscal Intermediaries are Required to Enter into the Provider Enrollment, Chain and Ownership System
A–02–080	•	October Medicare Outpatient Code Editor Specifications Version 18.0 for Bills From Hospitals That Are Not Paid Under the Outpatient Prospective Payment System
A–02–081	•	Modification of Audit and Cost Report Settlement Expectations in Change Request 1468
A–02–082	•	October Outpatient Code Editor Specifications Version (V3.2)
A–02–083	•	System Tracking for Audit and Reimbursement Instructions: End Stage Renal Disease Audits and Hospice Cost Reports
A–02–084	•	Fiscal Year 2003 Prospective Payment System Hospital, Skilled Nursing Facility and Other
A–02–085	•	Applicable Bill Types for Ambulance Services (Revenue Code 540)
A–02–086	•	The Supplemental Income/Medicare Beneficiary Data for Fiscal Year 2001 For Inpatient Prospective Payment System Hospitals
A–02–087	•	Clarification of Provider Billing Requirements Under the Outpatient Prospecitve Payment System
A–02–088	•	Installation of Version 28.0 of the Provider Statistical and Reimbursement Report
A–02–089	•	Temporary Procedures for Cost-Based Payments for Certified Registered Nurse Anesthetists Services Furnished by Outpatient Prosepctive Payment System Hospitals
A–02–090	•	File Descriptions and Instructions for Retrieving the 2003 Physician, Clinical Lab, Durable Medical Equipment, Prosthetics/Orthotics and Supplies, and Therapy Fee Schedule Payment Amounts through CMS's Mainframe Telecommunications Systems
A–02–091	•	Modifications to the Health Care Eligibility Benefit Response (271) and Direct Data Entry Screens for Home Health Agencies and Hospice Providers
A–02–092	•	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, FY 2002 (66 FR 39828, August 1, 2001) and FY 2003 (67 FR 49982, August 1, 2002)
A–02–093	•	Instructions for Implementing the Long-Term Care Hospital Prospective Payment System
		Program Memorandum Carriers (CMS Pub. 60B) (Superintendent of Documents No. HE 22.8/6–5)
B–02–039	•	Common Working File Category Changes
B–02–040	•	Common Working File Category Changes
B–02–041	•	Billing for Implanted Durabale Medical Equipment, Prosthetic Devices, Replacement Parts, Accessories and Supplies
B–02–042	•	Transmittal B–02–042 was resscinded and will not be used in the future
B–02–043	•	Acceptance of Special Characters in the Common Working File and the Durable Medical Equipment Regional Carrier Standard System
B–02–044	•	Change in Jurisdiction for Topical Hyperbaric Oxygen Chamber
B–02–045	•	VIPS Medicare System Implemntation to Process ICD–9–CM Codes Using Date of Service and Not Date of Receipt
B–02–046	•	Updating the Carrier Locality Edit at the Common Working File
B–02–047	•	Durable Medical Equipment Regional Carrier—Appeal Messages on Medicare Summary Notice and Medicare Remit Notice
B–02–048	•	Reasonable Charge Data Disclosure Requirements for Ambulance Services
B–02–049	•	Common Working File Change for Billing for Glucose Test Strips and Supplies—Follow-up to Change Request 1612
B–02–050	•	Additional Remark Code for Claims of Therapy Services Possibly Subject to Home Health Conslidated Billing
B–02–051	•	Implementation of the Health Insurance Portability and Accountability Act Health Care Eligiblity Benefit Inquiry/Response Transaction (270/271) Standard
B–02–052	•	Implementation of the National Council for Prescription Drug Programs Telecommunications Standard Version 5.1 and the Equivalent Batch Standard Version for Retail Pharmacy Drug Transactions
B–02–053	•	Implementation of the ASC X12N 278 Version 4010 Implmentation Guide for Electronic Referral Certification and Authorization
B–02–054	•	Sending Copies of Appeal Notices to Appointed Representatives, Including the Amount in Controversy Remaining in Review Determination Letters, and Using Bullets in Appeals Correspondence
B–02–055	•	Updates to the Place of Service Code Set

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 2002 Through September 2002]

Transmittal No.		Manual/Subject/Publication No.
B–02–056	•	Furlong Lawsuit Settlement Payments
B–02–057	•	Addition to Two ''WW'' Codes to Identify a New Source for Etoposide
B–02–058	•	Changes to Correct Coding Edits, Version 9.0, Effective January 1, 2003
B–02–059	•	Activation of the Automated Unsolicited Response for Skilled Nursing Facility Consolidated Billing and Global Payment Demonstrations
B–02–060	•	Payment Policy When More Than One Patient is Onboard an Ambulance
B–02–061	•	Schedule for Completing the Calendar year 2003 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–02–091	•	New Waived Tests—June 17, 2002
AB–02–092	•	Procedures Subject to Home Health Consolidated Billing
AB–02–093	•	Coverage and Billing for Intravenous Immune Globulin (IVIg) for the Treatment of Autoimmune Muccocutaneous Blistering Diseases
AB–02–094	•	Disclosure Desk Reference for Call Centers
AB–02–095	•	Prohibition on New Trading Partner Agreements with Certain Entities For the Purpose of Coordination of Benefits
AB–02–096	•	Coverage and Billing of the Diagnosis and Treatment of Peripheral Neuropathy With Loss of Protective Senation in People with Diabetes
AB–02–097	•	Carrier, Durable Medical Equipment Regional Carrier Intermediary and Regional Home Health Intermediary Processing Requirements for Claims Edited by Common Working File for Medicare Beneficiaries in State or Local Custody Under a Penal Authority
AB–02–098	•	Process for Entering Local Medical Review Policies and Certain Articles and Frequently Asked Questions into the Medicare Coverage Database
AB–02–099	•	Standardize the CICS Level, CICS Transaction Server 1.3 to be Utilized by All Medicare Contractors
AB–02–100	•	Modification of Medicare Policy for Erythropoietin
AB–02–101	•	Changes to Common Working File Edits for Skilled Nursing Facility Consolidated Billing
AB–02–102	•	Medicare Secondary Payer Debt Referral and Write Off Closed Instructions; (1) Expansion and Clarification of Medicare Secondary Payer Debt Collections Improvement Act of 1996 Activities; (2) Additional ''Write—Off—Closed Instructions'' (Supplemental Instructions for PM AB–01–24)
AB–02–103	•	Expand Standard Date Format and Review Common Working File Y2K Wrapper Logic for Beneficiary Cross Reference Internal Files and Satellite File Header and Response Records
AB–02–104	•	October Quarterly Update for 2002 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Fee Schedule
AB–02–105	•	Medical Review of Medicare Payments for Nail Debridgement Services
AB–02–106	•	Medicare Summary Notice—Inclusion of Appeals Information, Removal of Fraud References and Office of Inspector General's Hotline Number
AB–02–107	•	Modify Application of ''I'' Validity Medicare Secondary Payor Records to the Common Working File by Medicare Contractors
AB–02–108	•	Clarification of Medicare Contractor Financial Reporting Instructions Outlined in Section 1900—Section 19602.21 of the Medicare Intermediary Manual and Section 4900—Section 4960.14 of the Medicare Carriers Manual (Issued May 2001)
AB–02–109	•	Common Working File, Fiscal Intermediary and Carrier Edits and Policy Clarification for Peripheral Neuropathy With Loss of Protective Sensation in People with Diabetes
AB–02–110	•	Implementation of National Coverage Determinations Regarding Clinical Determinations Regarding Clinical Diagnostic Laboratory Services
AB–02–111	•	Implementation of Certain Initial Determination and Appeal Provisions Within § 521 of the Medicare, Medicaid and State Child Health Insurance Program Benefits Improvement and Protection Act of 2000
AB–02–112	•	Final Update to the 2002 Medicare Physician Fee Schedule Database
AB–02–113	•	Elimination of Official Level III Healthcare Common Procedure Coding System Codes/Modifiers and Unapproved Local Codes/Modifiers and Unapproved Local Codes/Modifiers
AB–02–114	•	Advanced Beneficiary Notice and Durable Medical Equipment Prosthetics, Orthotics & Supplies Refund Requirements—Implementation of Form CMS–R–131 Advance Beneficiary Notice, and of Limits on Beneficiary Liability for Medicare Equipment and Supplies
AB–02–115	•	Expanded Coverage of Position Emission Tomography Scans and Related Claims Processing Changes
AB–02–116	•	Data Center Testing and Production—Electronic Correspondence Referral System User Manual 5.0
AB–02–117	•	Transition Schedule for Implementation of the Ambulance Fee Schedule
AB–02–118	•	Notice of Interest Rate for Medicare Overpayment and Underpayments
AB–02–119	•	Medicare Coordinated Care Demonstration Payment for Railroad Retirement Beneficiaries
AB–02–120	•	Coding Instructions for IN–111 Zevalin and Y–90 Zevalin
AB–02–121	•	Provider/Supplier Plan Quarterly Report Format
AB–02–122	•	Appeals Quality Improvement and Data Analysis Activities
AB–02–123	•	Information on Medicare+Choice Private Fee-for-Service Plans—Information Only
AB–02–124	•	Updates of Rates and Wage Index for Ambulatory Surgical Center Payment Effective October 1, 2002
AB–02–125	•	Provider Education Article: Durable Medical Equipment Ordered With Surrogate Unique Physician Identification Number
AB–02–126	•	Establishing a Uniform Process for the Preparation and Mailing of Case Files From The Contractor, the Office of Hearings and Appeals, of the Social Security Administration
AB–02–127	•	Program Management Provider/Supplier Education and Training
AB–02–128	•	Coverage and Billing for Percutaneous Image-Guided Breast Biopsy
AB–02–129	•	Claims Processing Requirements for Clinical Diagnostic Laboratory Services Based on the Negotiated Rulemaking

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 2002 Through September 2002]

Transmittal No.	Manual/Subject/Publication No.
AB–02–130	• Definitions of Ambulance Services
AB–02–131	• Clarification of Medicare Policy Regarding the Implementation of the Ambulance Fee Schedule
AB–02–132	• Year 2003 Healthcare Common Procedure Coding System Annual Update Reminder
AB–02–133	• Publication and Maintenance of a Directory of Electronic Billing Ventors
	Hospital Manual (CMS Pub. 10) (Superintendent of Documents No. HE 22.8/2)
787	• Coding for Adequacy of Hemodialysis
788	• Payment for Services Furnished by a Critical Access Hospital
789	• General Information About the Program
790	• ICD–9–CM Coding for Diagnostic Tests
	Home Health Agency Manual (CMS—Pub. 11) (Superintendent of Documents No. HE 22.8/5)
302	• Combined to the Home
303	• General Information About the Program
	Skilled Nursing Facility Manual (CMS—Pub. 12) (Superintendent of Documents No. HE 22.8/3)
373	• Coverage and Patient Classification
374	• General Information About the Program
	Hospice Manual (CMS—Pub. 21) (Superintendent of Documents No. HE 22.8/18)
65	• General Information About the Program
	Outpatient Physical Therapy and Comprehensive Outpatient Rehabilitation Facility Manual (CMS—Pub. 9) (Superintendent of Documents No. HE 22.8/9)
16	• General Information About the Program
	Coverage Issues Manual (CMS—Pub. 6) (Superintendent of Documents No. HE 22.8/14)
157	• Photodynamic Therapy
	• Photosensitive Drugs
158	• Speech Generating Devices
159	• Percutaneous Image-Guided Breast Biopsy
	Rural Health Clinic Manual & Federally Qualified Health Centers Manual (CMS—Pub. 27) (Superintendent of Documents No. HE 22.8/19:985)
37	• General Information About the Program
	Rural Dialysis Facility Manual (Non-Hospital Operated) (CMS—Pub. 29) (Superintendent of Documents No. HE 22.8/13)
93	• Coding for Adequacy of Hemodialysis
	Provider Reimbursement Manual—Part 2 Provider Cost Reporting Forms and Instructions Chapter 36/Form CMS–2552–96 (CMS Pub. 15–2–36)
9	• Hospital and Hospital Healthcare Complex Cost Report

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 2002 Through September 2002]

Transmittal No.		Manual/Subject/Publication No.
		Medicare Program Integrity Manual (CMS—Pub. 100–8)
27	•	Contractor must review Local Medical Review Policy
28	•	Local Medical Review Policies Reconsideration Process
29	•	Introduction
		Definitions Related to Enrollment
		Applicant versus Provider/Supplier
		General Instructions
		Forms
		Contractors
		Forms Disposition
		Application Sectional Instructions for Carriers
		Processing the Application
		Identification
		Adverse Legal Actions
		Practice Location
		Ownership and Managing Control Information (Organizations)
		Ownership and Managing Control Information (Individuals)
		Chain Home Office Information
		Billing Agency
		Electronic Claims Submission Information
		Staffing Company
		Surety Bond Information
		Capitalization Requirement for Home Health Agencies
		Contact Person
		Penalties for Falsifying Information on This Enrollment Application
		Certification Statement
		Delegate Official
		Attachment
		Ambulance Services Suppliers—Attachment 1
		State License Information
		Description of Vehicle
		Qualification of Crew
		Certified Basic Life Support
		Certified Advanced Life Support
		Medical Director Information
		Independent Diagnostic Testing Facilities—Attachment 2
		Entities That Must Enroll as Independent Diagnostic Testing Facilities
		Review of Attachment 2, Independent Diagnostic Testing Facility
		Enrollment Checks
		Special Considerations
		Reassignment of Benefits—Form CMS–855R
		Individual Reassignment of Medicare Benefits
		Supplier Identification
		Individual Practitioner Identification
		Practice Location
		Statement of Termination
		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
		Special Processing Situations
		Community Metal Health Centers
		Benefit Improvement and Protection Act of 2000 Provisions
		Community Mental Health Centers Enrollment and Change of Ownership Site
		Visits
		Process
		Deactivation of Billing Numbers of Inactive Community Mental Health Centers
		State Survey/Regional Offices Process
		Changes in Requested 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

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 2002 Through September 2002]

Transmittal No.		Manual/Subject/Publication No.
		Denials Failure to Sign and/or Date the Application Processing Matrix Verification and Validation of Information Fraud Investigation Database Healthcare Integrity and Protection Data Bank Social Security Death Index Uncovering Fraud and Abuse General Services Administration Debarment Special Processing Situations Mass Immunizers Who Roster Bill Opt-Out Physicians Enrollment of Hospitals, Assignment of Billing Numbers Railroad Retirement Board Mass Immunization and Roster Billers Site Visits Administrative Appeals Tracking Requirements Retention of Records Provider/Suppliers Education Web Site Security Safeguards Documentation
		Managed Care Manual (CMS–Pub. 100–16) (Superintendent of Documents No. HE 22)
10	•	Quality Assessment and Performance Improvement Projects General Non-Clinical Focus Areas-Non-Clinical Focus Areas Applicable Enrollees Quality Improvement System for Managed Care Document Standard Quality Assessment and Performance Improvement Projects Phase In Requirements Ongoing Requirements Document Standard Focus Areas Clinical Focus Area Applicable to All Enrollees Attributes of Quality Assessment and Performance Improvement Selection of Topics for Medicare+Choice Selected Projects and Local Marketplace Initiatives Sources of Information Medicare+Choice Using Physician Incentive Plans Quality Indicators Significant, Sustained Improvements Sustained Improvement Over Time Types of Quality Assurance Program Improvement Projects National Quality Assurance Program Improvement Projects Medicare+Choice Organization Selected Quality Assurance Program Improvement Projects Other Quality Assurance Program Improvement Projects Process for Centers for Medicare and Medicaid Services Multi-Year Quality Assurance Program Improvement Projects Approval Evaluation of Quality Assurance Program Improvement Projects Terminology Deeming Requirements General Rule Obligations of Deemed Medicare+Choice Organizations Deemed Status and Center for Medicare and Medicaid Services Surveys Removals of a Medicare+Choice Organization's Deemed Status Centers for Medicare and Medicaid Services Role Oversight of Accrediting Organizations Obligations of Accrediting Organizations with Deeming Authority Application Requirements Reporting Requirement Reconsideration of Application Denials, Removal of All Approval of Deeming Authority, or Non-Renewals of Deeming Authority Informal Hearing Procedures Informal Hearing Findings Final Reconsideration Determinations

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July 2002 Through September 2002]

Transmittal No.		Manual/Subject/Publication No.
		Background
		Specifics Applicable to Consumer Assessment of Health Plans Study and Health Plan
		Employer Data and Information Set
		Healthplan Employer Data Information Sets Submission Requirements
		The Medicare Health Outcomes Survey Requirements
		Medicare Consumer Assessment of Health Plan Survey Requirements for Enrollees And Disenrollees
11	•	Lock-in Requirements/Selecting a Primary Care Physician—How to Access Care in a Health Maintenance Organization's Emergency Care Cross Reference to Quality Improvement System for Managed Care 2.3.1.7
		Appeal Rights
		Benefits and Plan Premium Information
		Final Verifications Review Process
		Guidelines for Outreach Program
		Submission Requirements
		Center for Medicare and Medicaid Services Review/Approval Process
		Model Direct Mail Letter
		Answers to Frequently Asked Questions About Promotional Activities
		Relationship of Value-Added Items and Services to Benefits and Other Operational Considerations
		Non Benefit Providing Third Party Marketing Materials
		Marketing Material Requirements for Non-English Speaking Populations Standard 2.3.3.2
12	•	Definitions
		Eligibility for Enrollment in Medicare+Choice Plans
		Completion of Enrollment Form
		Election Periods and Effective Dates
		Annual Election Period
		Open Enrollment Period
		Open Enrollment Period Through 2004
		Open Enrollment Period Through 2005
		Open Enrollment Period in 2006 and Beyond
		Open Enrollment for Newly Eligible Individuals in 2005 and Beyond
		Special Election Period
		Special Election Period for Exceptional Conditions
		Special Election Period for Beneficiaries Aged 65
		Effective Date of Coverage
		Effective Date of Voluntary Disenrollment
		Enrollment Procedures
		Format of Enrollment Forms
		Medicare+Choice Organizational Denial of Enrollment
		After the Effective Date of Coverage
		Procedures After Reaching Capacity
		Disenrollment Procedures
		Voluntary Disenrollment by Member
		Medigap Guaranteed Issue Notification Requirements
		Members Who Change Residence
		Failure to Pay Premiums
		Disenrollment Procedure for Employer Group Health Plans
		Multiple Transactions
		Cancellation of Enrollment
		Reinstatement Due to Mistaken Disenrollment Made By Member
		Medicare/Medicaid Sanction—Reinstatement Report (CMS Pub. 69)
06–02	•	Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—June 2002
07–02	•	Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—July 2002
09–02	•	Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—August 2002

ADDENDUM IV.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER

(July 2002 through September 2002)

Publication date	FR Vol. 67 page	CFR part(s)	File code*	Regulation title
07/01/2002	44073	42 CFR 412, and 413	CMS–1069–F2	Medicare Program; Prospective Payment System for Inpatient Rehabilitation Facilities; Correcting Amendment.
07/17/2002	46949	42 CFR Chap. IV	CMS–1227–N	Medicare Program; Town Hall Meeting on the Outcome Assessment Information Set (OASIS).

ADDENDUM IV.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER—Continued
(July 2002 through September 2002)

Publication date	FR Vol. 67 page	CFR part(s)	File code*	Regulation title
07/26/2002	48800	42 CFR 405	CMS–3074–F2	Medicare Program; End-Stage Renal Disease: Removing of Waiver Conditions for Coverage Under a State of Emergency in the Houston, Texas Area.
07/26/2002	48801	42 CFR 413	CMS–1883–F3	Medicare Program; Revision of the Procedures for Requesting Exceptions to Cost Limits for Skilled Nursing Facilities and Elimination of Reclassifications; Technical Correction.
07/26/2002	48802	42 CFR 146	CMS–2033–IFC	Technical Change to Requirements for the Group Health Insurance Market; Non-Federal Governmental Plans Exempt From HIPPA Title I Requirements.
07/26/2002	48839	42 CFR Chap. IV	CMS–6012–N2	Medicare Program; Establishment of The Negotiated Rulemaking Committee on Special Payment Provisions and Requirements for Prosthetics and Certain Custom-Fabricate Orthotics; Meeting Announcement.
07/26/2002	48840	42 CFR 413	CMS–1199–P	Medicare Program; Electronic Submission of Cost Reports.
07/26/2002	48905		CMS–4037–N	Medicare Program; Meeting of the Advisory Panel on Medicare Education—September 26, 2002.
07/31/2002	49798		CMS–1202–N	Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update.
08/01/2002	49928		CMS–1205–N	Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for FY 2003 Rates.
08/01/2002	49982	42 CFR 405, 412, 413, and 485.	CMS–1203–F	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2003 Rates.
08/09/2002	52092	42 CFR 405, 410, and 419.	CMS–1206–P	Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2003 Payment Rates; and Changes to Payment Suspension for Unfiled Cost Reports.
08/16/2002	53644	42 CFR 405, 410 and 419.	CMS–1206–P (OFR correction).	Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2003 Payment Rates; and Changes to Payment Suspension for Unfiled Cost Reports; Correction.
08/22/2002	54532	42 CFR 438	CMS–2104–F	Medicare Program; Medicaid Managed Care: New Provisions.
08/22/2002	54534	42 CFR 400, 405, and 426.	CMS–3063–P	Medicare Program; Review of National Coverage Determinations and Local Coverage Determinations.
08/23/2002	54660		CMS–1216–N	Medicare Program; September 23 and 24, 2002, Meeting of the Practicing Physicians Advisory Council and Request for Nominations.
08/23/2002	54657		CMS–2140–FN	Medicare and Medicaid Programs; Approval of Deeming Authority for Critical Access Hospitals by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).
08/23/2002	54659		CMS–3098–N	Medicare Program; Meeting of the Executive Committee of the Medicare Coverage Advisory Committee—September 25, 2002.
08/30/2002	55851		CMS–2136–PN	Medicare Program; State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals: Federal Fiscal Year 2002.
08/30/2002	55954	42 CFR 412, 413 and 476.	CMS–1177–F	Medicare Program; Prospective Payment System for Long-Term Care Hospitals: Implementation and FY 2003 Rates.
08/30/2002	56092		CMS–1211–N	Medicare Program; Hospital Wage Index for Fiscal Year 2003.
09/04/2002	56618	42 CFR 403	CMS–4027–F	Medicare Program; Medicare-Endorsed Prescription Drug Card Assistance Initiative.
09/27/2002	60993	42 CFR 408	CMS–1221–F	Medicare Program; Supplementary Medical Insurance Premium Surcharge Agreements.
09/27/2002	61116		CMS–4043–N	Medicare Program; Solicitation for Proposals for the Physician Group Practice Demonstration.

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

(July 2002 through September 2002)

Publication date	FR Vol. 67 page	CFR part(s)	File code*	Regulation title
09/27/2002	61130	....	CMS–9014–N	Medicare and Medicaid Programs: Quarterly Listing of Program Issuances—April 2002 Through June 2002.

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

Addendum V—National Coverage Determinations (April 2002 Through June 2002)

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 a NCD. We identify completed decisions by title, effective date, and section of the publication where the decision can be found. Also, please note that in some cases more than one NCD was made affecting single procedure. 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 FOR QUARTERLY NOTICE

[Coverage Issues Manual—CMS Pub. 06]

Section	Title	Effective date
45–30	Photosensitive Drugs	January 1, 2003.
45–32	Levocarnitine for the Treatment of Carnitine Deficiency in ESRD Patients	January 1, 2003.
35–77	Neuromuscular Electrical	April 1, 2003.
35–102	Electrical Stimulation for Wound Healing	April 1, 2003.

PROGRAM MEMORANDA

PM number	Title	Effective date
No items for this quarterly notice.		

JOINT LETTER AND FEDERAL REGISTER PUBLICATION

Date	Title	Effective date
No items for this quarterly notice.		

Decision Memoranda Announcing Maintenance of Existing National Coverage Determination

The following decision memoranda announce the agency's intention to issue NCDs or they announce the agency's determination that NCDs are inappropriate and thus reasonable and necessary determinations are left to contractor discretion. The relevant sections of the Coverage Issues Manual, however, have not yet been revised. The revisions will occur at a later date.

Date of memo	Title	CIM section
No items for this quarterly notice.		

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 assigns each device with a Food and Drug Administration-approved investigational device exemption to one of two categories. To obtain more information about the classes or categories, please refer to the **Federal Register** notice published on April 21, 1997 (62 FR 19328).

The following information presents the device number and category (A or B).

Investigational Device Exemption Numbers, 2nd Quarter 2002

IDE/Category

G010013 B

G010134 B
G010188 B
G010328 B
G020002 B
G020025 A
G020030 B
G020046 B
G020048 B
G020050 B
G020051 B
G020052 B
G020054 B
G020056 A
G020057 B
G020061 B
G020062 B
G020063 B
G020064 B
G020065 B
G020068 B
G020070 B
G020072 B
G020073 B
G020075 B
G020079 B
G020080 B
G020082 B
G020085 B
G020087 B
G020090 B
G020092 B
G020094 B
G020096 B
G020097 B
G020098 B
G020099 B
G020100 B
G020106 B
G020107 B
G020108 B
G020109 B
G020112 B
G020113 B
G020114 B
G020116 A
G020119 B
G020121 B
G020122 B
G020126 B
G020127 A
G020130 B
G020132 B
G020133 B
G020135 B
G020165 B

[FR Doc. 02–32197 Filed 12–26–02; 8:45 am]

BILLING CODE 4120–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval of New Jersey State Plan Amendment 02–10

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

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing to be held on February 4, 2003, 10 a.m., Centers for Medicare & Medicaid Services' New York Regional Office, 26 Federal Plaza, Room 38–110A; New York, New York 10278–0063, to reconsider our decision to disapprove New Jersey State Plan Amendment 02–10.

CLOSING DATE: Requests to participate in the hearing as a party must be received by the presiding officer by January 13, 2003.

FOR FURTHER INFORMATION CONTACT: Kathleen Scully-Hayes, Presiding Officer, CMS, 2520 Lord Baltimore Drive, Suite L, Baltimore, Maryland 21244–2670, Telephone: (410) 786–2055.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider the decision to disapprove New Jersey State Plan Amendment (SPA) 02–10. This SPA was disapproved on September 19, 2002. In this amendment, New Jersey proposes to establish a new target group for case management services for youth and young adults under the age of 21 who are in the care of the Juvenile Justice Commission as a result of a commitment order. The SPA further specifies that the target group is limited to youth and young adults who reside in their own homes, the homes of relatives, community-based residences or residential group centers, or other community-based living arrangements as a result of their original placement or conditional release from a public institution.

At issue is whether CMS properly concluded as a basis for disapproving the amendment that: (1) The State had not demonstrated that the proposed services were within the statutory definition of case management services found in section 1915(g)(2) of the Social Security Act (the Act); (2) the proposed services are available without charge to the user and thus payment under the amendment is not reasonable and necessary and would duplicate payment under other program authorities; and (3) the amendment would restrict beneficiary freedom of choice by limiting providers to employees of New Jersey's Juvenile Justice Commission.

Medicaid coverage of targeted case management is authorized by section 1915(g) of the Act, which defines case management as services that assist beneficiaries in gaining access to needed services and does not include the direct provision of those services. Because the services proposed as Medicaid targeted case management are segments of the State's juvenile justice program, CMS believes that they are integral components of the direct services and administrative functions of that juvenile justice program. In this instance, Medicaid payment for portions of the juvenile justice program would duplicate payment under other programs that are the responsibility of the State Government.

During CMS conversation with the State, section 8435 of the Technical and Miscellaneous Revenue Act of 1988, Public Law Number 100–647 was discussed. In this section, Congress clarified that the Secretary may not deny approval of either an SPA or a claim on the basis that the state is required to provide such services under state law, or is or was otherwise, paying for the services using non-Federal funds. However, section 8435 also expressly states that this was not to be construed to require the Secretary to make payment for case management services that are provided without charge to the users of such services. Approval of this amendment, therefore, would be contrary to this express statutory provision, since this SPA seeks payment from the Medicaid program for services that are available without charge to the users.

In addition, while states are free to set qualifications for providers, a state must comply with Medicaid law and regulations concerning freedom of choice at section 1902(a)(23) of the Act and the implementing regulation at 42 CFR 431.51. These provisions require that a state plan permit beneficiaries to obtain services from any qualified provider that undertakes to provide the services. Section 1915(g)(1) of the Act states, ''The provision of case management services under this subsection shall not restrict the choice of the individual to receive medical assistance in violation of section 1902(a)(23).'' The proposed SPA restricts beneficiary choice of case managers by imposing standards that are not reasonably related to the qualifications of providers, but instead limits available providers to employees of the Juvenile Justice Commission.

Section 1116 of the Act and 42 CFR Part 430 establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a state plan or plan amendment. The CMS is required to publish a copy of the notice to a state Medicaid agency that informs the agency of the time and place of the hearing and the issues to be considered. If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.

Any individual or group that wants to participate in the hearing as a party