42229). The notice solicited proposals from for-profit entities to demonstrate that they could successfully provide comprehensive coordinated care for the frail elderly under a prepaid fully-capitated payment system.

On November 26, 2004, we published a notice in the **Federal Register** (69 FR 68931) withdrawing the August 10, 2001 solicitation. To date, we have received one application, and we do not want to foreclose the application process for other interested parties. Therefore, we are canceling the previously published notice of withdrawal.

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

Authority: Section 1894(h) and 1934(h) of the Social Security Act (42 U.S.C. 1395).

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

Dated: February 17, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–3553 Filed 2–24–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9025–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—October Through December 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 October 2004 through December 2004, relating to the Medicare and Medicaid programs. This notice provides information on national coverage determinations (NCDs) 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 Timothy Jennings, Office of Strategic Operations and Regulatory Affairs, Centers for Medicare & Medicaid Services, C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–2134.

Questions concerning Medicare 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 Willinghan, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Centers for Medicare & Medicaid Services, C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–6141.

Questions concerning all other information may be addressed to Margaret Teeters, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Centers for Medicare & Medicaid Services, C5–13–18, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–4678.

SUPPLEMENTARY INFORMATION:

I. Program Issuances

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs. These programs pay for health care and related services for 39 million Medicare beneficiaries and 35 million Medicaid recipients. Administration of the two programs involves (1) furnishing information to Medicare beneficiaries and Medicaid recipients, health care providers, and the public and (2) maintaining effective communications with regional offices, State governments, State Medicaid agencies, State survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, and others. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act). We also issue various manuals, memoranda, and statements necessary to administer the programs efficiently.

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

II. How To Use the Addenda

This notice is organized so that a reader may review the subjects of manual issuances, memoranda, substantive and interpretive regulations, NCDs, and FDA-approved 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 NCD 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 NCD publication titled ''Treatment of Obesity,'' use CMS-Pub. 100–03, Transmittal No. 23.

(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: February 14, 2005.

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.

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); June 25, 2004 (69 FR 35634); September 24, 2004 (69 FR 57312); and December 30, 2004 (69 FR 78428).

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

[October Through December 2004]

Transmittal No.	Manual/Subject/Publication Number
	Medicare General Information (CMS-Pub. 100–01)
11	Manual Revision Regarding Waiver of Annual Deductible and Coinsurance for Both Ambulatory Surgery Center Facility, and Ambulatory Surgery Center/Hospital Outpatient Department Physician Services Exceptions to Annual Deductible and Coinsurance.
12	New Policy and Refinements on Billing Non-covered Charges to Fiscal Intermediaries.
	Applications of Deductible and Coinsurance in Liability and Indemnification Situations.
13	Medicare Termination of Beneficiaries With End-Stage Renal Disease.
14	Scheduled Release for January Updates to Software Programs and Coding/Files.
	Medicare Benefit Policy (CMS-Pub. 100–02)
23	Revised Requirements for Chiropractic Billing of Active/Corrective Treatment And Maintenance Therapy Full Replacement of CR 3063
	Chiropractor's Services.
	Necessity of Treatment.
	Treatment Parameters.
24	Revision of § 300.5.1, Chapter 15 of the Medicare Benefit Policy Manual to Include 22x Type of Bill for Diabetes Self-Management Training.
	Special Claims Processing Instructions for Fiscal Intermediary.
25	Implementation of Coverage of Religious Nonmedical Health Care.
	Institution Items and Services Furnished in the Home, Medicare Modernization Act Section 706.
	Coverage of Religious Nonmedical Health Care Institution Items and Services Furnished in the Home.
	Coverage and Payment of Durable Medical Equipment aUnder the Religious Nonmedical Health Care Institution Home Benefit.
	Coverage and Payment of Home Visits Under the Religious Nonmedical Health Care Institution Home Benefit.
26	Inclusion of Forteo as a Covered Osteoporosis Drug and Clarification of Manual.
	Instructions Regarding Osteoporosis Drugs.
	Medical Supplies (Except for Drugs and Biologicals Other Than Covered Osteoporosis Drugs) and the Use of Durable Medical Equipment.
	Covered Osteoporosis Drugs.
27	New End-Stage Renal Disease Composite Payment Rates Effective January 1, 2005.
28	Hospice Pre-Election Evaluation and Counseling Services.
	Documentation.
	Payment.
	Medicare National Coverage Determinations (CMS-Pub. 100–03)
22	This Transmittal has been rescinded and replaced with Transmittal 25.
23	Treatment of Obesity.
24	Dementia and Neurodegenerative Diseases.
25	Percutaneous Transluminal Angioplasty.
26	Electrocardiographic Services.
	Medicare Claims Processing (CMS-Pub. 100–04)
305	Disabling the Common Working File 57x3 Consistency Error Code.
306	Full Replacement of CR 3415, 3rd Update to the 2004 Medicare Physician Fee Database.
307	This Transmittal has been rescinded and replaced with Transmittal 314.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October Through December 2004]

Transmittal No.	Manual/Subject/Publication Number
308	Two New Medicare Summary Notice (MSN) Messages for Parenteral Pumps-DMERC Only.
	Durable Medical Equipment.
309	Fiscal Year 2005 Inpatient Prospective Payment System, Long Term Care.
	Hospital and Other Bill Processing Changes Related to the Inpatient.
	Prospective Payment System Final Rule.
310	Billing Requirements for Positron Emission Tomography Scans for Dementia and Neurodegenerative Diseases.
	Billing Instructions.
	Positron Emission Tomography Scan Qualifying Conditions and Healthcare.
	Common Procedure Coding System Code Chart.
	Coverage for Positron Emission Tomography Scans for Dementia and Neurodegenerative Disease.
311	Instructions for Completion of Form CMS–1450.
	Health Insurance Portability and Accountability Act Health Care and Coordination of Benefits.
	Coordination of Benefits.
	General Instructions for Completion of Form CMS—1450 for Billing.
312	Issued to a specific audience, not posted to Internet/Intranet due to confidentiality of instruction.
313	Remittance Advice Remark Code and Claim Adjustment Reason Code Update.
314	Percutaneous Transluminal Angioplasty.
315	Temporary Change in Carrier Jurisdictional Pricing Rules for Purchased Diagnostic Services.
316	Clarification of Messages in Chapter 1, Section 10.1.1.1 to Match Official Listing on the WPC-Electronic Data Interchange Web Site.
	Claims Processing Instructions for Payment Jurisdiction for Claims Received on or After April 1, 2004.
317	Clarification to Chapter 26 of the Internet Only Manual.
	Patient and Insured Information.
	Provider of Service or Supplier Information.
318	Clarification of CR 3176—Payment Amounts for End-Stage Renal Disease Drug.
	Administration Supplies: Healthcare Common Procedure Coding System A4657 and A4913.
319	Comprehensive Outpatient Rehabilitation Facility/Outpatient Physical Therapy.
	Edit for Billing Inappropriate Supplies.
320	Reminder Notice of the Implementation of the Ambulance Transition.
	Schedule.
321	Instructions for Downloading the Medicare Zip Code File.
322	Release Medlearn Article for Change Request CR 2813 End-Stage Renal Disease Reimbursement for Automated Multi-Channel Chemistry Test(s).
323	Update Regarding the Use of American Dental Association's (ADA) Current Dental Terminology Codes on Medicare Contractor's Web Sites and Other Electronic Media.
	Displaying Material With Content Development Team Codes.
	Use of Content Development Team Nomenclature and Descriptors.
	American Dental Association Copyright Notice.
	Point and Click License, and Shrink Wrap License.
	Samples of Content Development Team Nomenclature and Descriptors.
324	Quarterly Update to Correct Coding Initiative (CCI) edits, Version 11.0, Effective January 1, 2005.
325	New Waived Tests—January 1, 2005.
326	Invalid Diagnosis Code Editing—Second Phase.
327	This Transmittal has been rescinded and replaced with Transmittal 374.
328	2005 Annual Update for Skilled Nursing Facility Consolidated Billing for the Common Working File and Medicare Carriers.
329	Durable Medical Equipment Regional Carrier Only—Payment to Providers/Suppliers Qualified To Bill Medicare for Prosthetics and Certain Custom-Fabricated Orthotics.
	Provider Billing for Prosthetics and Orthotic Services.
330	Durable Medical Equipment Carrier—Beneficiary Submitted Claims, Process First Claim.
	General Billing for DME, Prosthetics, Orthotic Devices, and Supplies.
331	Durable Medical Equipment Carrier—Beneficiary Submitted Claims, Process First Claim.
332	New Policy and Refinements on Billing Noncovered Charges to Fiscal Intermediaries.
	Provider Billing of Noncovered Charges to Fiscal Intermediaries.
	General Information on Institutional Noncovered Charges Prior to Billing.
	Provider-Liable Fully Noncovered Outpatient Claims.
	Summary of All Types of Institutional No Payment Claims.
	General Operational Information on Institutional Noncovered Charges.
	Noncovered Charges on Institutional Demand Bills.
	Traditional Demand Bills.
	Summary of Methods for Institutional Demand Billing.
	Line-Item Modifiers Related to Reporting of Noncovered Charges When Covered and Noncovered Services Are on the Same Institutional Claim.
	Clarifying Institutional Instructions for Outpatient Therapies Billed As Noncovered, on Other Than Hold Harmless Prospective Payment System Claims, and for Critical Access Hospitals Billing the Same Health Common.
	Procedure Coding System Requiring Specific Time Increments.
	Instructions for Noncovered Charges on Institutional Ambulance Claims.
	Clarification on Notice Requirements Related to Billing Noncovered Charges for ''Bundled'' Institutional Benefits: Laboratory and Rural Health Clinic/Federally Qualified Health Clinic.
333	Issued to a specific audience, not posted to the Internet/Intranet due to the confidentiality of instruction.
334	Payment of Beneficiary Submitted Flu Claims and Flu Claims Submitted by Non-Enrolled Providers.
335	This Transmittal has been rescinded and replaced with Transmittal 400.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October Through December 2004]

Transmittal No.	Manual/Subject/Publication Number
336	Indian Health Service or Tribal Hospitals including Critical Access Hospital.
	Payment Methodology for Inpatient Social Admissions and Outpatient Services Occurring During Concurrent Stays.
	Indian Health Service/Tribal Hospital Inpatient Social Admits.
337	Change in Hospital Type of Bill for Billing Diagnostic and Screening Mammographies.
	Mammography Services.
	Computer-Aided Detection Add-On Codes.
	Billing Requirements—Fiscal Intermediary Claims.
	Rural Health Clinic/Federally Qualified Health Center Claims With Dates of Service Prior to January 1, 2002.
	Rural Health Clinic/Federally Qualified Health Center Claims With Dates of Service on or After January 1, 2002.
	Fiscal Intermediary Requirements for Nondigital Screening Mammographies.
	Mammograms Performed With New Technologies.
338	Removal of the Skilled Nursing Facility No Pay File.
339	Issued to a specific audience, not posted to the Internet/Intranet due to the Sensitivity of Instruction.
340	Annual Update of Healthcare Common Procedure Coding System Codes Used for Home Health Consolidated Billing Enforcement.
341	Implementation of the Medicare Physician Fee Schedule (MPFS) National Abstract File for Purchased Diagnostic Tests and Interpretations.
	Payment Jurisdiction Among Local Carriers for Services Paid Under the Physician Fee Schedule and Anesthesia Services.
	Payment Jurisdiction for Purchased Services.
	Payment to Physician or Other Supplier for Purchased Diagnostic Tests—Claims Submitted to Carriers.
	Payment to Supplier of Diagnostic Tests for Purchased Interpretations.
	Abstract File for Purchased Diagnostic Tests/Interpretations.
342	Change to the Common Working File Skilled Nursing Facility Consolidated.
	Edits for Ambulance Transports to or From a Diagnostic or Therapeutic Site Ambulance Services.
	Skilled Nursing Facility Billing.
343	Clarification: Modifiers for Transportation of Portable X-rays.
	Transportation Component.
344	Update of Healthcare Common Procedure Coding System Codes and File Names, Descriptions and Instructions for Retrieving the 2005 Ambulatory Surgery.
	Center Healthcare Common Procedure Coding System Deletions and Master Listing.
345	This Transmittal is rescinded and replaced with Transmittal 353.
346	This Transmittal is rescinded and replaced with Transmittal 352.
347	Inpatient Rehabilitation Facility Classification Requirements.
	Medicare Inpatient Rehabilitation Facility Classification Requirements.
	Criteria That Must Be Met By Inpatient Rehabilitation Hospitals.
	Verification Process To Be Used To Determine if the Inpatient Rehabilitation.
	Facility Met the Classification Criteria.
	Verification of Compliance Using International Classification of Disease 9th Edition Clinical Modification and Impairment Group Codes.
348	January 2005 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing File, Effective January 1, 2005.
349	This Transmittal is rescinded and replaced with Transmittal 359.
350	Editing for Part B Carriers and Durable Medical Equipment Regional Carriers for Duplicate Claims in Process at the Same Time.
351	Editing of Hospitals and Skilled Nursing Facilities Part B Inpatient Services.
352	Three Places After the Decimal Point for Application Service Provider Drug File.
353	Durable Medical Equipment Regional Carrier—Revision to CR 2631.
	Requirements for Durable Medical Equipment Regional Carrier Claims.
	Claims Processing Instructions for Payment Jurisdiction for Claims Received on or After April 1, 2004—Durable Medical Equipment Regional Carrier Only.
354	DMERC—Beneficiary Submitted Claims, Process First Claim.
355	This Transmittal has been rescinded and replaced with Transmittal 375.
356	This Transmittal has been rescinded and replaced with Transmittal 376.
357	Implementation of Coverage of Religious Nonmedical Health Care Institution.
	Items and Services Furnished in the Home, MMA section 706.
	Noncovered Charges on Outpatient Bills.
	Billing and Payment of Religious Nonmedical Health Care Institution Items and Services Furnished in the Home.
	Inclusion of Forteo As a Covered Osteoporosis Drug and Clarification of Manual Instructions Regarding Osteoporosis Drugs.
	Osteoporosis Injections as Home Health Agency Benefit.
358	This Transmittal replaces Transmittal 349.
359	Annual Update of Healthcare Common Procedure Coding System Codes for Skilled Nursing Facility Consolidated Billing.
360	Medicare Modernization Act Drug Pricing Update—Payment Limit for J0207.(Amifostine).
361	Update to the Prospective Payment System for Home Health Agencies for Calendar Year 2005.
	Annual Updates to the Home Health Pricer.
362	2005 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment.
363	Common Working File Editing for the Initial Preventive Physical Examination.
364	Issued to a specific audience, not posted to Internet/Intranet due to the confidentiality of instruction.
365	Issued to a specific audience, not posted to Internet/Intranet due to the confidentiality of instruction.
366	This Transmittal has been rescinded and replaced with Transmittal 425.
367	Instructions for Completion of Form CMS–1450.
368	Fee Schedule Update for 2005 for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies.
369	New Case-Mix Adjusted End-Stage Renal Disease (ESRD) Composite.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October Through December 2004]

Transmittal No.	Manual/Subject/Publication Number
	Payment Rates and New Composite Rate Exceptions Window for Pediatric.
	ESRD Facilities.
	Outpatient Provider Specific File.
	Calculation of Case Mix Adjusted Composite Rate.
	Required Information for In-Facility Claims Paid Under the Composite Rate.
370	Updated Billing Instructions for Rural Health Clinics and Federally Qualified.
	Health Centers.
	General Billing Requirements.
	Special Federally Qualified Health Centers Requirements.
	Reporting of Preventive Services in the Federally Qualified Health Centers.
	Benefit by Independent Federally Qualified Health Centers.
	Reporting of Specific Healthcare Common Procedure Coding System Codes for Hospital-based Federally Qualified Health Centers.
	General Billing Requirements for Preventive Services.
	Bills Submitted to Fiscal Intermediary.
	Special Instructions for Independent and Provider-Based Rural Health Clinics/Federally Qualified Health Centers.
	Claims Submitted to Intermediaries for Mass Immunizations of Influenza and
	Pneumococcal Pneumonia Vaccine
	Payment for Computer Add-on Diagnostic and Screening Mammograms for Fiscal Intermediary and Carriers.
	Rural Health Centers/Federally Qualified Health Centers Claims With Dates of Service Prior to January 1, 2002.
	Rural Health Centers/Federally Qualified Health Centers Claims With Dates of Service on or After January 1, 2002.
	Healthcare Common Procedure Coding Codes for Billing.
	Additional Coding Applicable to Claims Submitted to Fiscal Intermediary.
	Special Billing Instructions for Rural Health Centers and Federally Qualified.
	Health Centers.
	Electrical Stimulation.
	Electromagnetic Therapy.
371	Payment for Referred Laboratory Automated Multi-Channel Chemistry Tests.
	Claims Processing Requirements for Panel and Profile Tests.
	History Display.
372	New End-Stage Renal Disease Composite Payment Rates Effective Lanuary 1, 2005.
	Publication of Composite Rates.
	Determining Individual Facility Composite Rate.
	Required Information for In-Facility Claims Paid Under the Composite Rate.
	Epoetin Alfa.
	Epoetin Alfa Facility Billing Requirement Using UB–92/Form CMS–1450.
	Payment Amount for Epoetin Alfa.
	Epoetin Alfa Provided in the Hospital Outpatient Departments.
	Darbepoetin Alfa for End-Stage Renal Disease Patients.
373	Clarification to IOM Chapter 17, Section 80.4 Regarding Claims for Blood Clotting Factors.
	Billing for Blood Clotting Factors.
374	This Transmittal has been rescinded and replaced with 388.
375	This Transmittal has been rescinded and replaced with 389.
376	Hospital Outpatient Prospective Payment System: Misclassified Drugs and Biologicals, Ganciclovir Long Act Implant, Beg Live Intravesical Vac, and Gallium ga 67; Adjustments Due to Misclassification.
377	Full Replacement of CR 3308, Fiscal Intermediary Shared System Changes To Allow for Provider Liability Days on Skilled Nursing Facility and Swing Bed Facility Inpatient Bills.
	Billing Skilled Nursing Facility Prospective Payment System Services.
	Provider Liability Instructions.
378	Low Osmolar Contrast Material/Laboratory Tests/Payment for Inpatient Servces.
	Furnished by a Critical Access Hospital.
	Payment for Inpatient Services Furnished by a Critical Access Hospital.
	Standard Method—Cost Based Facility Services, With Billing of Carrier for Professional Services.
	Clinical Diagnostic Laboratory Tests Furnished by Critical Access Hospitals.
379	Changes to the Laboratory National Coverage Determination Edit Software for January 2005.
380	Revisions and Corrections to Chapter 29 of the IOM, Claims Processing Manual—Appeals.
	CMS Decisions Subject to the Administrative Appeals Process.
	Who May Appeal.
	Provider or Supplier Appeals When the Beneficiary Is Deceased.
	Where To Appeal and Initial Determinations.
	Social Security Office.
	Part A Fiscal Intermediary.
	Providers Right To Appeal Certain Initial Determinations.
	Part B Carrier (or Fiscal Intermediary Acting As a Carrier).
	Quality Improvement Organization.
	Time Limits for Filing Appeals.
	Amount in Controversy Requirements.
	Limitation on Liability.
	Part A Appeals Procedures.
	Finding Good Cause for Late Filing of Part A Redetermination.
	General.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October Through December 2004]

Transmittal No.	Manual/Subject/Publication Number
	Establishment of Time Limits for Filing. Conditions Which Establish Good Cause. Procedures To Establish Good Cause. Examples of Situations Where Good Cause Exists. Where Good Cause Is Not Found. Redetermination of a Part A Payment Determination. Place and Manner of Filing Requests for Redeterminations and What Constitutes a Request for Redetermination. Evaluating the Evidence and Making the Redetermination. Preparing the Determination. Completing the Determination. Notice of Further Appeal Rights. Preventing Duplicate Payment in Reversal Cases. Effectuating Favorable Final Appellate Decisions That a Beneficiary Is ''Confined To Home''—Regional Home Health Intermediaries Only. Model Medicare Redetermination Notice. Request for Hearing Under Part A. Right to Representation Under Part A. Reconsiderations, Hearings, and Appeals Where a Quality Improvement. Organization Has Review Responsibility. Reconsiderations. Hearings. Appeals of Institutional Supplementary Medical Insurance (Part B) Claim Decisions. Appeals by Hospitals of Diagnosis Related Group Assignments Under Prospective Payment System—Review of Initial Diagnosis Related Group Assignments. Part B Appeals Procedures for Fiscal Intermediaries and Administrative Law Judge Instructions for Fiscal Intermediaries Redetermination and Hearing Officer (HO) Hearing Supplemental Medical Insurance. Redetermination. What Constitutes a Request for Redetermination & Handling Beneficiary Inquiries. Elements of a Redetermination. Requests for Hearing. Preparation for the Hearing. In-Person and Telephone Hearing Procedures. Request for Hearing Before an Administrative Law Judge. Scope and Effect of Office of Hearings & Appeals, Social Security. Administration Administrative Law Judge Decisions Under Part A. Determining the Amount in Controversy for Administrative Law Judge Hearing. Requests Filed With Social Security Administration. Requests Filed With the Fiscal Intermediary. Action on Incoming Requests for Administrative Law Judge Hearing. Requests for Claim File (Sent by Hearing Office). Examination of Claim File. Prehearing Case Redetermination. Routing the Administrative Law Judge Hearing Claim File. Effectuating Decisions. Effectuating Favorable Final Appellate Decisions That a Beneficiary Is ''Confined To Home''—Regional Home Health Intermediaries Only.Effectuation of Reversal of Decision Where There Was Subsequent Utilization of Benefits in the Same Benefit Period. Effect of Court Decisions. Standard Exhibits Referred to in Sections 40.5–50.7. Part B Appeals Procedures—Carriers. Initial Determinations. Steps in the Appeals Process: Overview. Fiscal Intermediary and Carrier Correspondence With Beneficiaries or Other Parties Regarding Appeals. Appointment of Representative—Introduction. Who May Be a Representative. How To Make and Revoke an Appointment. Rights and Responsibilities of a Representative. Timeliness of an Appeal Request and Completeness of Appointment. Incapacitation of Death of Beneficiary. Disclosure of Individually Identifiable Beneficiary Information to Amount in Controversy—General Requirements. Additional Considerations for Calculation of the Amount in Controversy. Aggregation of Claims to Meet the Amount in Controversy. General Procedure To Establish Good Cause. Good Cause Not Found for Beneficiary, or for Provider, Physician, or Other Supplier. General Guidelines. Letter Format. How To Establish Reading Level. Required Elements in Appeals Correspondence. Disclosure of Information to Third Parties. Fraud and Abuse Investigations. Medical Consultants Used.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October Through December 2004]

Transmittal No.	Manual/Subject/Publication Number
	Multiple Beneficiaries.
	Redetermination—The First Level of Appeal.
	Filing a Request for Redetermination.
	Time Limit for Filing a Request for Redetermination.
	The Redetermination.
	The Redetermination Determination.
	Redetermination Determination.
	Informing the Beneficiary and Provider Communities About the Telephone.
	Redetermination Process.
	Redetermination Determination Letters.
	Hearing Officer Hearing—The Second Level of Appeal.
	Time Limit for Filing a Request for a Hearing Officer Hearing.
	Request for a Hearing Officer Hearing Filed Prior to a Redetermination.
	Timely Processing Requirements.
	Contractor Responsibilities—General.
	Requests for Transfer of In-Person Hearing.
	Acknowledgment of Request for a Hearing Officer Hearing.
	Case File Development.
	In-Person Hearing.
	Telephone Hearing.
	Qualifications and General Responsibilities.
	Preparation for the Hearing Officer Hearing.
	Scheduling the Date, Time and Place of Hearing.
	Pre-Hearing Review of the Evidence.
	Forwarding Copy of Case File Prior to Telephone Hearing.
	The Hearing Officer Hearing Decision Timeliness.
	Delaying Effectuation.
	Hearing Officer Reply to Reopening Request.
	Requests for Part B Administrative Law Judge Hearing.
	Forwarding Request to Social Security Administration/Office of Hearings & Appeals.
	Case File Preparation.
	Effectuation Time Limits.
	Requests for Case Files.
	Part A and Part B Quality Improvement and Data Analysis Activities.
	Workload Data Analysis Program.
	Quality Improvement Activities.
	Submitting Summary Reports to CMS.
	Managing Appeals Workloads.
	Standard Operating Procedures.
	Execution of Workload Prioritization.
	Workload Priorities.
	Reopening and Revision of Claim Determinations and Decisions.
	Development of Appeals.
	How Issues May Arise.
	Summary of Conditional Under Which a Determination or Decision May Be Reopened.
	Determining Date of Initial or Appeal Determination or Decision.
	Who May Reopen an Initial Appeal Determination or Decision.
	Actions to Permit Reopening Within the 1 Year or 4 Year Period.
	Good Cause for Reopening.
	Definitions.
	Unrestricted Reopening.
	Reopening an Initial Determination.
	Reopening a Redetermination or Redetermination Determination.
	Reopening a Hearing Officer Hearing Decision.
	Notice of Results of Reopening.
	Exception to Sending Notice of Revision to Parties—Cases Involving Limitation of Recovery for Beneficiary.
	Refusal to Reopen Is Not an ''Initial Determination''.
	Revised Determination or Decision.
382	Independent Laboratory Billing for the Technical Component (TC) of Physician Pathology Services to Hospital Patients.
	Payment for Pathology Services.
383	This revision rescinded Transmittal.
384	Inpatient Psychiatric Facility Prospective Payment System.
385	January 2005 Update of the Hospital Outpatient Prospective Payment System.
	Summary of Outpatient Prospective Payment System Outpatient Code Editor.
	Data Changes and Outpatient Prospective Payment System Pricer Logic.
	Changes; Changes to Payment for Diagnostic Mammography.
386	Hospice Pre-election Evaluation and Counseling Services.
387	This instruction is to inform the fiscal intermediaries that the January 2005.
	Outpatient Prospective Payment System Outpatient Code Editor Specifications have been updated with new additions, changes, and deletions.
388	Issued to a specific audience, not posted to Internet/Intranet due to confidentiality of instruction.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October Through December 2004]

Transmittal No.	Manual/Subject/Publication Number
389	Issued to a specific audience, not posted to Internet/Intranet due to confidentiality of instruction.
390	Announcement of Medicare Rural Health Clinics and Federally Qualified Health Centers Payment Rate Increase—Skilled Nursing Facility Consolidated.Billing As It Applies to Rural Health Clinics and Federally Qualified Health.Center Services.
391	Issued to a specific audience, not posted to Internet/Intranet due to confidentiality of instruction.
392	The Supplemental Security Income Medicare Beneficiary Data for Fiscal Year 2003 for Inpatient Rehabilitation Facility Prospective Payment System. LIP Adjustment: The Supplemental Security Income Medicare Beneficiary Data for Inpatient Rehabilitation Facility Paid Under Prospective Payment System.
393	ZThis revision is rescinded and replaced with revision 401.
394	This revision is rescinded and replaced with revision 396.
395	Ambulance Fee Schedule—Medical Conditions List.
396	New Dispensing/Supply Fee Codes for Oral Anti-Cancer, Oral Anti-Emetic, Immunosuppressive, and Inhalation Drugs. Pharmacy Supply Fee.
397	Durable Medical Equipment Regional Carrier /Local Carriers/Statistical. Analysis Durable Medical Equipment Regional Carrier—Drug Pricing. Limits as of January 1, 2005. Payment Rules for Drugs and Biologicals. Medicare Modernization Act Drug Pricing—Average Sales Price. Single Drug Pricer. Calculation of the Payment Allowance Limit for Durable Medical Equipment. Regional Carriers Drugs. Calculation of the Average Wholesale Price. Detailed Procedures for Determining Average Wholesale Prices and the Drug.Payment Allowable Limits. Background. Review of Sources for Medicare Covered Drugs and Biologicals. Use of Generics. Find the Strength and Dosage. Restrictions. Inherent Reasonableness for Drugs and Biologicals. Injection Services. Injections Furnished to End-Stage Renal Disease Beneficiaries.
398	Issued to a specific audience, not posted to Internet/Intranet due to confidentiality of instruction.
399	Expansion of the Existing Interrupted Stay Policy Under Long Term Care. Hospital Prospective Payment System.
400	Incorrect Reporting of Miles Time Units Services Indicator When Drugs are Billed Using a National Drug Code. Miles/Times/Units/Services. Methodology of Coding Number of Services, Miles Times Units Services. Count and Miles Times Units Services Indicator Fields.
401	2005 Part B Deductible Update to the Back Page of Medicare Summary Notices. Back of the Medicare Summary Notices—Carriers and Intermediaries.
402	January Update to the Medicare Outpatient Code Editor Version 20.1 for Bills from Hospitals That Are Not Paid Under the Outpatient Prospective Payment System.
403	January 2005 Update of the Hospital Outpatient Prospective Payment System: Billing Devices That Do Not Have Transitional Pass-Through Status, and That Are Not Classified As New Technology Ambulatory Payment Classification Groups. Requirements That Hospitals Report Device Codes on Claims on Which They Report Specified Procedures. Edits for Claims On Which Specified Procedures Are To Be Reported With Device. Codes.
404	January 2005 Update of the Hospital Outpatient Prospective Payment System: Changes to Coding and Payment for Drug Administration. Billing and Payment for Drugs and Biologicals. Coding and Payment for Drug Administration.
405	Emergency Change to Carrier Instructions for the End-Stage Renal Disease. 50/50 Rule Implementation.
406	Update to Health Care Claims Status Category Codes and Health Care Claim Status Codes for Use With the Health Care Claim Status Request and Response ASC X12N 276/277.
407	Hospital Billing for Repetitive Services. Inpatient Billing From Hospitals and Skilled Nursing Facilities. Frequency of Billing for Outpatient Services to Fiscal Intermediaries. Hospital and Community Mental Health Center Reporting Requirements for Services Performed on the Same Day.
408	Cardiovascular Disease Screening. Healthcare Common Procedure Coding System Coding for Cardiovascular Screening. Carrier Billing Requirements. Fiscal Intermediary Billing Requirements. Diagnosis Code Reporting. Medicare Summary Notices. Remittance Advice Remark Codes. Claims Adjustment Reason Codes.
409	Diabetes Screening Tests.
410	Medicare Health Insurance Portability & Accountability Act Electronic Claims. Compliance Report—Reporting Timeframe Extension.
411	Ambulance Inflation Factor.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October Through December 2004]

Transmittal No.	Manual/Subject/Publication Number
412	Skilled Nursing Facility Consolidated Billing Services Furnished Under an ''Arrangement'' With an Outside Entity.
	''Under Arrangements'' Relationships.
	Skilled Nursing Facility and Supplier Responsibilities.
413	Medicare Part A Skilled Nursing Facility Prospective Payment System Pricer.
	Update Fiscal Year 2005 for 9 Metropolitan Statistical Areas With New Wage.Index Values Effective January 1, 2005.
	Skilled Nursing Facility Prospective Payment System Pricer Software.
414	Emergency Update to the 2005 Medicare Physician Fee Schedule Database.
415	Temporary Change in Carrier Jurisdictional Pricing Rules for Purchased Diagnostic Services.
416	Interest Payment on Clean Claims Not Paid Timely.
417	This revision rescinded and replaced revision 294.
418	Issued to a specific audience, not posted to Internet/Intranet due to the confidentiality of instruction.
419	This Transmittal has been rescinded and replaced with Transmittal 423.
420	Good Cause Waiver of Late Claim Filing Payment Reduction Penalty and Monitoring of Late Claims Submissions.
	Extend Time for Good Cause.
	Conditions Which Establish Good Cause.
	Procedure To Establish Good Cause.
	Good Cause Is Not Found.
	Preparing Common Working File (CWF) Claim Records for Services Subject to 10 Percent Payment Reduction.
	Monitoring Late Claims Submission Violations.
	Sample Notification Letter.
	Violations That Are Not Developed for Referral.
421	Correction to January 2005 Annual Update of Healthcare Common Procedure Coding.
	System Codes Used for Skilled Nursing Facility Consolidated Billing Enforcement.
422	Update to Fiscal Year 2005 Wage Index for Inpatient Prospective Payment and Outpatient Prospective Payment System Hospitals .
	Medicare Secondary Payer (CMS-Pub. 100–05)
20	Secondary Payer (Medicare Secondary Payer) Savings Report Redesign.
	Monthly Intermediary Report (Form CMS–1563) and Monthly Carrier Report.
	(Form CMS–1564) on Medicare Secondary Payer Savings.
	Savings Calculations.
	Source of Savings.
	Type of Savings.
	Pre-payment Savings—Cost Avoid (Unpaid Medicare Secondary Payer Claims).
	Pre-payment Savings—Full Recoveries.
	Pre-payment Savings—Partial Recoveries.
	Post-payment Savings—Full Recoveries.
	Post-payment Savings—Partial Recoveries.
	Total Post-payment Savings.
	Electronic Submission.
	Data Entry of the Forms CMS–1563 and CMS–1564.
	System Calculations for Forms CMS–1563 and CMS–1564.
21	Instructions on Processing Certain Types of Medicare Secondary Payer.Claims and to Balance the Outbound Remittance Advice.
	Instructions to Physicians and Suppliers on How To Submit Claims to a Medicare Carrier When There Are One or More Primary Payers.
22	Medicare Secondary Payer Debt Referral Instructions and Debt Collection Improvement Act of 1996 Activities.
	Courtesy Copy of All Medicare Secondary Payer Group Health Plan-Based.
	Recovery Demand Packages to the Employer's Insurer/Third Party Administrator.
	Insurer/Third Party Administrator Courtesy Copy Letter.
	Medicare Secondary Payer Debt Referral, ''Write-Off—Closed'' Instructions and Debt Collection Improvement Act of 1996 Activities.
	Background.
	Debt Selection, Verification of Debt, and Updating of Interest.
	''Intent to Refer'' Letter and Inquiries/Replies Related to Debt Improvement Act of 1996 Activities
	Debt Collection System, Debt Collection System Input, Debt Transmission, Documentation to Treasury.
	Actions Subsequent to Debt Collection System Input.
	Medicare Secondary Payer Debt Collection Improvement Act of 1996 Tracking Report for Referral/Collection.
	Monitoring Debts Excluded From the Debt Collection Improvement Act of 1996.
	Referral Process.
	Financial Reporting.
	Compromise Requests and Extended Repayment Agreement Requests, and Waiver of Interest Requests.
	Miscellaneous Questions and Answers.
	Medicare Financial Management (CMS-Pub. 100–06)
55	Reporting Appeals Redetermination Information on Forms CMS–2591 and 2590.
56	Revision to Balancing Requirement on Form 5, Line 10, of the Contractor.
	Reporting of Operational and Workload Data.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October Through December 2004]

Transmittal No.	Manual/Subject/Publication Number
57	Revised Reporting Requirements for Contractor Reporting of Operational Workload Data Health Professional Shortage Area Quarterly Report.
58	Issued to specific audience, not posted to Internet/Intranet due to sensitivity of instruction.
59	Notice of New Interest Rate for Medicare Overpayments and Underpayments.
60	Revised Instructions on Contractor Procedures for Provider Audit and the Provider Statistical & Reimbursement Report.
	Submission of Cost Report Data to CMS.
	Desk Review Exceptions Resolution Process.
	Definition of Field Audits.
	Purpose of Field Audits.
	Establishing the Objective/Scope of the Field Audit.
	Audit Confirmation Letter.
	Entrance Conference.
	Tests of Internal Control.
	Designing Tests/Sampling.
	Pre-Exit Conference.
	Finalization of Audit Adjustments.
	Exit Conference.
	Medicare Cost Report and All Related Documents.
	Qualifications.
	Internal Quality Control.
	Final Settlement of the Cost Report.
	Audit Responsibility When Provider Changes Contractors.
	Audits of Home Offices.
	Standards for Issuance of an Audit Report for a Home Office.
	Provider Permanent File.
	Contractor Responsibility in Suspected Fraud or Abuse Cases.
61	New Location Code Interstate Commerce Commission, Status Code AR and Modified Intent Letter for Unfiled Cost Reports Only.
	Recovery of Overpayment Due to Overdue Cost Report.
	Provider Overpayment Recovery System User Manual.
	List of Status Codes.
	Content of Demand Letters—Fiscal Intermediary Serviced Providers.
	Medicare State Operations Manual (CMS-Pub. 100–07)
3	Medicare Systems Acceptance of New Provider Numbers for Federally Qualified Health Centers.
4	Guidance to Surveyors for Long Term Care Facilities.
5	Revisions to Appendix P (Survey Protocols for Long Term Care Facilities) and Appendix PP (Guidance to Surveyors for Long Term Care Facilities).
	Medicare Program Integrity (CMS-Pub. 100–08)
84	This revision is rescinded and replaced by revision 86.
85	This revision is rescinded and replaced by revision 87.
86	Payment for Emergency Medical Treatment and Labor Act—Mandated Screening and Stabilization Services.
87	Informing Beneficiaries About Which Local Medical Review Policy and/or Local Coverage Determination and/or National Coverage Determination Is Associated With Their Claim Denial.
88	Timeframes for Processing 855 Enrollment Applications.
	Provider Enrollment, Chain and Ownership System.
89	Updating Financial Reporting Requirements for Medical Review and Local Provider Education and Training.
	Medical Review and Local Provider, Education, and Training.
	Medical Review Overview.
	Reporting Medical Review Workload and Cost Information and Documentation in Contractor Administrative, Budget & Financial Management II.
	Contractor Administrative, Budget & Financial Management II Reporting for Medical Review Activities.
	Automated Review Workload and Cost (Activity Code 21001).
	Routine Review Workload and Cost (Activity Code 21002).
	Data Analysis Cost (Activity Code 21007).
	Third Party Liability or Demand Bills Workload and Cost (Activity Code 21010).
	Policy Reconsideration/Revision Activities (Activity Code 21206).
	Medical Review Program Management Costs (Activity Code 21207).
	New Policy Development Activities (Activity Code 21208).
	Complex Probe Review Workload and Cost (Activity Code 21220).
	Prepay Complex Review Workload and Cost (Activity Code 21221).
	Post-pay Complex Review Workload and Cost (Activity Code 21222).
	Medicare Integrity Program Comprehensive Error Rate Testing Support.
	Medicare Integrity Program Comprehensive Error Rate Testing Support.(Activity Code 21901).
	Reporting Internal Staff Training.
	Reporting Medical Review Savings in Contractor Reporting of Operational & Workload Data.
	Local Provider Education and Training Overview.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October Through December 2004]

Transmittal No.	Manual/Subject/Publication Number
	Reporting Local Provider Education and Training Workload and Cost Information and Documentation in Contactor Administrative, Budget & Financial Management II.
	One-on-One Provider Education a Workload and Cost (Activity Code 24116).
	Education Delivered to Group of Providers Workload and Cost (Activity Code 24117).
	Education Delivered via Electronic or Paper Media Workload and Cost (Activity Code 24118).
90	Prepayment Review of Claims for Medical Review Purposes.
91	Revision of Program Integrity Manual, Section 3.11.1.4.
	Requesting Additional Documentation.
92	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of instruction.
	Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100–09)
00	None.
	Medicare Managed Care (CMS-Pub. 100–16)
63	Home Health Services Appeals.
64	Surveys, Contracting Strategy, Grievances and Appeals.
	Medicare Business Partners Systems Security (CMS-Pub. 100–17)
05	Consortium Contractor Management Officer and CMS Project Officer. The (Principal) Systems Security Officer. Personnel Security/Suitability. IT Systems Security Program Management. System Security Plan. Risk Assessment. Information Technology Systems Contingency Plan. Annual Compliance Audit. Corrective Action Management Process and Plans of Action and Milestones. Computer Security Incident Response. Systems Security Profile. Fraud Control. Patch Management. Security Management Resources. Security Configuration Management. National Institute of Standards and Technology. Information Security Levels. Level 4: High Criticality and National Security Interest. Security Room. Intrusion Detection System. Internet Security.
	Demonstrations (CMS-Pub. 100–19)
07	Expansion of Coverage for Chiropractic Services Demonstration.
08	This revision is rescinded and replaced with Transmittal 9.
09	This revision is rescinded and replaced with Transmittal 10.
10	Issued to a specific audience, not posted to Internet/Intranet due to sensitivity of instruction.
11	Medicare Coordinated Care Demonstration—Override of Certain Medicare Secondary Payer Edit Codes.
12	Chemotherapy Demonstration Project.
13	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
	One Time Notification (CMS-Pub. 100–20)
118	Shared Systems Maintainer Hours for Resolution of Problem Detected As a Result of Implementation of Change Request 2525 and Change Request 2527.
119	Shared System Maintainer Hours for Resolution of Problem Detected During Health Insurance Portability and Accountability Act Transaction Release Testing.
120	Override of Common Working File Edit for Observation Services Exceeding 48 Hours.
121	Modification to Fiscal Intermediary Standard System Regarding Common Working File Initiated Adjustments.
122	Shared System and Common Working File Renovation of Override Code Process and Recognition of Four 2-byte Modifier Fields on the Part B Query Record—For Multi-Carrier System Phased Implementation Approach Only.
123	Instructions for Pricing Treprostinil (Q4077).
124	Common Working File Duplicate Claim Edit for Referred Clinical Diagnostic and Purchased Diagnostic Services.
125	This revision is rescinded and replaced with revision 127.
126	Transmittal replaced by Transmittal 27 in Pub. 100–02, Medicare Benefit Policy.
127	Instructions Applicable to the Audit of Hospitals That Are Part of an Affiliated Group in Relation to the ''Redistribution of Unused Resident Positions,'' Section 422 of the Medicare Modernization Act of 2003, P.L. 108–173, for Purposes of Graduate Medical Education Payments.
128	Promoting Medicare's Preventive Benefits and Services on an Annual Basis.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October Through December 2004]

Transmittal No.	Manual/Subject/Publication Number
129	2005 Drug Administration Coding Revisions.
130	Development of a Coordination of Benefits Agreement Auxiliary File and Modification of the Health Insurance Portability and Accountability Act 837 Coordination of Benefits Flat File and National Council for Prescription Drug Program File.
131	Coverage of Routine Costs of Clinical Trials Involving Investigational Device Exemption Category A Devices.
132	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of instruction.
133	Shared System Maintainer Hours for Resolution of Problems Detected as a Result of Implementation of Change Request 2525 and Change Request 2527

ADDENDUM IV.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER

[October Through December 2004]

Publication date	FR vol. 69 page number	CFR parts affected	File code	Title of regulation
October 6, 2004	59929		CMS–5015–N	Medicare Program; Care Management for High-Cost Beneficiaries (CMHCB) Demonstration.
October 7, 2004	60242	403, 412, 413, 418, 460, 480, 482, 483, 485, 489.	CMS–1428–CN2	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates; Corrections.
October 7, 2004	60158		CMS–1249–CN	Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Corrections.
October 7, 2004	60157		CMS–1360–CN	Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Fiscal Year 2005; Correction.
October 22, 2004	62124	484	CMS–1265–F	Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2005.
October 22, 2004	62057		CMS–1302–N	Medicare Program; Town Hall Meeting on the Medicare Provider Feedback Group (MPFG) November 16, 2004.
October 22, 2004	62056		CMS–1484–N	Medicare Program; November 22, 2004, Meeting of the Practicing Physicians Advisory Council.
October 22, 2004	62055		CMS–4078–N	Medicare Program; Meeting of the Advisory Panel on Medicare Education—November 30, 2004.
November 15, 2004	66922	412 and 413	CMS–1213–F	Medicare Program; Prospective Payment System for Inpatient Psychiatric Facilities.
November 15, 2004	66918		CMS–1267–N	Medicare Program; Coverage and Payment of Ambulance Services; Recalibration of Conversion Factor; Inflation Update for CY 2005.
November 15, 2004	66236	403, 405, 410, 411, 414, 418, 424, 484, and 486.	CMS–1429–FC	Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005.
November 15, 2004	65682	419	CMS–1427–FC	Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates.
November 26, 2004	69252	405 and 489	CMS–4004–FC	Medicare Program; Expedited Determination Procedures for Provider Service Terminations.
November 26, 2004	69178	416	CMS–1478–P	Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures.
November 26, 2004	68944		CMS–3149–N	Medicare Program; Meeting of Medicare Coverage Advisory Committee—January 25, 2005.
November 26, 2004	68935		CMS–1374–GNC	Medicare Program; Criteria and Standards For Evaluating Intermediary, Carrier, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Regional Carrier Performance During Fiscal Year 2005.
November 26, 2004	68931		CMS–2202–FN	Medicare and Medicaid Programs; Approval of Application for Deeming Authority for Ambulatory Surgical Centers by the American Association for Accreditation of Ambulatory Surgery Facilities, Inc.
November 26, 2004	68931		CMS–5011–WN	Medicare and Medicaid Programs; Notice of Withdrawal of the Solicitation of Proposals for the Private, for-Profit Demonstration Project for the Program of All-Inclusive Care for the Elderly (PACE).

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

[October Through December 2004]

Publication date	FR vol. 69 page number	CFR parts affected	File code	Title of regulation
November 26, 2004	68815	447	CMS–2175–F	Medicaid Program; Time Limitation on Recordkeeping Requirements Under the Drug Rebate Program.
November 30, 2004	69686	484	CMS–1265–CN2	Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2005; Correction.
November 30, 2004	69536	403, 412, 413, 418, 460, 480, 482, 483, 485, and 489.	CMS–1428–N	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates; Extension for the Hospital Applications To Receive Increases in Full Time Equivalent Resident Caps for Graduate Medical Education Payment.
December 23, 2004	76947		CMS–5036–N	Medicare Program; Solicitation for Proposals for the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities.
December 30, 2004	78720	26 CFR Parts 54 and 602, 29 CFR Part 2590, 45 CFR Parts 144 and 146.	CMS–2151–F	HIPAA Program; Final Regulations for Health Coverage Portability for Group Health Plans and Group Health Insurance Issuers Under HIPPA Titles I and IV.
December 30, 2004	78800	26 CFR Part 54, 29 CFR Part 2590, 45 CFR Part 146.	CMS–2158–P	HIPAA Program; Notice of Proposed Rulemaking for Health Coverage Portability: Tolling Certain Time Periods and Interaction With the Family and Medical Leave Act Under HIPAA Titles I and IV.
December 30, 2004	78825	26 CFR Part 54, 29 CFR Part 2590, 45 CFR Part 146.	CMS–2150–NC	HIPAA Program; Request for Information on Benefit-Specific Waiting Periods Under HIPAA Titles I and IV.
December 30, 2004	78526	403, 412, 413, 418, 460, 480, 482, 483, 485, and 489.	CMS–1428–F2	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal 2005 Rates; Correcting Amendment.
December 30, 2004	78466		CMS–1292–N	Medicare Program; Town Hall Meeting on the Fiscal Year 2006 Applications for New Medical Services and Technologies Add-on Payments Under the Hospital Inpatient Prospective Payment Systems Scheduled for February 23, 2005.
December 30, 2004	78464		CMS–1285–N	Medicare Program; Meeting of the Advisory Panel on Ambulatory Payment Classification (APC) Groups (Panel)—February 23, 24, and 25, 2005 and Re-chartering of APC Panel on November 8, 2004.
December 30, 2004	78445		CMS–1249–CN2	Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Corrections.
December 30, 2004	78444		CMS–4077–FN	Medicare Program; Approval of the National Committee for Quality Assurance Deeming Authority for Medicare Advantage Local Preferred Provider Organizations.
December 30, 2004	78442		CMS–9026–N	Medicare Program; Timeline for Publication of Medicare Final Regulations After Proposed or Interim Final Regulations.
December 30, 2004	78428		CMS–9042–N	Medicare and Medicaid Program; Quarterly Listing of Program Issuances—July 2004 Through September 2004.
December 30, 2004	78426		CMS–2490–N	CLIA Program; Continued Approval of the American Association of Blood Banks for Deeming Authority.
December 30, 2004	78336	422	CMS–4041–IFC	Medicare Program; Modifications to Managed Care Rules.
December 30, 2004	78315	419	CMS–1427–CN	Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates; Wage Index Tables and Corrections.

Addendum V—National Coverage Determinations

[October Through December 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

[October Through December 2004]

Title	NCDM section	TN#	Issue date	Effective date
Treatment of Obesity	40.5	R23NCD	10/01/04	10/01/04
Changes to the Laboratory NCD Edit Software for January 2005	N/A	R38CP	11/26/04	01/03/05
Dementia and Neurodegenerative Diseases	220.6.13	R24NCD	10/01/04	09/15/04
Percutaneous Transluminal Angioplasty	20.7	R25NCD	10/15/04	10/12/04
Electrocardiographic Services	20.15	R26NCD	12/10/04	08/26/04

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 non-experimental 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 4th quarter, October Through December 2004.

G010041
G020001
G020105
G040026
G040081
G040086
G040090
G040115
G040117
G040133
G040135
G040136
G040157
G040163
G040164
G040165
G040169
G040170
G040171
G040173
G040174
G040175
G040177
G040178
G040179
G040180
G040181
G040182
G040183
G040185
G040187
G040188
G040189
G040193
G040197
G040199
G040201
G040202
G040207
G040210
G040211
G040212
G040213
G040215
G040216
G911803

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 No.	Approved CFR Sections in Title 42, Title 45, and Title 20 (NOTE: Sections in Title 45 are preceded by ''45 CFR,'' and sections in Title 20 are preceded by ''20 CFR'')
0938–0008	414.40, 424.32, 424.44
0938–0022	413.20, 413.24, 413.106
0938–0023	424.103
0938–0025	406.28, 407.27
0938–0027	486.100–486.110
0938–0033	405.807
0938–0035	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
0938–0050	413.20, 413.24, 431.151, 435.1009, 440.220, 440.250, 442.1, 442.10–442.16, 442.30, 442.40, 442.42,
0938–0062	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

OMB Control No.	Approved CFR Sections in Title 42, Title 45, and Title 20 (NOTE: Sections in Title 45 are preceded by "45 CFR," and sections in Title 20 are preceded by "20 CFR")
0938–0080	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	431.800–431.865 493.1405, 493.1411, 493.1417, 493.1423, 493.1443, 493.1449, 493.1455, 493.1461
0938–0151	493.1469, 493.1483, 493.1489
0938–0155	405.2470
0938–0170	493.1269–493.1285
0938–0193	430.10–430.20, 440.167
0938–0202	413.17, 413.20
0938–0214	411.25, 489.2, 489.20
0938–0236	413.20, 413.24
0938–0242	442.30, 488.26
0938–0245	407.10, 407.11
0938–0246	431.800–431.865
0938–0251	406.7
0938–0266	416.41, 416.47, 416.48, 416.83
0938–0267	410.65, 485.56, 485.58, 485.60, 485.64, 485.66
0938–0269	412.116, 412.632, 413.64, 413.350, 484.245
0938–0270	405.376
0938–0272	440.180, 441.300–441.305
0938–0273	485.701–485.729
0938–0279	424.5
0938–0287	447.31
0938–0296	413.170, 413.184
0938–0301	413.20, 413.24
0938–0302	418.22, 418.24, 418.28, 418.56, 418.58, 418.70, 418.74, 418.83, 418.96, 418.100
0938–0313	489.11, 489.20, 482.12, 482.13, 482.21, 482.22, 482.27, 482.30, 482.41, 482.43, 482.45, 482.53, 482.56
0938–0328	482.57, 482.60, 482.61, 482.62, 482.66, 485.618, 485.631
0938–0334	491.9, 491.10
0938–0338	486.104, 486.106, 486.110
0938–0354	441.60
0938–0355	442.30, 488.26
0938–0357	409.40–409.50, 410.36, 410.170, 411.4—411.15, 421.100, 424.22, 484.18, 489.21
0938–0358	412.20–412.30
0938–0359	412.40–412.52
0938–0360	488.60
0938–0365	484.10, 484.11, 484.12, 484.14, 484.16, 484.18, 484.20, 484.36, 484.48, 484.52
0938–0372	414.330
0938–0378	482.60–482.62
0938–0379	442.30, 488.26
0938–0382	442.30, 488.26
0938–0386	405.2100–405.2171
0938–0391	488.18, 488.26, 488.28
0938–0426	476.104, 476.105, 476.116, 476.134
0938–0429	447.53
0938–0443	473.18, 473.34, 473.36, 473.42
0938–0444	1004.40, 1004.50, 1004.60, 1004.70
0938–0445	412.44, 412.46, 431.630, 456.654, 466.71, 466.73, 466.74, 466.78
0938–0447	405.2133
0938–0448	405.2133, 45 CFR Parts 5, 5b; 20 CFR Parts 401, 422E
0938–0449	440.180, 441.300–441.310
0938–0454	424.20
0938–0456	412.105
0938–0463	413.20, 413.24, 413.106
0938–0467	431.17, 431.306, 435.910, 435.920, 435.940–435.960
0938–0469	417.126, 422.502, 422.516
0938–0470	417.143, 417.800–417.840, 422.6
0938–0477	412.92
0938–0484	424.123
0938–0501	406.15
0938–0502	433.138
0938–0512	486.304, 486.306, 486.307
0938–0526	475.102, 475.103, 475.104, 475.105, 475.106
0938–0534	410.338, 424.5
0938–0544	493.1–493.2001
0938–0564	411.32
0938–0565	411.20–411.206
0938–0566	411.404, 411.406, 411.408
0938–0573	412.230, 412.256
0938–0578	447.534

OMB Control No.	Approved CFR Sections in Title 42, Title 45, and Title 20 (NOTE: Sections in Title 45 are preceded by "45 CFR," and sections in Title 20 are preceded by "20 CFR")
0938–0581	493.1–493.2001
0938–0599	493.1–493.2001
0938–0600	405.371, 405.378, 413.20
0938–0610	417.436, 417.801, 422.128, 430.12, 431.20, 431.107, 434.28, 483.10, 484.10, 489.102, 493.801, 493.803, 493.1232, 493.1233, 493.1234, 493.1235, 493.1236, 493.1239, 493.1241, 493.1242, 493.1249, 493.1251, 493.1252, 493.1253, 493.1254, 493.1255, 493.1256, 493.1261, 493.1262, 493.1263, 493.1269, 493.1273, 493.1274, 493.1278
0938–0612	493.1283, 493.1289, 493.1291, 493.1299
0938–0618	433.68, 433.74, 447.272
0938–0653	493.1771, 493.1773, 493.1777
0938–0657	405.2110, 405.2112
0938–0658	405.2110, 405.2112
0938–0667	482.12, 488.18, 489.20, 489.24
0938–0679	410.38
0938–0685	410.32, 410.71, 413.17, 424.57, 424.73, 424.80, 440.30, 484.12
0938–0686	493.551–493.557
0938–0688	486.304, 486.306, 486.307, 486.310, 486.316, 486.318, 486.325
0938–0690	488.4–488.9, 488.201
0938–0691	412.106
0938–0692	466.78, 489.20, 489.27
0938–0701	422.152
0938–0702	45 CFR 146.111, 146.115, 146.117, 146.150, 146.152, 146.160, 146.180
0938–0703	45 CFR 148.120, 148.124, 148.126, 148.128
0938–0714	411.370–411.389
0938–0717	424.57
0938–0721	410.33
0938–0723	421.300–421.318
0938–0730	405.410, 405.430, 405.435, 405.440, 405.445, 405.455, 410.61, 415.110, 424.24
0938–0732	417.126, 417.470
0938–0734	45 CFR Part 5b
0938–0739	413.337, 413.343, 424.32, 483.20
0938–0742	422.300–422.312
0938–0749	424.57
0938–0753	422.000–422.700
0938–0754	441.151, 441.152
0938–0758	413.20, 413.24
0938–0760	Part 484 Subpart E, 484.55
0938–0761	484.11, 484.20, 422.1–422.10, 422.50–422.80, 422.100–422.132, 422.300–422.312, 422.400–
0938–0763	422.404, 422.560–422.622
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, 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,
0938–0790	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	422.568
0938–0832	Parts 489 and 491
0938–0833	483.350–483.376, 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,
0938–0841	457.1005, 457.1015, 457.1180
0938–0842	412.23, 412.604, 412.606, 412.608, 412.610, 412.61a4, 412.618, 412.626, 413.64
0938–0846	411.352–411.361
0938–0857	Part 419
0938–0860	Part 419
0938–0866	45 CFR Part 162
0938–0872	413.337, 483.20
0938–0873	422.152
0938–0874	45 CFR Parts 160 and 162
0938–0878	Part 422 Subpart F & G
0938–0883	45 CFR Parts 160 and 164
0938–0884	405.940
0938–0887	45 CFR 148.316, 148.318, 148.320
0938–0897	412.22, 412.533
0938–0907	412.230, 412.304, 413.65
0938–0910	422.620, 422.624, 422.626
0938–0911	426.400, 426.500
0938–0916	483.16, 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, 438.402, 438.404, 438.406, 438.408, 438.410, 438.414

OMB Control No.	Approved CFR Sections in Title 42, Title 45, and Title 20 (NOTE: Sections in Title 45 are preceded by ''45 CFR,'' and sections in Title 20 are preceded by ''20 CFR'')
0938–0920	438.416, 438.710, 438.722, 438.724, 438.810
0938–0921	414.804

[FR Doc. 05–3551 Filed 2–24–05; 8:45 am]
BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3119–FN]

RIN 0938–AM36

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

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

ACTION: Final notice.

SUMMARY: This notice finalizes the procedures proposed in the **Federal Register** on December 24, 2003 (68 FR 74607). It establishes the procedures for maintaining the lists of codes that were included in the national coverage determinations (NCDs) that were announced in an addendum to the final rule published in the **Federal Register** on November 23, 2001 (66 FR 58788). The final notice also sets forth the circumstances in which a laboratory is permitted to use the date a specimen was retrieved from storage for testing as the date of service instead of the date of collection.

DATES: *Effective Date:* The notice is effective on March 28, 2005.

FOR FURTHER INFORMATION CONTACT: Jackie Sheridan-Moore, (410) 786–4635.

SUPPLEMENTARY INFORMATION:

I. Background

A. Current Statutory Authority and Medicare Policies

Sections 1833 and 1861 of the Social Security Act (the Act) provide for payment of, among other things, clinical diagnostic laboratory services under Medicare Part B. A laboratory furnishing tests on human specimens must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578) enacted on October 31, 1988, as implemented by the regulations set forth at 42 CFR part 493. Part 493 applies to all laboratories seeking payment under the Medicare and Medicaid programs.

Under section 1842(a) of the Act, we contract with carriers to perform bill processing and benefit payment functions for Medicare Part B (Supplementary Medical Insurance). Under section 1816(a) of the Act, we contract with fiscal intermediaries to perform claims processing and benefit payment functions for Medicare Part A (Hospital Insurance). Fiscal intermediaries also process claims payable from the Medicare Part B trust fund that are submitted by providers that participate in Medicare Part A, like hospitals and skilled nursing facilities. We use the term ''contractor(s)'' to mean carriers and fiscal intermediaries.

Medicare contractors review and adjudicate claims for services to ensure that Medicare payments are made only for services that are covered under Medicare Part A or Part B. If a contractor develops a local coverage determination (LCD) (formerly called local medical review policies (LMRP)), its LCD/LMRP applies only within the geographic area it serves as stated in the September 26, 2003 notice (68 FR 55636). Current guidance regarding the development of LCDs/LMRPs appears in section 13.1.3 of the Program Integrity Manual (HCFA Pub. 100–8).

B. Legislation

Section 4554(b)(1) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–133) enacted on August 5, 1997, mandates the use of a negotiated rulemaking committee to develop national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B by January 1, 1999. Section 4554(b)(2) of the BBA requires that these national coverage policies be designed to promote program integrity and national uniformity and simplify administrative requirements for clinical diagnostic laboratory services payable under Medicare Part B.

As directed by this statutory provision, we convened a negotiated rulemaking committee that developed recommendations for coverage and administrative policies in accordance with the provisions of the BBA. On March 10, 2000, we published a proposed rule in the **Federal Register** (65 FR 13082) proposing to adopt the committee's recommendations. The final rule was published on November 23, 2001 in the **Federal Register** (66 FR 58788).

C. National Coverage Determinations (NCDs)

The final rule on coverage and administrative policies for clinical diagnostic laboratory services includes an addendum containing NCDs for 23 clinical diagnostic laboratory tests. These NCDs are binding on all Medicare carriers, intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans.

In accordance with the recommendations of the negotiated rulemaking committee, we developed these clinical diagnostic laboratory NCDs in a prescribed format. Each NCD has the following sections: the official title of the NCD, other names or abbreviations, description, Healthcare Common Procedure Coding System (HCPCS) codes, indications, limitations, International Classification of Diseases, Ninth Edition, Clinical Modification (ICD–9–CM) codes covered by the Medicare program, reasons for denial, ICD–9–CM codes denied, ICD–9–CM codes that do not support medical necessity, sources of information, coding guidelines, documentation requirements, and other comments.

For each of the clinical diagnostic laboratory service NCDs (laboratory NCDs), every ICD–9–CM diagnosis code falls into one of the three code lists. The list of covered codes is intended to reflect the coding translation of the conditions enumerated in the narrative indications section of the NCDs.

On April 27, 1999, we published a notice (64 FR 22619) outlining our procedures for developing and revisiting NCDs. We further updated the NCD process in a notice published in the **Federal Register** on September 26, 2003 (68 FR 55634). In the November 23, 2001 final rule (66 FR 58793) for coverage and administrative policies for clinical diagnostic laboratory services, we stated that we will use the NCD process for making changes to the laboratory NCDs. At the conclusion of the NCD decision-making process, decision memoranda will be published on the CMS Web site that announce the policy we intend to issue and discuss the evidence we evaluated and our rationale for the final national coverage