

institutions; *Number of Respondents:* 200; *Total Annual Responses:* 200; *Total Annual Hours:* 8,000.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* The State Children's Health Insurance Program and Supporting Regulations in 42 CFR 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; *Form No.:* CMS-R-308 (OMB# 0938-0841); *Use:* States are required to submit title XXI plans and amendments for approval by the Secretary pursuant to section 2102 of the Social Security Act in order to receive funds for initiating and expanding health insurance coverage for uninsured children. States are also required to submit State expenditure and statistical reports, annual reports and State evaluations to the Secretary as outlined in title XXI of the Social Security Act and furnish assorted notices to recipients; *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Government; *Number of Respondents:* 426; *Total Annual Responses:* 12,629,586; *Total Annual Hours:* 864,973.

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

Dated: June 18, 2004.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances. [FR Doc. 04-14538 Filed 6-24-04; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2189-CN]

RIN 0938-ZA46

Medicaid Program; Real Choice Systems Change Grants; Correction Notice

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

ACTION: Notice; correction.

SUMMARY: This document corrects technical errors that appeared in the notice published in the **Federal Register** on May 18, 2004 entitled "Medicaid Program; Real Choice Systems Change Grants."

DATES: *Effective Date:* May 18, 2004.

FOR FURTHER INFORMATION CONTACT: Mary Guy, (410) 786-2772.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 04-11241 of May 18, 2004 (69 FR 28133), there were technical errors that are identified and corrected in the Correction of Errors section below. The provisions in this correction notice are effective as if they had been included in the document published May 18, 2004. Accordingly, the corrections are effective May 18, 2004.

II. Correction of Errors

In FR Doc. 04-11241 of May 18, 2004 (69 FR 28133), make the following corrections:

1. On page 28139, in column 2, "Application Deadline," of the table entitled, "Table of Real Choice Systems Change Grants—FY 2004," "OFR—Insert 60 days after the date of publication in the **Federal Register**" is removed, and "July 19, 2004" is added in its place wherever it appears.

2. On page 28140, in column 2, "Application Deadline," of the table entitled, "Table of Real Choice Systems Change Grants—FY 2004," "OFR—Insert 60 days after the date of publication in the **Federal Register**" is removed, and "July 19, 2004" is added in its place wherever it appears.

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a notice such as this take effect. We can waive this procedure, however, if we find good cause that a notice and comment procedure is impracticable,

unnecessary, or contrary to the public interest and incorporate a statement of the finding and its reasons in the notice issued.

We find it unnecessary to undertake notice and comment rulemaking because this notice merely provides technical corrections and does not make any substantive policy changes. Therefore, for good cause, we waive notice and comment procedures.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: June 16, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid.

[FR Doc. 04-14053 Filed 6-24-04; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9022-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—January 2004 Through March 2004

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 January 2004 through March 2004, 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 (IDE) numbers approved by the Food and Drug Administration (FDA) 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 Medicare National Coverage Determinations (NCDs) 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 FDA-approved Category B IDE numbers listed in Addendum VI may be addressed to Eileen Davidson, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, S3-26-10, 7500 Security Boulevard, Baltimore, MD 21244-1850, or you can call (410) 786-6874.

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

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

SUPPLEMENTARY INFORMATION:

I. Program Issuances

The Centers for Medicare & Medicaid Services (CMS) is responsible for

administering the Medicare and Medicaid programs. These programs pay for health care and related services for 39 million Medicare beneficiaries and 35 million Medicaid recipients.

Administration of the two programs involves (1) furnishing information to Medicare beneficiaries and Medicaid recipients, health care providers, and the public and (2) maintaining effective communications with regional offices, State governments, State Medicaid agencies, State survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, and others. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act). We also issue various manuals, memoranda, and statements necessary to administer the programs efficiently.

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

II. How to Use the Addenda

This notice is organized so that a reader may review the subjects of manual issuances, memoranda, substantive and interpretive regulations, national coverage determinations (NCDs), and Food and Drug Administration (FDA)-approved investigational device exemptions (IDEs) published during the subject quarter to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals may wish to review Table I of our first three notices (53 FR 21730, 53 FR 36891, and 53 FR 50577) published in 1988, and the notice published March 31, 1993 (58 FR 16837). Those desiring information on the Medicare National Coverage Determination Manual (NCDM, formerly the Medicare Coverage Issues Manual (CIM)) may wish to

review the August 21, 1989, publication (54 FR 34555). Those interested in the revised process used in making NCDs under the Medicare program may review the September 26, 2003, publication (68 FR 55634).

To aid the reader, we have organized and divided this current listing into six addenda:

- Addendum I lists the publication dates of the most recent quarterly listings of program issuances.
- Addendum II identifies previous **Federal Register** documents that contain a description of all previously published CMS Medicare and Medicaid manuals and memoranda.
- Addendum III lists a unique CMS transmittal number for each instruction in our manuals or Program Memoranda and its subject matter. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manuals.
- Addendum IV lists all substantive and interpretive Medicare and Medicaid regulations and general notices published in the **Federal Register** during the quarter covered by this notice. For each item, we list the—
 - Date published;
 - Federal Register** citation;
 - Parts of the Code of Federal Regulations (CFR) that have changed (if applicable);
 - Agency file code number; and
 - Title of the regulation
- Addendum V includes completed NCDs, or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCDM 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' 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.

For each CMS publication listed in Addendum III, CMS publication and transmittal numbers are shown. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the Medicare Benefit Policy publication titled "Restoring Composite Rate Exceptions for Pediatric Facilities Under the End-Stage Renal Disease Composite Rate System," use CMS-Pub. 100-02, Transmittal No. 07.

(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: June 14, 2004.

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.

January 10, 2000 (65 FR 1400)
May 30, 2000 (65 FR 34481)
June 28, 2002 (67 FR 43762)
September 27, 2002 (67 FR 61130)
December 27, 2002 (67 FR 79109)
March 28, 2003 (68 FR 15196)
June 27, 2003 (68 FR 38359)
September 26, 2003 (68 FR 55618)
December 24, 2003 (68 FR 74590)
March 26, 2004 (69 FR 15837)

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

An extensive descriptive listing of Medicare manuals and memoranda was published on June 9, 1988, at 53 FR 21730 and supplemented on September 22, 1988, at 53 FR 36891 and December 16, 1988, at 53 FR 50577. Also, a complete description of the former CIM (now the NCDM) was published on August 21, 1989, at 54 FR 34555. A brief description of the various Medicaid manuals and memoranda that we maintain was published on October 16, 1992, at 57 FR 47468.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS
[January 2004 Through March 2004]

Transmittal No.	Manual/Subject/Publication No.
Medicare General Information (CMS-Pub. 10001)	
02	Scheduled Release for April Updates to Software and Pricing/Codes Files
03	New Part B Annual Deductible
Medicare Benefit Policy (CMS-Pub. 10002)	
07	Restoring Composite Rate Exceptions for Pediatric Facilities Under the End-Stage Renal Disease Composite Rate System
08	Policy Changes to Reflect Billing for Darbepoetin Alfa and Epoetin
Medicare National Coverage Determinations (CMS-Pub. 10003)	
07	Electrical Stimulation and Electromagnetic Therapy for the Treatment of Wounds
08	Current Perception Threshold/Sensory Nerve Conduction Threshold Test
09	Cardiac Output Monitoring by Thoracic Electrical Bioimpedance
Medicare Claims Processing (CMS-Pub. 10004)	
60	Manualization of 2632, New Computer-Aided Detection Codes for Screening and Diagnostic Digital Mammography Services Health Common Procedure Coding System and Diagnosis Codes for Mammography Services Computer-Aided Detection Addon Codes Computer-Aided Detection Billing Charts Outpatient Hospital Mammography Payment Table Payment for Computer Add-on Diagnostic and Screening Mammograms for Fiscal Intermediary and Carriers Critical Access Hospital Payment Critical Access Hospital Mammography Payment Table Skilled Nursing Facility Mammography Payment Table Rural Health Claim/Federally Qualified Health Center Claims with Dates of Service on or After January 1, 2002 Fiscal Intermediary Data for Common Working File and the Provider Statistical and Reimbursement Report Carrier Processing Requirements Part B Carrier Claim Record for Common Working File Carrier and Common Working File Edits Mammograms Performed with New Technologies
61	Revises Diagnosis Coding Instructions for Requests for Anticipated Payment and Claims to Conform with Health Insurance Portability and Accountability Act of 1996 Requirements
62	Correction to January 2004 Annual Update of Health Common Procedure Coding System Codes Used for Home Health Consolidated Billing Enforcement
63	Special Rules for Critical Access Hospital Outpatient Billing
64	Coding Change for Ventricular Assist Devices for Beneficiaries in a Medicare+Choice Plan
65	ANSI X12 Transaction 835 Companion Document Change for Carriers, Durable Medical Equipment Regional Carriers, and Intermediaries
66	Quarterly Update to Correct Coding Initiative Edits, Version 10.1, Effective April 1, 2004
67	Revision to Change Request 2912: Coding, Testing, and Implementation Phases of Change Request 2631 for Jurisdiction
68	New Requirements for Critical Access Hospitals. These Changes Have Been Established with the Medicare Prescription Drug Improvement, and Modernization Act of 2003, PL 108173
69	Criteria for Using the CB Modifier
70	Implementation of the Annual Desk Review Program for Hospital Wage Data: Cost Reporting Periods Beginning On or After October 1, 2000, Through September 30, 2001 (Fiscal Year 2005 Wage Index)
71	Changes to the Laboratory National Coverage Determination Edit Software for April 2004
72	Update of Address for the Railroad Retirement Board
73	Medicare Code Editor and IPPS Transfers between Hospitals
74	Intravenous Immune Globulin
75	Medicare Modernization Act Pricing File Clarifications
76	Manualization of Skilled Nursing Facilities Inpatient Part A Billing Services Included in Part A PPS Payment Not Billable Separately by the Skilled Nursing Facility Services Beyond the Scope of the Part A Skilled Nursing Facility Benefit Carrier Claims Processing for Consolidated Billing for Physician and Non-Physician Practitioner Services Rendered to Beneficiaries in a Part A Skilled Nursing Facility Stay Correct Place of Service Code for Skilled Nursing Facility Claims Common Working File Edits Reject and Unsolicited Response Edits Utilization Edits Duplicate Edits Edit for Ambulance Services Edit for Clinical Social Workers Common Working File Override Codes Coding Files and Updates

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[January 2004 Through March 2004]

Transmittal No.	Manual/Subject/Publication No.
	Annual Update Process
	Beneficiaries in a Part A Covered Stay
	Carrier Claims Processing for Consolidated Billing for Physician and Physician Practitioner Services Rendered to Beneficiaries in a NonCovered Skilled Nursing Facility Stay
77	Change in Methodology for Determining Payment for Outliers
	Outlier Payments: CosttoCharge Ratios
78	Update to Medicare Secondary Payment Module to Apportion Prospective Payment System Outlier Amounts to All Service and APC Lines That are Pricer Related
	Billing and Payment in a Health Professional Shortage Area
79	End Stage Renal Disease Reimbursement for Automated MultiChannel Chemistry Test(s)
80	Extend Medicare Coverage for Certain Colorectal Cancer Screenings at Skilled Nursing Facility
	Billing Requirements for Claims Submitted to Intermediaries
81	Report Of Admission Date and Additional Edit Requirements for the X12N 837 Coordination of Benefits Transaction Form Locator 2 Untitled
82	EndStage Renal Disease Data for Use In Adjudicating Claims
	Utilization of REMIS for Carrier Claims Adjudication
83	New "K" Codes for Wheelchair Cushions
84	Additional Guidelines for Implementing the National Council for Prescription Drug Program
	National Council for Prescription Drug Program Implementation
85	Payment of Skilled Nursing Facility Claims for Beneficiaries Disenrolling From Terminating Medicare+Choice
	Definitions
	Laboratories Billing for Referred Tests
	Claims Information and Claims Forms and Formats
	Paper Claim Submission to Carriers
	Electronic Claim Submission to Carriers
	Referring Laboratories
	Reporting of Pricing Localities for Clinical Laboratory Services
	Jurisdiction of Referral Laboratory Services
	Examples of Reference Laboratory Jurisdiction Rules
86	X12N 837 Professional Implementation Guide Edits
87	Coverage and Billing for Home Prothrombin Time International Normalized Ratio
	Anticoagulation Management
	IPPS Transfers Between Hospitals
88	Implementation of Section 414 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003
	General Coverage and Payment Policies
	Billing Methods
	Definitions
	Intermediary and Carrier Calculation of Payment Amount
	General
	Components of the Ambulance Fee Schedule
	ZIP Code Determines Fee Schedule Amounts
	Transition Overview
89	2003 Clinical Lab Fee Schedule and Lab Services Subject to Reasonable Charge Elimination of the 90day Grace Period for Health Common Procedure Coding System (Level I and Level II)
	Deleted Health Common Procedure Coding
	System Codes/Modifiers
	Access to Clinical Diagnostic Lab Fee Schedule Files
	Fee Schedules Used by All Intermediaries and Regional Home Health Intermediaries
90	Bundled Services for Skilled Nursing Facility
	Edit for Therapy Services Separately Payable When Furnished by a Physician
91	CR 3077, Processing NonCovered Home Health Prospective Payment System Charges
	Intermediary Processing of NoPayment Bills
92	CR 3070, April Quarterly Update to Jan 2004 Annual Update of Health
	Common Procedure Coding System Used for Skilled Nursing Facility
	Consolidated Billing Enforcement
	Consolidated Billing Requirements for Skilled Nursing Facility
	Services Included in Part A PPS Payment Not Billable Separately by the Skilled Nursing Facility
	Other Excluded Services Beyond the Scope of a Skilled Nursing Facility
	Part A Benefit
	Cardiac Catheterization
	Computerized Axial Tomography Scans
	Magnetic Resonance Imaging
	Outpatient Surgery and Related Procedures—Inclusion
	Radiation Therapy
	Angiography, Lymphatic, Venous and Related Procedures
	Emergency Services
	Services Excluded from Part A PPS Payment and the Consolidated Billing
	Requirement on the Basis of Beneficiary Characteristics and Election
	ESRD Services
	Coding Applicable to Services Provided in a Renal Dialysis Facility or Skilled Nursing Facility as Home

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued
[January 2004 Through March 2004]

Transmittal No.	Manual/Subject/Publication No.
	Coding Applicable to EPO Services
	Other Services Excluded from Skilled Nursing Facility Prospective Payment System and Consolidated Billing
	Ambulance Services
	Chemotherapy, Chemotherapy Administration, and Radioisotope Services
	Certain Customized Prosthetic Devices
	Screening and Preventive Services
	Therapy Services
93	Remittance Advice Remark Code and Claim Adjustment Reason Code Update CR 3122
94	Additional Information in Medicare Summary Notices to Beneficiaries About Skilled Nursing Facility Benefits CR 3098
	Other Billing Situations
	Skilled Nursing Facilities
	Benefit Limits
	Instalacion de Enfermeria Especializada
	Limites En Los Beneficios
95	Elimination of the 90-day Grace Period for ICD 9—CM Codes CR 3094
	Relationship of ICD—9—CM Codes and Date of Service
96	Update to Claims Status Codes CR 3017
	Health Care Claims Status Category Codes and Health Care Claim Status Codes For Use with the Health Care Claim Status Request and Response ASC X12N 276/277
97	Implementation of New Medicare Redetermination Notice CR 2620
98	Consolidation of Claims Crossover Process: Common Working File Functionality
	Crossover Claims Requirements
	Fiscal Intermediary Requirements
	Carrier/Durable Medical Equipment Regional Carrier Requirements
	Consolidated Claims Crossover Process
	Claims Crossover Disposition Indicators
	Assignment of Claims and Transfer Policy
	Beneficiary Insurance Assignment Selection
	Form CMS—1500 (ANSI X12N 837 COB (Version 4010))
	Remittance Advice Messages
	Returned Medigap Notices
	Coordination of Medicare with Medigap and Other Complementary Health Insurance Policies
	Standard Medicare Charges for COB Records
	Consolidation of the Claims Crossover Process
	Electronic Transmission—General Requirements
	ANSI X12N 837 COB (Version 4010) Transaction Fee Collection
	Medigap Electronic Claims Transfer Agreements
	Intermediary Crossover Claim Requirements
	Carrier/DMERC Crossover Claim Requirements
99	HIPAA X12N 837 Coordination of Benefits Gap Fill Additional Instruction CR 3100
	Crossover Requirements
100	Outpatient Clinical Laboratory Tests Furnished by Hospitals with Fewer than 50 Beds in Qualified Rural Areas CR 3130
	Hospital Billing Under Part B
101	Restoring Composite Rate Exceptions for Pediatric Facilities Under the End-Stage Renal Disease Composite Rate System CR 3119
	Processing Requests for Composite Rate Exception
102	New Waived Test—April 1, 2004 Certificate of Waiver
103	Optional Method for Outpatient Services: Cost-Based Facility Services Plus 115 Percent Fee Schedule Payment for Professional Services CR 3114
104	Durable Medical Equipment Regional Carrier and VMS-Instructions for Processing CR 3141
	Billing Drugs Electronically—National Council of Prescription Drug Programs
105	First Update to the 2004 Medicare Physician Fee Schedule Database CR 3128
106	Modification of Requirements in CR 2716, Common Working File Edits to Ensure Accurate Coding and Payment for Discharge and/or Transfer Policies CR 3137
107	Health Insurance Portability and Accountability of Act of 1996 X12N 837
	Health Care Claim Implementation Guide Editing Additional Instruction CR 3031
	X12N 837 Institutional Implementation Guide Edits
	FI Requirements
	Edits Performed by the Fiscal Intermediary
108	Type of Service Corrections, Chapter 26, Section 10.7 CR 3018
109	Updated Policy and Claims Processing Instructions for Ambulatory Blood Pressure Monitoring Billing CR 2726
	Diagnostic Blood Pressure Monitoring
	Ambulatory Blood Pressure Monitoring Billing Requirements
110	New Requirement for Payment of Drugs CR 3078
	Drugs Furnished in Dialysis Facilities
111	Payment for Services Provided Under a Contractual Arrangement CR 3083
	General Billing Requirements
	Payment to Facility in Which Services Are Performed—Carrier Claims
	Carrier Payment to Health Care Delivery System—Carrier Claims
	Definition of Health Care Delivery System

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[January 2004 Through March 2004]

Transmittal No.	Manual/Subject/Publication No.
112	Changes to Outpatient Prospective Payment System Change Request 3144
113	Claims Requiring Adjustment as a Result of April 2004 Changes to the Outpatient Prospective Payment System Change Request 3145
114	Changes in Payment Floor Calculation for Claims Submitted Electronically in a Non-HIPAA Change Request 2981 Receipt Date Payment Ceiling Standards Payment Floor Standards Determining and Paying Interest
115	Durable Medical Equipment Regional Carrier and Voucher Insurance Plan, Processing National Drug Code Numbers—Clarification to Change Request 3141
116	End-Stage Renal Disease Miscellaneous Code Processing Clarification Durable Medical Equipment Regional Carrier Claims Processing Instructions
117	Instructions for Downloading the Medicare Zip Code File
118	Policy Changes To Reflect Billing for Darbepoetin Alfa and Epoetin Epoetin Alfa (EPO) Facility Billing Requirements Using UB-92/Form CMS-1450 Other Information Required on the Form CMS-1500 for Epoetin Alfa (EPO) Completion of Subsequent Form CMS-1500 Claims for Epoetin Alfa (EPO) Payment Amount for Epoetin Alfa (EPO) Payment for Epoetin Alfa (EPO) in Other Settings Epoetin Alfa (EPO) Provided in the Hospital Outpatient Departments Epoetin Alfa (EPO) Furnished to Home Patients Darbepoetin Alfa (Aranesp) for ESRD Patient Darbepoetin Alfa (Aranesp) Facility Billing Requirements Using UB-92/Form CMS-1450 Darbepoetin Alfa (Aranesp) Supplier Billing Requirements (Method II) on the Form CMS-1500 and Electronic Equivalent Other Information Required on the Form CMS-1500 for Darbepoetin Alfa (Aranesp) Completion of Subsequent Forms CMS-1500 Claims for Darbepoetin Alfa (Aranesp) Payment Amount for Darbepoetin Alfa (Aranesp) Payment for Darbepoetin Alfa (Aranesp) in Other Settings Payment for Darbepoetin Alfa (Aranesp) in the Hospital Outpatient Department Darbepoetin Alfa (Aranesp) Furnished to Home Patients Billable UB-92 Revenue Codes Under Method II
119	Medicare Modernization Act Drug Pricing Update-Drug Exceptions
120	January Medicare OCE Specifications Version 19.1R1
121	Manualization of Place of Service Code Set Program Memorandum Revision to Group Home Code Description Item 14-33—Provider of Service or Supplier Information Place of Service Codes (POS) and Definitions
122	Revision to Required Messages in Change Request 2944, Implementation of Skilled Nursing Facility/Consolidated Billing Edit for Therapy Codes
123	April Outpatient Code Editor
124	Billing and Coding Requirements for Electromagnetic Therapy for the Treatment of Wounds Wound Treatments Electrical Stimulation Electromagnetic Therapy
125	Manualization of the Sacral Nerve Stimulation Sacral Nerve Stimulation Coverage Requirements Billing Requirements Healthcare Common Procedural Coding System Payment Requirements for Test Procedures (Healthcare Common Procedural Coding System Codes 64585, 64590, and 64595) Payment Requirements for Device Codes A4290, E0752, and E0756 Payment Requirements for Codes C1767, C1778, C1883, and C1897 Bill Types Revenue Codes Claims Editing
126	Clarification of ICD-9-Coding Clarification of ICD-9-CM Diagnosis and Procedure Codes
127	2004 Jurisdiction List Use and Acceptance Healthcare Common Procedural Codes and Modifiers
128	Deep Brain Stimulation for Essential Tremor and Parkinson's Disease Coverage Billing Requirements Part A Intermediary Billing Procedures Payment Requirements Part A Methods Bill Types Revenue Codes Allowable Codes Allowable Covered Diagnosis Codes Allowable Covered Procedure Codes

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued
[January 2004 Through March 2004]

Transmittal No.	Manual/Subject/Publication No.
	Healthcare Common Procedure Coding System
	Ambulatory Surgical Centers
	Claims Editing for Intermediaries
	Remittance Advice Notice for Intermediaries
	Medicare Summary Notices Messages for Intermediaries Provider Notification
129	Additional Info and Corrections to Previous Transmittals Re: HCPCS Codes and Modifiers for Low Osmolar, etc.
130	Chapter 32, Section 60 ff
	Coverage Billing for Home Prothrombin Time (INR) Monitoring for Anticoagulation Management
	Coverage Requirements
	Intermediary Payment Requirements
	Part A Payment Methods
	Intermediary Billing Procedures
	Bill Types
	Revenue Codes
	Intermediary Allowable Codes
	Allowable Covered Diagnosis Codes
	Healthcare Common Procedure Coding System for Intermediaries
	Carrier Billing Instructions
	Healthcare Common Procedure Coding System for Carriers
	Applicable Diagnosis Code for Carriers
	Carrier Claims Requirements
	Carrier Payment Requirements
	Carrier and Intermediary General Claims Processing Instructions
	Remittance Advice Notice
	Medicare Summary Notice Messages
131	Revised Payment Allowance Percentage for Durable Medical Equipment
	Regional Carrier Drugs—Off Cycle Release
	Payment Allowance Limit for Drugs and Biologicals Not Paid on a Cost or Prospective Payment Basis
132	April 2004 Update of the Hospital Outpatient Prospective Payment System Updates
Medicare Secondary Payer (CMS-Pub. 100-05)	
08	Common Working File Medicare Secondary Payor Modifications Change Request 2775
	Medicare Secondary Payor Add Transactions
	Medicare Secondary Payor Change Transaction
	Medicare Secondary Payor Delete Transaction
	Automatic Notice of Change to Medicare Secondary Payor Auxiliary File
09	Converting Health Insurance Portability and Accountability Act of 1996 Individual Relation Change Request 3116
	Conversion of Health Insurance Portability and Accountability Act of 1996 Individual Relationship Codes to Common Work File Patient Relationship Codes for the Creation of Medicare Secondary Payor HUSP Transactions
10	Update to the Shared Systems to Send the Appropriate Medicare Fee Schedule Amount Change Request 2955
11	Medicare Secondary Payor Policy for Certain Services Change Request 3064
	General Policy
	Selection of Bill Sample
12	Interim Non-System Solution: Converting Health Insurance Portability and Accountability Act Individuals Relationship Codes to Common Working File Converting Health Insurance Portability and Accountability Act Individual Relationship Codes to Common Working File Patient Relationship Codes
13	Update to the ECRS User Guide v7.0 and Quick Reference Card v7.0
Medicare Financial Management (CMS-Pub. 100-06)	
33	Coordination of Medicare and Complementary Insurance Programs
	Coordination of Medicare with the Federal Grants-In-Aid Program
	Furnishing Title XVIII Claims Information
	Treatment of Administrative Cost of Furnishing Information to State Agencies
	Coordination of Medicare and Medicare Supplemental (Medigap) Health Insurance Policies
34	Chapter 7—Internal Control Requirements Update
	Risk Assessment
	Fiscal Year 2004 Medicare Control Objectives
	Requirements
	Certification Statement
	Executive Summary
	Report of Material Weaknesses
	Report of Reportable Conditions
35	Unsolicited/Voluntary Refunds
	General Information
	Office of the Inspector General Initiatives
	Unsolicited/Voluntary Refund Accounts

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued
 [January 2004 Through March 2004]

Transmittal No.	Manual/Subject/Publication No.
36	Receiving and Processing Unsolicited/Voluntary Refund Checks When Identifying Information is Provided Handling Checks or Associated Correspondence with Conditional Endorsements Receiving and Processing Unsolicited/Voluntary Refund Checks When Identifying Information Is Not Provided CMS Reporting Requirements Overpayment Refund—Summary Report Unsolicited/Voluntary Refund Checks—Summary Report Education Medicare Contractor Transaction Report Due Date Heading Body of Report
37	Installation of Version 33 of the Provider Statistical and Reimbursement Reporting System.
Medicare Program Integrity (CMS—Pub. 100–08)	
66	Progressive Corrective Action General Information Review of Data Probe Reviews Target Medical Review Activities Requesting Additional Information Provider Error Rate Provider Feedback and Education Overpayments Fraud Track Interventions Track Appeals Implementation Vignettes
67	The Medicare Coverage Databases Change Request 2976 Comprehensive Error Rate Testing Program Safeguard Contractor Affiliated Contractor Full PSC Communication with the Comprehensive Error Rate Testing Contractor Overview of the Comprehensive Error Rate Testing Process AC/Full PSC Requirements Surrounding Comprehensive Error Rate Testing Reviews Providing Sample Information to the Comprehensive Error Rate Testing Contractor Providing Review Information to the Comprehensive Error Rate Testing Contractor Providing Feedback Information to the Comprehensive Error Rate Testing Contractor Disputing/Disagreeing with a Comprehensive Error Rate Testing Decision Handling Overpayments and Underpayments Resulting from the Comprehensive Error Rate Testing Findings Handling Appeals Resulting from Comprehensive Error Rate Testing Initiated Denials Tracking Overpayments and Appeals Potential Fraud AC/Full PSC Requirements Involving Comprehensive Error Rate Testing Information Dissemination AC/Full PSC CERT Points of Contact AC/Full PSC Error Rate Reduction Plan
68	Program Requirements to Support Medical Review of Home Health Prospective
69	Payment System Change Request 2519 Revision of Enrollment Instructions Change Request 3159 Contractor Duties Processing the Application Identification Practice Location Ownership and Managing Control Information (Individuals) Qualification of Crew Review of Attachment 2, Independent Diagnostic Testing Facilities Reassignment of Benefits Statement of Termination Reassignment of Benefits Statement Attestation Statement Practice Location Ownership and Managing Control Information (Individuals) Changes of Information—New Form CMS855 Data Approval and Recommendations for Approval Time Frame for Application Processing
Medicare Contractor Beneficiary And Provider Communications (CMS Pub. 100–09)	
04	Provider/Supplier Communications

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued
[January 2004 Through March 2004]

Transmittal No.	Manual/Subject/Publication No.
	<p>Introduction</p> <p>Provider Communications—Program Elements</p> <p>Provider Service Plan</p> <p>Provider Inquiry Analysis</p> <p>Provider Data Analysis</p> <p>Provider Communications Advisory Group</p> <p>Bulletins/Newsletters</p> <p>Seminars/Workshops/Teleconferences</p> <p>New Technologies/Electronic Media</p> <p>Training of Providers in Electronic Claims Submission</p> <p>Provider Education and Beneficiary Use of Preventive Benefits</p> <p>Internal Development of Provider Issues</p> <p>Training of Provider Education Staff</p> <p>Partnering with External Entities</p> <p>Other Provider Education Subjects and Activities</p> <p>Provider Education Material</p> <p>Provider Service Plan Quarterly Activity Report</p> <p>Charging Fees to Providers for Medicare Education and Training Activities</p> <p>Provider Information and Education Materials and Resource Directory</p> <p>Provider/Supplier Communication—Program Elements</p> <p>Provider/Supplier Service Plan</p> <p>Provider/Supplier Inquiry Analysis</p> <p>Provider/Supplier Data Analysis</p> <p>Provider/Supplier Communications Advisory Group</p> <p>Bulletins/Newsletters</p> <p>Seminars/Workshops/Teleconferences</p> <p>New Technologies/Electronic Media</p> <p>Training of Providers/Suppliers in Electronic Claims Submission</p> <p>Provider/Supplier Education and Beneficiary Use of Preventive Benefits</p> <p>Internal Development of Provider/Supplier Issues</p> <p>Training of Provider/Supplier Education Staff</p> <p>Partnering with External Entities</p> <p>Other Specific Provider/Supplier Education Subjects and Activities</p> <p>Provider/Supplier Education Material</p> <p>PSP Quarterly Activity Report</p> <p>Charging Fees to Providers/Suppliers for Medicare Education and Training Activities</p> <p>Provider/Supplier Information and Education Materials and Resource Directory</p>
	<p>Medicare EndStage Renal Disease Network Organizations (CMS Pub. 10014)</p>
05	<p>Chapter 4 Information Management</p> <p>Background/Authority</p> <p>Responsibilities</p> <p>System Capacity</p> <p>Hardware/Software Requirements</p> <p>CMS Computer Systems Access</p> <p>Data Security</p> <p>Confidentiality of Data</p> <p>Database Management</p> <p>Patient Database Mandatory Data Element</p> <p>Patient Database Updates</p> <p>CMS Directed Changes (Notifications) to the Network Patient Database</p> <p>Facility Database Mandatory Data Elements</p> <p>Submission of Facility Database Elements</p> <p>ESRD Data and Reporting Requirements</p> <p>Centers for Medicare & Medicaid Services EndStage Renal Disease Forms</p> <p>Centers for Medicare & Medicaid Services EndStage Renal Disease Program Forms</p> <p>Centers for Medicare & Medicaid Services EndStage Renal Disease Clinical Performance Measures Data Forms</p> <p>CMS ESRD Beneficiary Selection Form</p> <p>Collection, Completion, Validation, and Maintenance of the EndStage Renal Disease CMS Forms</p> <p>Processing Form CMS–2728–U3</p> <p>Processing Form CMS–2746 (EndStage Renal Disease Death Notification Form)</p> <p>Processing Form CMS2744 (EndStage Renal Disease Facility Survey)</p> <p>Tracking System for EndStage Renal Disease Forms</p> <p>Compliance Rates for Submitting EndStage Renal Disease Forms</p> <p>CMS Forms Data Discrepancies and Data Corrections</p> <p>Renal Transplant Data</p> <p>Reporting on Continued Status of Medicare EndStage Renal Disease</p>

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued
[January 2004 Through March 2004]

Transmittal No.	Manual/Subject/Publication No.
	<ul style="list-style-type: none"> Beneficiaries Coordination of Additional Renal Related Information VISION Data Validation 06 Chapter 6—Community Information and Resources Quarterly Progress and Status Report Provision of Educational Information—Providers/Facilities Provision of Educational Information—Patients Provision of Technical Assistance 07 Resolution of Difficult Situations and Grievances Chapter 7—Sanctions and EndStage Renal Disease Complaint Grievances Network's Role Prior to Initiating Sanction Recommendations Written Documentation Requirements for Sanction Recommendations Forwarding Sanction Recommendations Project Officer's Role in Sanction Procedures Regional Officer's Role in Sanction Procedures Duration and Removal of Alternative Sanctions Quality of Care Referrals Definitions for the EndStage Renal Disease Complaint and Grievance Process Role of Network in a Complaint/Grievance End-Stage Renal Disease Complaint and Grievance Process Facility Awareness of the Complaint/Grievance Process Use of Facility Complaint/Grievance Process Determination of Network Involvement Receiving a Complaint/Grievance Request of Grievance in Writing Referring Complaints and Grievances Written Acknowledgment of Grievance Investigation of Complaints and Grievances Life-Threatening Situations Challenging Patient Situations Advocating for Patient Rights Addressing a Complaint or Grievance Follow-Up of a Grievance Conclusion of a Grievance Investigation Report and Letter to the Grievant Complaint/Grievance Is Closed Complaint/Grievance Is Resolved Complaint/Grievance Is Referred Complaint/Grievance Is Reopened Improvement Plans Content of Improvement Plans Time Period for Review and Acceptance/Rejection of Improvement Plans Tracking System Conclusion of Improvement Plans Identity of Complainant/Grievant Identity of Practitioner Identity of Facility Personal Representative
	Medicare Managed Care (CMS Pub. 100-16)
45	<ul style="list-style-type: none"> Chapter 13 Revision 1 Written Notification by Medicare+Choice Organizations Withdrawal of Request for Reconsideration Filing a Request for DAB Review Standard Service Requests Effectuating Decisions by All Other Review Entities Independent Review Entity Monitoring of Effectuation Requirements Data
46	<ul style="list-style-type: none"> Chapter 19—January Updates General Cost-Based Managed Care Organizations Only Medicare+Choice Managed Care Organizations Only Cost-Based Managed Care Organizations Only Medicare+Choice Organizations Only Submission of Correction Transaction Records Prior Commercial Months Field "Special Status" Beneficiaries—Medicare+Choice Organizations "Special Status"—Hospice "Special Status"—End-Stage Renal Disease "Special Status"—Institutionalized "Special Status"—Working Aged

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued
[January 2004 Through March 2004]

Transmittal No.	Manual/Subject/Publication No.
47	<p>When to Submit "Special Status" Information (Medicare+Choice Organizations Only)</p> <p>Timeliness Requirements</p> <p>Sending the Transaction File to Centers for Medicare & Medicaid Services</p> <p>Electronic Data Transfer</p> <p>Data Processing Vendor</p> <p>CMS' Transaction Reply/Monthly Activity Report</p> <p>Transaction Reply Field Information</p> <p>Plan Payment Report</p> <p>Demographic Report Managed Care Organizations Only</p> <p>Monthly Membership Report</p> <p>Bonus Payment Report</p> <p>Retroactive Payment Adjustment Policy</p> <p>Standard Operating Procedures for State and County Code Adjustments</p> <p>Standard Operating Procedures for Medicaid Retroactive Adjustments</p> <p>Standard Operating Procedures for EndStage Renal Disease Retroactive Adjustments</p> <p>Processing of Working Aged Retroactive Adjustments</p> <p>Standard Operating Procedures for Retroactive Adjustment of Plan Elections</p> <p>Medicare Customer Service Center Disenrollments</p> <p>Duplicate Payment Prevention by CostBased Managed Care Organization</p> <p>Chapter 7—Medicare+Choice Enrollment and Disenrollment</p> <p>Prefatory Note</p> <p>General Rules for M+C Payments</p> <p>Enrollees With End-Stage Renal Disease</p> <p>Medicare+Choice Payment Methodology</p> <p>A Minimum Specified Amount or "Floor" Rate</p> <p>Adjustment of Capitation Rates for National Coverage Determinations and Legislative Changes in Benefits</p> <p>Criteria for Meeting "Significant Cost"</p> <p>Rules Coverage and Payment of "Significant Cost" National Coverage Determination Before Adjustments to Annual Medicare+Choice Capitation Rate Are Effective After Adjustments to the Annual Medicare+Choice Capitation Rates Are in Effect</p> <p>Adjustment of Capitation Rates for Working Aged Status</p> <p>Adjustment of Capitation Rates for Demographic Characteristics and Health Status</p> <p>Transition to a Comprehensive Risk Adjustment Method</p> <p>Transition Schedule for Implementation of the Risk Adjustment Method</p> <p>The CMS—HCC Risk Adjustment Method for Adjustment of Capitation Rates</p> <p>Demographic Factors Under the CMS—HCC Risk Adjustment Method</p> <p>Age and Sex</p> <p>Medicaid Eligibility</p> <p>Originally Disabled</p> <p>The Medicare+Choice-Health Care Compare Classification System</p> <p>Institutional Adjuster in the CMS-Health Care Compare Model</p> <p>Implementation of the CMS-Health Care Compare Model</p> <p>Elimination of the Data Lag</p> <p>Implementation of the Adjustment for Long-Term Institutionalization</p> <p>New Enrollees</p> <p>Calculation of Beneficiary Risk Scores</p> <p>Calculation of Monthly Payments to Medicare+Choice Organizations</p> <p>The Rescaling Factor</p> <p>Adjustment to Rescaling Factors for Budget Neutrality</p> <p>Adjustment in Rescaling Factors for Coding Intensity</p> <p>Calculating the Payment Amount Per Medicare+Choice Enrollee</p> <p>Changes in Methodology for PACE and Certain Demonstrations</p> <p>Application of Frailty Model</p> <p>Application of Frailty Factor to Medicare+Choice Organizations</p> <p>Exclusions from Risk Adjustment Payment</p> <p>Data Collection and Submission for Risk Adjustment Care</p> <p>Hospital Inpatient Data</p> <p>Outpatient Hospital</p> <p>Physician Data</p> <p>Alternative Data Sources</p> <p>Data Collection</p> <p>Diagnosis Submission</p> <p>Submission Methods</p> <p>Submission Frequency</p> <p>Certification of Data Accuracy, Completeness, and Truthfulness</p> <p>Data Validation</p> <p>Announcement of Annual Capitation Rates and Methodology Change</p> <p>Terminology</p> <p>Policy</p> <p>Special Rules for Medicare+Choice Payments to Department of Veterans Affairs Facilities</p>

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued
 [January 2004 Through March 2004]

Transmittal No.	Manual/Subject/Publication No.
	Eligibility for Bonus Payment/The Period of Application Reconciliation Process for Changes in Risk Adjustment Factors Additional Information on Coverage of Clinical Trials Community and Institutional Annual Risk Factors for the CMS-Health Care Compare Model with Constraints and Demographic/Disease Interactions List of Disease Groups (Health Care Compare) with Hierarchies CMS-HCC Demographic Model for New Enrollees Data Collection for Risk Adjustment/Facility Types and Physician Specialties Retired Material on the PIP-DCG Payment Methodology (Former Sections 90 and 110, Exhibits 4 and 5) Retired Material on the Congestive Heart Failure Extra Payment Initiative (Former Section 100 and Exhibits 6 and 7)
48	Grievances, Organization Determinations, and Appeals
49	Chapter 4—Benefits and Beneficiary Protections Access and Availability Rules for Coordinated Care Plans Rules for All Medicare+Choice Organizations to Ensure Continuity of Care
50	Chapter 20—Plan Communications Guide View Beneficiary Factors (Option 9) System Description GROUCH Options Downloading Your Group Health Plan Monthly Report The Common Working File Logging Onto Common Working File
51	Beneficiary Eligibility Data Revisions to Chapter 2—Medicare+Choice Enrollment and Disenrollment End-Stage Renal Disease End-Stage Renal Disease and Enrollment Effective Date
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
04	Federal Laws Introduction The (Principal) Systems Security Officer IT Systems Security Program Management System Security Plan Risk Assessment Certification Information Technology Systems Contingency Plan Annual Compliance Audit Corrective Action Plan Computer Security Incident Response Information Security Levels Level 4: High Criticality and National Security Interest Sensitive Information Protection Requirements Restricted Area Security Room Secured Interior/Secured Perimeter Container Locked Container Security Container Safe/Vaults Locking Systems for Secured Areas and Security Rooms Intrusion Detection Equipment Internet Security Core Security Requirements and the Contractor Assessment Security Tool CMS Core Set of Security Requirements Medicare Information Technology Systems Contingency Planning An Approach to Fraud Control Glossary
One Time Notification (CMS Pub. 10020)	
56	Program Integrity Management Reporting System for Part A Phase 4
57	Instructions for Fiscal Intermediary Standard System and MultiCarrier System Healthcare Integrated General Ledger Accounting System Changes
58	Program Integrity Management Reporting System Fiscal Year 2004 H and T Codes
59	Temporary 5 % Payment Increase for Home Health Services Furnished in a Rural Area CR 3085
60	Instructions for Fiscal Intermediary Standard System and MultiCarrier System Healthcare Integrated General Ledger Accounting System Changes

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued
[January 2004 Through March 2004]

Transmittal No.	Manual/Subject/Publication No.
61	FY 2004 Graduate Medical Education Payments as Required by the Medicare Modernization Act of 2003
62	Physician SelfReferral Prohibition 12/22/2003 18Month Moratorium on Physician Investment in Specialty Hospitals CR 3036
63	Durable Medical Equipment Regional Carriers DeWall Posture Protector
64	Implementation of Sections 401, 402, 504, and 508(a) of the Medicare Modernization Act of 2003
65	Implementation of Sec. 508(f) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003
66	CWF Corrections to the 270/271 Transaction

ADDENDUM IV.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER
(January 2004 Through March 2004)

Publication date	FR vol. 69 page number	CFR parts affected	File code	Title of regulation
January 6, 2004	820	42 CFR Part 419	CMS-1371-IFC.	Medicare Program; Hospital Outpatient Prospective Payment System; Payment Reform for Calendar Year 2004.
January 6, 2004	665	CMS-4065-N	Medicare Program; Meeting of the Advisory Panel on Medicare Education.
January 6, 2004	661	CMS-1373-N	Medicare Program; Notice of One-Time Appeal Process for Hospital Wage Index Classification.
January 6, 2004	565	42 CFR Part 447	CMS-2188-P	Medicaid Program; Time Limitation on Recordkeeping Requirements Under the Drug Rebate Program.
January 7, 2004	508	42 CFR Part 447	CMS-2175-IFC.	Medicare Program; Time Limitation on Recordkeeping Requirements Under the Drug Rebate Program.
January 7, 2004	1084	42 CFR Parts 405 and 414	CMS-1372-IFC.	Medicare Program; Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004.
January 23, 2004	3434	45 CFR Part 162	CMS-0045-F	HIPAA Administrative Simplification: Standard Unique Health Identifier for Health Care Providers.
January 23, 2004	3371	CMS-1362-N	Medicare Program; February 23-24, 2004, Meeting of the Practicing Physicians Advisory Council.
January 23, 2004	3370	CMS-1375-N	Medicare Program; Request for Nominations to the Advisory Panel on Ambulatory Payment Classifications Group.
January 30, 2004	4820	42 CFR Part 412	CMS-1263-P	Medicare Program; Prospective Payment System for Long-Term Care Hospitals: Proposed Annual Payment Rate Updates and Policy Changes.
January 30, 2004	4464	42 CFR Parts 412, 413, and 424	CMS-1213-N	Medicare Program; Prospective Payment System for Inpatient Psychiatric Facilities; Extension of Comment Period.
February 13, 2004	7340	CMS-1373-N2	Medicare Program; Revisions to the One-Time Appeal Process for Hospital Wage Index Classification.
February 27, 2004	9326	CMS-2200-N	Medicare Program; Request for Nominations for the State Pharmaceutical Assistance Transition Commission.
February 27, 2004	9324	CMS-1268-N	Medicare Program; Town Hall Meeting on the Fiscal Year 2005 Applications for New Medical Services and Technologies Add-on Payments Under the Hospital Inpatient Prospective Payment.
February 27, 2004	9323	CMS-4090-N	Medicare Program; Town Hall Meeting on Proposed Collection—Comment Request for Skilled Nursing Facility Advance Beneficiary Notice.
February 27, 2004	9322	CMS-3112-N	Medicare Program; Calendar Year 2004 Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses (NTIOLs) Furnished by Ambulatory Surgical Centers (ASCs).
February 27, 2004	9321	CMS-4070-N	Medicare Program; Request for Nominations for the Advisory Panel on Medicare Education.
February 27, 2004	9282	42 CFR Part 473	CMS-3121-P	Medicare and Medicaid Programs; Requirements for Long Term Care Facilities; Nursing Services; Posting of Nurse Staffing Information.
March 5, 2004	10455	CMS-2200-N2	Medicare Program; Establishment of the State Pharmaceutical Assistance Transition Commission.

ADDENDUM IV.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER—Continued
(January 2004 Through March 2004)

Publication date	FR vol. 69 page number	CFR parts affected	File code	Title of regulation
March 26, 2004	16054	42 CFR Parts 411 and 424	CMS-1810-IFC.	Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships.
March 26, 2004	15884	CMS-4071-N	Medicare Program; Listening Session on Performance Measures for Public Reporting on the Quality of Hospital Care—April 27, 2004.
March 26, 2004	15850	CMS-2062-N	Medicaid Program; Disproportionate Share Hospital Payments.
March 26, 2004	15837	CMS-9020-N	Medicare and Medicare Programs; Quarterly Listing of Program Issuances—October 2003 Through December 2003.
March 26, 2004	15835	CMS-2183-N	Funding Opportunity Title: Medicaid Program; Medicaid Infrastructure Grant Program To Support the Competitive Employment of People With Disabilities.
March 26, 2004	15755	42 CFR Part 421	CMS-1219-P	Medicare Program; Durable Medical Equipment Regional Carrier (DMERC) Service Areas and Related Matters.
March 26, 2004	15729	42 CFR Parts 410 and 414	CMS-1476-CN2.	Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2004; Correction.
March 26, 2004	15703	42 CFR Parts 405 and 414	CMS-1372-CN.	Medicare Program; Changes to the Medicare Payment for Drugs for Calendar Year 2004, Correction.

Addendum V—National Coverage Determinations [January 2004 Through March 2004]

A national coverage determination (NCD) is a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under Title XVIII of the Social Security Act, but does not include a determination of what code, if any, is assigned to a particular item or

service covered under this title, or determination with respect to the amount of payment made for a particular item or service so covered. We include below all of the NCDs that were issued during the quarter covered by this notice. The entries below include information concerning completed decisions as well as sections on program and decision memoranda, which also announce pending decisions

or, in some cases, explain why it was not appropriate to issue an NCD. We identify completed decisions by the section of the NCDM 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 DETERMINATIONS
(January 2004 Through March 2004)

100-03	Title	Issue date	Effective date
270.1	Electrical Stimulation and Electromagnetic Therapy for the Treatment of Wounds	03/19/04	07/01/04
20.16	Cardiac Output Monitoring by Thoracic Electrical Bioimpedance	01/23/04	02/23/04
160.23	Current Perception Threshold/Sensory Nerve Conduction Threshold Test	03/19/04	04/01/04

100-04	Title	Issue date	Effective date
TR 71	Clinical Lab Table Update for April 2004	01/23/04	04/05/04

Addendum VI—FDA-Approved Category B IDEs

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c) devices fall into one of three classes. To assist CMS under this categorization process, the FDA assigns one of two categories to each FDA-approved IDE. Category A refers to experimental IDEs, and Category B refers to nonexperimental IDEs. 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 list includes all Category B IDEs approved by FDA during the 1st quarter, January 2004 Through March 2004.

IDE	Category
G010093	B
G020138	B

IDE	Category
G020290	B
G030194	B
G030235	B
G030261	B
G030263	B
G030264	B
G030265	B
G030267	B
G030268	B
G030269	B

IDE	Category	OMB number	Approved CFR sections	OMB number	Approved CFR sections
G040001	B	0938-0151 ...	493.1405, 493.1411,	0938-0448 ...	405.2133, 45 CFR 5, 5b; 20
G040005	B		493.1417, 493.1423,		CFR Parts 401, 422E
G040007	B		493.1443, 493.1449,	0938-0449 ...	440.180, 441.300-441.310
G040008	B		493.1455, 493.1461,	0938-0454 ...	424.20
G040009	B		493.1469, 493.1483,	0938-0456 ...	412.105
G040012	B		493.1489	0938-0463 ...	413.20, 413.24, 413.106
G040013	B	0938-0155 ...	405.2470	0938-0467 ...	431.17, 431.306, 435.910,
G040014	B	0938-0170 ...	493.1269-493.1285		435.920, 435.940-435.960
G040016	B	0938-0193 ...	430.10-430.20, 440.167	0938-0469 ...	417.107, 417.478
G040018	B	0938-0202 ...	413.17, 413.20	0938-0470 ...	417.143, 417.800-417.840,
G040019	B	0938-0214 ...	411.25, 489.2, 489.20		422.6
G040021	B	0938-0236 ...	413.20, 413.24	0938-0477 ...	412.92
G040022	B	0938-0242 ...	442.30, 488.26	0938-0484 ...	424.123
G040024	B	0938-0245 ...	407.10, 407.11	0938-0501 ...	406.15
G040025	B	0938-0246 ...	431.800-431.865	0938-0502 ...	433.138
G040027	B	0938-0251 ...	406.7	0938-0512 ...	486.304, 486.306, 486.307
G040028	B	0938-0266 ...	416.41, 416.47, 416.48,	0938-0526 ...	475.102, 475.103, 475.104,
G040029	B		416.83		475.105, 475.106
G040030	B	0938-0267 ...	410.65, 485.56, 485.58,	0938-0534 ...	410.38, 424.5
G040031	B		485.60, 485.64, 485.66	0938-0544 ...	493.1-493.2001
	B	0938-0269 ...	412.116, 412.632, 413.64,	0938-0564 ...	411.32
			413.350, 484.245	0938-0565 ...	411.20-411.206
		0938-0270 ...	405.376	0938-0566 ...	411.404, 411.406, 411.408
		0938-0272 ...	440.180, 441.300-441.305	0938-0573 ...	412.230, 412.256
		0938-0273 ...	485.701-485.729	0938-0578 ...	447.534
		0938-0279 ...	424.5	0938-0581 ...	493.1-493.2001
		0938-0287 ...	447.31	0938-0599 ...	493.1-493.2001
		0938-0296 ...	413.170, 413.184	0938-0600 ...	405.371, 405.378, 413.20
		0938-0300 ...	431.800	0938-0610 ...	417.436, 417.801, 422.128,
		0938-0301 ...	413.20, 413.24		430.12, 431.20, 431.107,
		0938-0302 ...	418.22, 418.24, 418.28,		434.28, 483.10, 484.10,
			418.56, 418.58, 418.70,	0938-0612 ...	489.102
			418.74, 418.83, 418.96,		493.801, 493.803, 493.1232,
			418.100		493.1233, 493.1234,
		0938-0313 ...	418.1-418.405		493.1235, 493.1236,
		0938-0328 ...	482.12, 482.13, 482.21,		493.1239, 493.1241,
			482.22, 482.27, 482.30,		493.1242, 493.1249,
			482.41, 482.43, 482.45,		493.1251, 493.1252,
			482.53, 482.56, 482.57,		493.1253, 493.1254,
			482.60, 482.61, 482.62,		493.1255, 493.1256,
			482.66, 485.618, 485.631		493.1261, 493.1262,
					493.1263, 493.1269,
		0938-0334 ...	491.9, 491.10		493.1273, 493.1274,
		0938-0338 ...	486.104, 486.106, 486.110		493.1278, 493.1283,
		0938-0354 ...	441.60		493.1289, 493.1291,
		0938-0355 ...	442.30, 488.26		493.1299
		0938-0357 ...	409.40-409.50, 410.36,	0938-0618 ...	433.68, 433.74, 447.272
			410.170, 411.4-411.15,	0938-0653 ...	493.1771, 493.1773,
			421.100, 424.22, 484.18,		493.1777
			489.21	0938-0657 ...	405.2110, 405.2112
		0938-0358 ...	412.20-412.30	0938-0658 ...	405.2110, 405.2112
		0938-0359 ...	412.40-412.52	0938-0667 ...	482.12, 488.18, 489.20,
		0938-0360 ...	488.60		489.24
		0938-0365 ...	484.10, 484.11, 484.12,	0938-0679 ...	410.38
			484.14, 484.16, 484.18,	0938-0685 ...	410.32, 410.71, 413.17,
			484.20, 484.36, 484.48,		424.57, 424.73, 424.80,
			484.52		440.30, 484.12
		0938-0372 ...	414.330	0938-0686 ...	493.551-493.557
		0938-0378 ...	482.60-482.62	0938-0688 ...	486.304, 486.306, 486.307,
		0938-0379 ...	488.26, 442.30		486.310, 486.316, 486.318,
		0938-0382 ...	488.26, 442.30		486.325
		0938-0386 ...	405.2100-405.2171	0938-0690 ...	488.4-488.9, 488.201
		0938-0391 ...	488.18, 488.26, 488.28	0938-0691 ...	412.106
		0938-0426 ...	476.104, 476.105, 476.116,	0938-0692 ...	466.78, 489.20, 489.27
			476.134	0938-0701 ...	422.152
		0938-0429 ...	447.53	0938-0702 ...	45 CFR 146.111, 146.115,
		0938-0443 ...	473.18, 473.34, 473.36,		146.117, 146.150, 146.152,
			473.42		146.160, 46.180
		0938-0444 ...	1004.40, 1004.50, 1004.60,	0938-0703 ...	45 CFR 148.120, 148.124,
			1004.70		148.126, 148.128
		0938-0445 ...	412.44, 412.46, 431.630,	0938-0714 ...	411.370-411.389
			456.654, 466.71, 466.73,	0938-0717 ...	424.57
			466.74, 466.78	0938-0721 ...	410.33
		0938-0447 ...	405.2133	0938-0722 ...	422.370-422.378

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 Numbers—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”)

OMB number	Approved CFR sections
0938-0008 ...	414.40, 424.32, 424.44
0938-0022 ...	413.20, 413.24, 413.106
0938-0023 ...	424.103
0938-0025 ...	406.28, 407.27
0938-0027 ...	486.100-486.110
0938-0033 ...	405.807
0938-0035 ...	407.40
0938-0037 ...	413.20, 413.24
0938-0041 ...	408.6, 408.22
0938-0042 ...	410.40, 424.124
0938-0045 ...	405.711
0938-0046 ...	405.2133
09380050	413.20, 413.24
0938-0062 ...	431.151, 435.1009, 440.220,
	440.250, 442.1, 442.10-
	442.16, 442.30, 442.40,
	442.42, 442.100-442.119,
	483.400-483.480, 488.332,
	488.400, 498.3-498.5
0938-0065 ...	485.701-485.729
0938-0074 ...	491.1-491.11
0938-0080 ...	406.7, 406.13
0938-0086 ...	420.200-420.206, 455.100-
	455.106
0938-0101 ...	430.30
0938-0102 ...	413.20, 413.24
0938-0107 ...	413.20, 413.24
0938-0146 ...	431.800, 431.865
0938-0147 ...	431.800-431.865

OMB number	Approved CFR sections	OMB number	Approved CFR sections
0938-0723 ...	421.300-421.318	0938-0897 ...	412.22, 412.533
0938-0730 ...	405.410, 405.430, 405.435, 405.440, 405.445, 405.455, 410.61, 415.110, 424.24	0938-0907 ...	412.230, 412.304, 413.65
0938-0732 ...	417.126, 417.470	0938-0910 ...	422.620, 422.624, 422.626
0938-0734 ...	45 CFR 5b	0938-0911 ...	426.400, 426.500
0938-0739 ...	413.337, 413.343, 424.32, 483.20	0938-0916 ...	483.16
0938-0742 ...	422.300-422.312	0938-0920 ...	438.6, 438.8, 438.10, 438.12, 438.50, 438.56, 438.102, 438.114, 438.202, 438.206, 438.207, 438.240, 438.242, 438.404, 438.406, 438.408, 438.410, 438.414, 438.416, 438.710, 438.722, 438.724, 438.810
0938-0749 ...	424.57		
0938-0753 ...	422.000-422.700		
0938-0754 ...	441.152		
0938-0758 ...	413.20, 413.24		
0938-0760 ...	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, 422.560-422.622		
0938-0768 ...	417.800-417.840		
0938-0770 ...	410.2		
0938-0778 ...	422.64, 422.111		
0938-0779 ...	417.126, 417.470, 422.64, 422.210		
0938-0781 ...	411.404-411.406, 484.10		
0938-0786 ...	438.352, 438.360, 438.362, 438.364		
0938-0787 ...	406.28, 407.27		
0938-0790 ...	460.12, 460.22, 460.26, 460.30, 460.32, 460.52, 460.60, 460.70, 460.71, 460.72, 460.74, 460.80, 460.82, 460.98, 460.100, 460.102, 460.104, 460.106, 460.110, 460.112, 460.116, 460.118, 460.120, 460.122, 460.124, 460.132, 460.152, 460.154, 460.156, 460.160, 460.164, 460.168, 460.172, 460.190, 460.196, 460.200, 460.202, 460.204, 460.208, 460.210		
0938-0792 ...	491.8, 491.11		
0938-0798 ...	413.24, 413.65, 419.42		
0938-0802 ...	419.43		
0938-0818 ...	410.141, 410.142, 410.143, 410.144, 410.145, 410.146, 414.63		
0938-0829 ...	422.620, 422.624, 422.626		
0938-0832 ...	489		
0938-0833 ...	483.350-483.376		
0938-0841 ...	431.636, 457.50, 457.60, 457.70, 457.340, 457.350, 457.431, 457.440, 457.525, 457.560, 457.570, 457.740, 457.750, 457.810, 457.940, 457.945, 457.965, 457.985, 457.1005, 457.1015, 457.1180		
0938-0842 ...	412.23, 412.604, 412.606, 412.608, 412.610, 412.614, 412.618, 412.626, 413.64		
0938-0846 ...	411.1, 411.350-411.357, 424.22		
0938-0857 ...	419		
0938-0860 ...	419		
0938-0866 ...	45 CFR Part 162		
0938-0872 ...	413.337, 483.20		
0938-0873 ...	422.152		
0938-0874 ...	45 CFR Parts 160 and 162		
0938-0878 ...	422		
0938-0883 ...	45 CFR Parts 160 and 164		
0938-0887 ...	45 CFR 148.316, 148.318, 148.320		

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services**

[CMS-3134-N]

Medicare Program; Town Hall Meeting on Potential Facility Qualifications for Expanded Coverage of Percutaneous Transluminal Angioplasty for Carotid Stenting Procedures**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Notice of meeting.

SUMMARY: This notice announces a Town Hall meeting to discuss potential facility qualifications and requirements to ensure that expanded Medicare coverage of Percutaneous Transluminal Angioplasty (PTA) for carotid stenting procedures would be safe, reasonable and necessary. Topics to be addressed include, but are not limited to, the degree of facility experience required, types of provider training programs to be developed and the rigor of these programs, supporting staff and specialty requirements, and specific stipulations that must be in place to ensure the correct use of this procedure in the appropriate patient population. Interventional radiologists, radiologists, neurological surgeons, cardiologists, neuro-radiologists, interventional cardiologists, interventional neurologists, vascular surgeons, neurologists, and other interested individuals are invited to this meeting to present their individual views on carotid stenting procedures. The opinions and alternatives provided during this meeting will assist us as we evaluate our policy on carotid stenting procedures for high-risk patients. The meeting is open to the public, but attendance is limited to space available.

DATES: The Town Hall meeting will be held on Tuesday August 17, 2004 at 8:30 a.m., e.s.t.

ADDRESSES: The Town Hall meeting will be held in the auditorium at the Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244.

Written Questions or Statements: Interested persons may send written comments by mail or electronically. We will accept written testimony, questions, or other statements, not to exceed 2-3 single-spaced, typed pages prior to, or within 14 days after the meeting. This time frame will allow us sufficient time for serious consideration and review of the submitted materials. Send written testimony, questions, or other statements to Rana Hogarth, OCSQ/CAG, C1-09-06, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244-1850 or to Rana.Hogarth@cms.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Rana Hogarth, (410) 786-2112. You may also send inquiries about this meeting via e-mail to MEllis@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

Medicare currently covers Percutaneous Transluminal Angioplasty of the Carotid Artery Concurrent with Stenting (CAG-00085N) in the context of Food and Drug Administration (FDA) approved Category B Investigational Device Exemption (IDE) Clinical Trials. Performance of Percutaneous Transluminal Angioplasty in the carotid artery used to treat obstructive lesions outside of these clinical trials is noncovered. Currently, Medicare is considering opening a National Coverage Determination to review coverage of carotid stenting procedures outside of the clinical trial setting. It is important that we establish facility qualifications and experience requirements that will ensure that carotid stenting procedures are performed in a manner which is safe, reasonable and necessary, and that would ensure beneficiaries needed pre- and post-procedure care.

II. Meeting Format

The initial portion of the meeting will be designed to elicit information on the appropriate experience requirements for facilities intending to offer carotid stenting procedures, suggestions for developing training programs, the rigor of these programs, and specific stipulations or limitations that must be in place to ensure appropriate use of this procedure. The remainder of the