requires only that a laboratory follow manufacturer's instructions and does not require routine inspections of waived testing. Thus, the requirements of the AABB are more stringent than the requirements of the CLIA regulations.

We have determined that the AABB has complied with the requirements under subpart E of part 493 and that the requirements of the AABB are equal to or more stringent than the condition-level requirements in subparts H, J, K, M, Q, and R of part 493.

Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

The AABB has revised its requirements to be equal to or more stringent than the CLIA requirements at § 493.801 through § 493.865.

Subpart J—Facility Administration for Nonwaived Testing

The AABB has revised its requirements to be equal to or more stringent than the CLIA requirements at § 493.1100 through § 493.1105. For example, the AABB requires laboratories to retain quality assessment records for five years, while the CLIA regulations require laboratories to retain these records for only two years.

Subpart K—Quality System for Nonwaived Testing

The quality control (QC) requirements of the AABB have been evaluated against the requirements of the CLIA regulations. The AABB has modified its survey process and made revisions to its standards encompassing general QC as well as specialty and subspecialty QC requirements in order to reflect the new QC requirements in the CLIA regulations. As such, we have determined that the AABB's requirements are equal to or more stringent than the requirements in the CLIA regulations. The specific requirements that are more stringent than the requirements of the CLIA regulations are the following:

- The requirement that laboratories meet the AABB's QC requirements for all waived testing they perform.
- The requirement for compliance with standards for parentage testing.
- The AABB's requirement that laboratories that perform provider-performed microscopy procedures must meet the same certification requirements as all other laboratories that perform moderate complexity testing.

Subpart M—Personnel for Nonwaived Testing

The AABB has revised its requirements to equal the CLIA requirements at § 493.1403 through § 493.1495 for laboratories that perform moderate and high complexity testing. The AABB personnel standards provide that the laboratory must meet CLIA requirements for personnel qualifications. The CLIA requirements for personnel responsibilities are encompassed in the revisions made to the AABB standards.

Subpart Q—Inspections

We have determined that the AABB's requirements for inspections are equal to or more stringent than the requirements of § 493.1771 through § 493.1780 of this subpart.

Subpart R—Enforcement Procedures

The AABB meets the requirements of subpart R to the extent it applies to accreditation organizations. The AABB policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, the AABB will deny, suspend, or revoke accreditation in a laboratory accredited by the AABB and report that action to CMS within 30 days. The AABB also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that the AABB's laboratory enforcement and appeal policies are equal to or more stringent than the requirements of this part 493 subpart R as they apply to accreditation organizations.

IV. Federal Validation Inspection and Continuing Oversight

The Federal validation inspections of AABB accredited laboratories may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by us or our agent, or the State survey agency, will be our principal means for verifying that the laboratories accredited by AABB remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide that CMS may rescind the approval of an accreditation organization, such as that of the AABB, for cause, before the end of the effective date of approval. If we determine that the AABB failed to adopt requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its inspection process, we may give it a probationary period, not to exceed one year, to allow the AABB to adopt comparable requirements.

Should circumstances result in our withdrawal of the AABB's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget did not review this notice because our publication of this notice is not a regulatory action under that Executive Order.

Authority: Section 353 of the Public Health Service Act (42 U.S.C.263a).

Dated: November 16, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 04–28152 Filed 12–29–04; 8:45 am]

BILLING CODE 3410–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9024–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July 2004 Through September 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 July 2004 through September 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 National Coverage Determinations publication titled ''Islet Cell Transplantation,'' use CMS–Pub. 100–03, Transmittal No. 18.

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

Dated: December 13, 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.

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)

June 25, 2004 (69 FR 35634)

September 24, 2004 (69 FR 57312)

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

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

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JULY THROUGH SEPTEMBER 2004

Transmittal No.	Manual/Subject/Publication Number
	Medicare General Information (CMS-Pub. 100–01)
08	Standard Terminology for Claims Processing Systems Standard Terminology Chart.
09	Transmittal rescinded and replaced with Transmittal 10.
10	Update to Medicare Deductible, Coinsurance and Premium Rates for Calendar Year 2005.
	Basis for Determining the Part A Coinsurance Amounts.
	Part B Annual Deductible.
	Medicare Benefit Policy (CMS-Pub. 100–02)
18	This revision rescinded Transmittal 12.
19	Hospital Services Covered Under Part B Outpatient Observation Services.
20	This revision rescinded Transmittal 17.
21	Medicare Comprehensive Outpatient Rehabilitation Facility Coverage.
	Comprehensive Outpatient Rehabilitation Facility Services Provided by Medicare.
	Required Services.
	Optional Comprehensive Outpatient Rehabilitation Facility Services.
	Rules for Provision of Services.
	Physician's Services.
	Physical Therapy Services.
	Occupational Therapy Services.
	Speech-Language Pathology Services.
	Respiratory Therapy Services.
	Prosthetic and Orthotic Devices and Supplies.
	Social Services.
	Psychological Services.
	Nursing Services.
	Drugs and Biologicals.
	Home Environment Evaluation.
	Outpatient Mental Health Treatment Limitation.
22	This revision rescinded transmittal 15.
	Medicare National Coverage Determinations (CMS-Pub. 100–03)
17	Manualization of the Negotiated Clinical Diagnostic Laboratory National Coverage Determinations.
	Urine Culture, Bacterial.
	Human Immunodeficiency Virus Testing (Prognosis Including Monitoring).
	Human Immunodeficiency Virus Testing (Diagnosis).
	Blood Counts.
	Partial Thromboplastin Time.
	Prothrombin Time.
	Serum Iron Studies.
	Collagen Crosslinks, Any Method.
	Blood Glucose Testing.
	Glycated Hemoglobin/Glycated Protein.
	Thyroid Testing.
	Lipid Testing.
	Digoxin Therapeutic Drug Assay.
	Alpha-fetoprotein.
	Carcinoembryonic Antigen.
	Human Chorionic Gonadotropin.
	Tumor Antigen by Immunoassay.
	Prostate Specific Antigen.
	Gamma Glutamyl Transferase.
	Hepatitis Panel/Acute Hepatitis Panel.
	Fecal Occult Blood Test.
18	Islet Cell Transplantation.
	Pancreas Transplants (Effective July 1, 1999).
	Islet Cell Transplantation in the Context of a Clinical Trial (Effective October 1, 2004).
19	Blood-Derived Products for Chronic Non-Healing Wounds.
20	Issued to a specific audience, not posted to Internet/Intranet due to sensitivity of Instruction.
21	Magnetic Resonance Spectroscopy for Diagnosing Brain Tumors.
	Magnetic Resonance Imaging.
	Magnetic Resonance Spectroscopy.
	Magnetic Resonance Angiography.
	Medicare Claims Processing (CMS-Pub. 100–04).
222	Skilled Nursing Facility Consolidated Billing Requirements for Durable Medical Equipment Prosthetic, Orthotics & Supplies.
	Skilled Nursing Facility Consolidated Billing and Durable Medical Equipment Provided by Durable Medical Equipment Prosthetic, Orthotics & Supplies Suppliers.
	General Information.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JULY THROUGH SEPTEMBER 2004—Continued

Transmittal No.	Manual/Subject/Publication Number
223	Positron Emissions Tomography Scans and Related Claims Processing.
	Positron Emission Tomography Scans—General Information.
	Billing Instructions.
	Use of Gamma Cameras and Full Ring and Partial Ring Positron Emissions Scanners.
	Positron Emission Tomography Scan Qualifying Conditions and Health.
	Common Procedure Coding System Code Chart.
	Positron Emissions Tomography Scans for Imaging of the Perfusion of the Heart Using Rubidium 82.
	Expanded Coverage of Positron Emission Tomography Scans for Solitary Pulmonary Nodules.
	Expanded Coverage of Positron Emissions Tomography Scans Effective for Services on or after July 1, 1999.
	Expanded Coverage of Positron Emissions Tomography Scans Effective for Services on or after July 1, 2001.
	Expanded Coverage of Positron Emissions Tomography Scans for Breast Cancer Effective for Dates on or after October 1, 2002.
	Coverage of Positron Emissions Tomography Scans for Myocardial Viability.
	Coverage of Positron Emissions Tomography Scans for Thyroid Cancer.
	Coverage of Positron Emissions Tomography Scans for Perfusion of the Heart Using Ammonia N–13.
224	October Quarterly Update to 2004 Annual Update of Health Common Procedure Coding System Codes Used For Skilled Nursing Facility.
	Consolidated Billing Enforcement.
225	Changes to the Laboratory National Coverage Determination Edit Software for October 2004.
226	Quarterly Update of Health Common Procedure Coding System Codes Used for Home Health Consolidated Billing Enforcement.
	Home Health Prospective Payment System Consolidated Billing and Primary Home Health Agency.
227	Local Medical Review Policy/Local Coverage Determination Medicare.
	Summary Notice Message Revision.
	Medical Necessity.
	Necesidad Médica.
228	General Policy.
	Patient and Insured Information.
229	Additional Clarification of Bill Type 22x and 23x Submitted by Skilled Nursing Facilities With Instructions for Involuntarily Moving A Beneficiary Out of the Skilled Nursing Facility and Ending a Benefit Period.
	Skilled Nursing Facility Prospective Payment System and Consolidated Billing Overview.
	Consolidated Billing Requirements for Skilled Nursing Facility.
	Other Excluded Services Beyond the Scope of a Skilled Nursing Facility Part A Benefit.
	Outpatient Surgery and Related Procedures ''Inclusions.
	Emergency Services.
	Dialysis and Dialysis Related Services to a Beneficiary With End Stage Renal Disease.
	End Stage Renal Disease Services.
	Coding Applicable to Epoetin Services.
	Coding for Darbepoetin Alfa.
	Ambulance Services.
	Screening and Preventive Services.
	Therapy Services.
	Situations that Require a Discharge or Leave of Absence.
	Billing Procedures for Periodic Interim Payment Method of Payment Ending A Benefit Period.
	Other Billing Situations.
	Billing for Outpatient Skilled Nursing Facility Services
230	Update to the Claims Status Codes.
	Health Care Claims Status Category Codes and Health Care Claims Status Codes for Use with Health Care Claims Status Request and Response.
231	Indian Health Service or Tribal Critical Access Hospital Payment Methodology for Inpatient and Outpatient Services.
	Payment for Inpatient Services Furnished by an Indian Health Service or Tribal Critical Access Hospital.
	Payment for Outpatient Services Furnished by an Indian Health Service or Tribal Critical Access Hopsital.
232	Issued to a specific audience, not posted to Internet/Intranet due to confidentiality of instruction.
233	Issued to a specific audience, not posted to Internet/Intranet due to confidentiality of instruction.
234	Standardized Responses to Provider Inquiries Regarding the Negotiated Laboratory National Coverage Determinations Edit Software.
235	Instructions for Downloading the Medicare Zip Code File.
236	2005 Durable Medical Equipment Prosthetic, Orthotics & Supplies Pricing.
	File Record Layout Expansion and New Pricing Procedures for Certain Durable Medical Equipment Prosthetic, Orthotics & Supplies Items Based on Modifiers.
	Payment of Durable Medical Equipment Prosthetic, Orhtotics & Supplies Items based on Modifiers.
	Intermediary Format for Durable Medical Equipment, Prosthetic, Orthotic and Supply Fee Schedule.
237	Implementation of Patient Status Code 65, Discharged/Transferred to a Psychiatric Hospital or Psychiatric Distinct Part Unit of a Hospital.
238	Health Insurance Portability and Accountability Act Institutional Health Care Claim Implementation Guide Additional Updates.
239	Transmittal 239 is Rescinded and replaced with Transmittal 270.
240	Expansion of the Existing Interrupted Stay Policy Under Long Term Care.
	Hospital Prospective Payment System.
241	Processing Part B Claims for Indian Health Services.
	General.
	Services That May Be Paid to Indian Health Service/Tribe/Tribal Organization Facilities.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JULY THROUGH SEPTEMBER 2004—Continued

Transmittal No.	Manual/Subject/Publication Number
	Services Paid Under the Physician Fee Schedule.
	Other Part B Services.
	Durable Medical Equipment.
	Prosthetics and Orthotics.
	Prosthetics Devices.
	Surgical Dressings and Splints and Casts.
	Therapeutic Shoes.
	Drugs.
	Clinical Laboratory Services.
	Ambulance Services.
	Claims Processing.
	Claims Processing Requirements for Benefits, Improvements & Protection Act of 2000 Services.
	Claims Processing Requirements for Medicare Modernization Act Enrollment and Billing for Durable Medical Equipment, Prosthetic, Orthotics & Supplies.
	Claims Processing for Durable Medical Equipment, Prosthetic, Orthotics & Supplies.
	Enrollment for Durable Medical Equipment, Prosthetic, Orthotics & Supplies.
	Claims Submission for Durable Medical Equipment, Prosthetic, Orthotics & Supplies.
	Enrollment and Billing for Clinical Laboratory and Ambulance Services Claims Submission and Processing for Clinical Laboratory and Ambulance Service.
	Enrollment for Clinical Laboratory and Ambulance Services and Part B drugs.
242	Quarterly Update to Correct Coding Initiative edits, Version 10.3, Effective October 1, 2004.
243	Patient Status Code and Reason for Patient Visit for the Hospital Outpatient Prospective Payment System.
	Patient Status Code and Reason for Patient Visit for the Hospital.
244	Transmittal 244 is Rescinded and Replaced with Transmittal 269.
245	Issued to a specific audience, not posted to Internet/Intranet due to confidentiality of instruction.
246	Issued to a specific audience, not posted to Internet/Intranet due to confidentiality of instruction.
247	Issued to a specific audience, not posted to Internet/Intranet due to confidentiality of instruction.
248	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 Carrier Drugs.
	Calculation of the Average Wholesale Price.
	Detailed Procedures for Determining Average Wholesale Price and the Drug.
	Payment Allowance 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.
249	New Medicare Summary Notice Message 31.18.
	Adjustments.
	Ajustes.
250	Coordination of Benefits Agreement Claims Selection Options.
	Consolidated Claims Crossover Process.
	Consolidation of the Claims Crossover Process.
251	Editing Of Hospital And Skilled Nursing Facility Part B Inpatient Services.
	Inpatient Part B Hospital Services.
	Editing of Hospital Part B Inpatient Services. Billing for Inpatient Skilled Nursing Facility Services Paid Under Part B.
	Editing of Skilled Nursing Facilities Part B Inpatient Services.
252	Paper Remittance Advice format change to accommodate the forced balancing Amount to balance at the claim level as well as the provider level, a flat file change, and a change in the companion document for fiscal intermediaries.
253	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.
254	October 2004 Outpatient Prospective Payment System Code Editor Specifications Version 5.3.
255	October Update to the Medicare Outpatient Code Editor Version 20.0 for Bills From Hospitals That Are Not Paid Under the Outpatient Prospective Payment System.
256	Use of Group Health Plan Payment System/Medicare Managed Care System To Pay Capitated Payments to Chronic Care Improvement Organizations Serving Medicare Fee-For-Service Beneficiaries Under Section 721 of the Medicare Modernization Act.
257	Shared Systems Changes for Medicare Part B Drugs for End Stage Renal Disease Independent Dialysis Facilities.
258	New Waived Tests—October 1, 2004.
259	Scheduled Release for October Updates to Software Programs and Pricing/Coding Files.
260	Cryosurgery of the Prostate.
	Cryosurgery of the Prostate Gland.
	Coverage Requirements.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JULY THROUGH SEPTEMBER 2004—Continued

Transmittal No.	Manual/Subject/Publication Number
	Billing Requirements.
	Payment Requirements.
261	Billing and Requirements for Islet Cell Transplantation for Beneficiaries in a National Institutes of Health Clinical Trial.
	Billing Requirements for Islet Cell Transplantation for Beneficiaries in a National Institutes of Health Clinical Trial.
	Healthcare Common Procedural Coding System Codes for Carriers.
	Applicable Modifier for Islet Cell Transplant Claims for Carriers.
	Special Billing and Payment Requirements for Carriers.
	Special Billing and Payment Requirements for Intermediaries.
	Special Billing and Payment Requirements Medicare Advantage Beneficiaries.
262	Confidential.
263	Inpatient Rehabilitation Facility Annual Update: Prospective Payment System.
	Pricer Changes for Fiscal Year 2005.
	Outlier Payments: Cost-to-Charge Ratios.
264	This Transmittal is Rescinded and Replaced with Transmittal 271.
265	Issued to a specific audience, not posted to Internet/Intranet due to confidentiality of instruction.
266	Revision of Common Working File Editing for Same-Day, Same-Provider Acute Care Readmissions.
	Repeat Admissions.
267	Crossover Patients in New Long Term Care Hospital.
	Billing Procedures for a Provider Assigned Multiple Provider Numbers or a Change in Provider Number.
	Crossover Patients in New Long Term Care Hospital.
268	Medicare Part A Skilled Nursing Facility Prospective Payment.
	System Pricer Update Fiscal Year 2005.
	Skilled Nursing Facility Prospective Payment System Pricer Software.
269	This Transmittal Replaces Transmittal 244.
270	This Transmittal Replaces Transmittal 239.
271	This Transmittal Replaces Transmittal 264.
272	October Quarterly Update for 2004 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Fee Schedule.
273	Modification of CMS' Medicare Contingency Plan for Health Insurance Portability & Accountability Act Implementation.
	Receipt Date.
	Payment Ceiling Standards.
	Payment Floor Standards.
	Determining and Paying Interest.
274	Good Cause Waiver of Late Claim Filing Payment Reduction Penalty.
	Extend Time for Good Cause.
	Conditions Which Establish Good Cause.
	Procedure to Establish Good Cause.
	Good Cause Is Not Found.
	Preparing Common Working File Claim Records for Services Subject to 10 Percent Payment Reduction.
275	The Supplemental Security Income/Medicare Beneficiary Data for Fiscal Year 2003 for Inpatient Prospective Payment System Hospitals.
276	Further Information Related to CR 3175, Distinct Part Units of Critical Access Hospitals.
	Requirements for Critical Access Hospital Services, Critical Access Hospital Skilled Nursing Care Services and Distinct Part Units.
	Inpatient Rehabilitation Facility Prospective Payment System.
	Billing Requirements Under Inpatient Rehabilitation Facility Prospective Payment System.
277	Sensitive.
278	This Transmittal is no longer sensitive and can be posted to Internet/Intranet.
279	Issued to a specific audience, not posted to Internet/Intranet due to sensitivity of instruction.
280	Issued to a specific audience, not posted to Internet/Intranet due to sensitivity of instruction.
281	Issued to a specific audience, not posted to Internet/Intranet due to confidentiality of instruction.
282	This Transmittal replaces Transmittal 274.
283	2005 Healthcare Common Procedure Coding System Annual Update Reminder.
	Health Care Common Procedure Coding System Annual Update Reminder.
284	Durable Medical Equipment Regional Carriers Only—Appeals of Duplicate Claims.
285	Addition of Physician Assistants, Nurse Practitioners and Clinical Nurse.
	Specialists as Emergency On-Call Providers for Critical Access Hospitals.
	Costs of Emergency Room On-Call Providers.
286	Medicare Physician Fee Schedule Database 2005 File Layout.
	Addendum.
287	Schedule for Completing the Calendar Year 2005 Fee Schedule Updates and the Participating Physician Enrollment Procedures.
288	Fiscal Year 2005 Payment for Services Furnished in Ambulatory Surgical Centers.
289	File Descriptions and Instructions for Retrieving the 2005 Pricing Files Through CMS'' Mainframe Telecommunications System.
	Recurring Update Notification Containing New Pricing File Names and Retrieval Dates for 2005.
290	October 2004 Update of the Hospital Outpatient Prospective Payment System.
291	Use of Transmission Date in the Service Date/Assessment Date Field for Inpatient Rehabilitation Facility Prospective Payment System Claims.
	Payment Adjustment for Late Transmission of Patient Assessment Data.
292	Confidential.
293	Confidential.
294	Sensitive/Controversial.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JULY THROUGH SEPTEMBER 2004—Continued

Transmittal No.	Manual/Subject/Publication Number
295	Transmittal 214 is Rescinded and Replaced with Transmittal 295.
296	This Transmittal replaces Transmittal 196.
297	Reasonable Charge Update for 2005 for Splints, Casts, Dialysis Supplies, Dialysis Equipment, Therapeutic Shoes, and Certain Intraocular Lenses.
298	This Transmittal replaces Transmittal 295.
299	Use of Condition Code 44, ''Inpatient Admission Changed to Outpatient''.
300	Payment For Outpatient End Stage Renal Disease-Related Services.
301	Transmittal 301 Replaces Transmittal 251.
302	Nursing Facility Visits (Codes 99301–99313).
303	Instructions for Completion of Form CMS–1450.
304	Transmittal 304 Replaces Transmittal 205.
	Medicare Secondary Payer (CMS-Pub. 100–05)
17	Clarification of CR 3064.
	General Policy.
18	Application of the Medicare Secondary Payer for the Working Aged Provision and the Medicare Secondary for the Disabled Provision to Former Spouses and Certain Family Members With Coverage Under the Federal Employees Health Benefits Program.
	Individuals Not Subject to the Limitation on Payment.
	Individuals Not Subject to Medicare Secondary Payer Provision.
19	Clarification of Medicare Secondary Payer Rules in Relation to a Temporary Leave of Absence.
	Rules Defining Employees Covered by Group Health Plans and Large Group Health Plans.
	Medicare Financial Management (CMS-Pub. 100–06)
49	Procedures For Re-Issuance and Stale Dating of Medicare Checks
50	Unsolicited/Voluntary Refunds
	General Information.
	Office of Inspector General Initiatives.
	Unsolicited/Voluntary Refund Accounts.
	Receiving and Processing Unsolicited/Voluntary Refund Checks When Identifying Information Is Provided.
51	This transmittal is rescinded and replaced with Transmittal 52.
52	Notice of New Interest Rate for Medicare Overpayments and Underpayments.
53	Change Request 3367, Debt Collection System, replaces Change Request 2952, Debt Collection System
54	Notification to Providers of Intent to Complete a Post-Payment Audit.
	Contractor's Responsibility Prior to Submission of Cost Reports.
	Medicare State Operations Manual (Pub. 100–07)
02	Provider Identification Number.
	Medicare Program Integrity (CMS-Pub. 100–08)
79	Local Medical Review Policy/Local Coverage Determination Medicare Summary.
	Notice Message Revision.
	Prepayment Edits.
80	Program Integrity Management Fraud and Abuse Complaint Screening Revisions. Complaint Screening.
81	Implementation of the Quarterly Strategy Analysis.
	The Quarterly Strategy Analysis.
	The Quarterly Strategy Analysis Format.
	Executive Summary.
	Problem Specific Activities.
	Problem Specific Activity Definitions.
	Narrative.
82	Home Health Demand Bills.
	Home Health.
	Effectuating Favorable Final Appellate.
	Decisions That a Beneficiary Is ''Confined to Home'' .
	Medical Review of Home Health Demand Bills.
83	Program Integrity Management Revisions for Chapter 4.
	Program Safeguard Contractor and Medicare Contractor Benefit Integrity Unit.
	Benefit Integrity Security Requirements.
	Medical Review for Benefit Integrity Purposes.
	Requests for Information from Outside Organizations.
	Conducting Investigations.
	Disposition of Cases.
	Types of Fraud Alerts.
	Background.
	Investigation, Case, and Suspension Entries.
	Initial Entry Requirements for Investigations.
	Referral of Cases to the Office of the Inspector General/Office of Investigations.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JULY THROUGH SEPTEMBER 2004—Continued

Transmittal No.	Manual/Subject/Publication Number
	Suspension. Referral to Quality Improvement Organizations Exceptions.
	Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100–09)
07	Confidential.
	Medicare Managed Care (CMS-Pub. 100–16)
56	Administrative Contracting Requirements.
57	Coverage of Clinical Trials. Hospital Inpatient Data. Diagnostic Coding and Guidelines for Data Collection From Provider Network.
58	Terminology.
59	State and County Code Corrections. Completion of Enrollment Form. Passive Elections. Eligibility Requirements for Medicare Medical Savings Account Plans. Annual Elective Period. Open Enrollment Period. Open Enrollment Period Through 2005. Open Enrollment Period in 2006. Open Enrollment Period in 2007 and Beyond. Open Enrollment for Newly Eligible Individuals in 2006 and Beyond. Open Enrollment Period for Institutionalized Individuals in 2006 and Beyond. Special Enrollment Period for Beneficiaries Age 65.
60	Streamlined Marketing Review Process. File and Use. Guidelines for Advertising and Pre-Enrollment Materials. Guidelines for Advertising Materials. Guidelines for Pre-Enrollment Materials.
61	Emergency and Urgently Needed Services.
62	Revisions to Chapter 13—Medicare+Choice Beneficiary Grievances, Organization Determinations and Appeals.
	Demonstrations (CMS-Pub. 100–19)
05	Use of Group Health Plan Payment System to Pay Capitated Payments to Non-Health Plan Demonstration/Program Sites Serving Medicare Fee For Service Beneficiaries—Updated List of Plan Numbers.
06	Revision of CR 3269 for the Demonstration Project to Clarify the Definition of Homebound (Homebound Demonstration).
	One Time Notification (CMS-Pub. 100–20)
92	Additional Instructions Related 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.
93	Temporary Skilled Nursing Facility Extension.
94	Shared System Maintainer Hours for Resolution of Problems Detected During Health Insurance Portability and Accountability Act. Transaction Release Testing.
95	Modifications to Post-payment Adjustment Process for Home Health Prospective Payment System Claims Failing to Report Prior Inpatient Discharges.
96	Annual Changes to the Amount in Controversy Thresholds For the Administrative Law Judge and Judicial Review. Levels of the Claim Appeals Process as Required by Section 940 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.
97	Implementation of the Business Segment Identifier in the Healthcare Integrated General Ledger Accounting System.
98	Change to Previous Transmittal Regarding the Discounted Use of Revenue Code 0910.
99	This One-Time Notification is a full replacement for Transmittal 86.
100	This Transmittal is Rescinded and Replaced with Transmittal 103.
101	Change of the Premera Blue Cross Medicare Part A Plan Under Contract to BCBSA to a Part A Fiscal Intermediary Contract with Noridian Mutual Insurance Company in the States of Washington and Alaska.
102	Update to the Healthcare Provider Taxonomy Codes/Medicare Specialty Code Crosswalk.
103	This Transmittal replaces Transmittal 100.
104	Confidential.
105	Confidential.
106	Medicare Modernization Act Drug Pricing Update-Payment Limits for J9045 (Carboplatin Injection) and (Rituximab Cancer Treatment).
107	Common Working File Analysis to Process Claims Per the Renovated Override Code Processing (re: CR3190) and Common Working File Analysis to Review System Edits for Additional 2-byte Modifiers Added in CR3190 (Phase 2).
108	New Remark Code Message for Use With Claims for Parental Pumps-Durable Medical Equipment Regional Carrier Only.
109	Billing Instructions for ADVATE rAHF-PFM on Medicare Claims.
110	Medicare Modernization Act Drug Pricing Update-Payment Limits for J100 (Depo-estradiol cypionate inj).
111	Creation of Common Working File Auxilliary File and Associated Logic to Property.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JULY THROUGH SEPTEMBER 2004—Continued

Transmittal No.	Manual/Subject/Publication Number
	Calculate Medicare-Equivalent Deductibles for Department of Veteran Affairs Claims.
112	This Transmittal replaces Transmittal 109.
113	Implementation of § 921 of the Medicare Modernization Act Provider Customer Program.
114	Sensitive.
115	Instructions for Fiscal Intermediary Standard System and Multi-Carrier System Healthcare Integrated General Ledger Accounting System Changes.
116	Notification of Medlearn Matters Article for Confidential Change Request (CR) 3301.

ADDENDUM IV.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER

[July 2004 Through September 2004]

Publication date	FR Vol. 69 page No.	CFR parts affected	File code	Title of regulation
July 1, 2004	40288	42 CFR Part 414	CMS–1492–IFC	Medicare Program; Medicare Ambulance MMA Temporary Rate Increases Beginning July 1, 2004.
July 23, 2004	44036		CMS–1334–N	Medicare Program; Public Meeting in Calendar Year 2004 for Coding and Payment Determinations for Power Wheelchairs.
July 23, 2004	44035		CMS–1364–N	Medicare Program; August 30, 2004, Meeting of the Practicing Physicians Advisory Council and Request for Nominations.
July 23, 2004	44034		CMS–4074–N	Medicare Program; Meeting of the Advisory Panel on Medicare Education—September 9, 2004.
July 23, 2004	44031		CMS–3142–NC	Medicare Program; Evaluation Criteria and Standards for Quality Improvement Program Contracts.
July 23, 2004	44029		CMS–3112–NC2	Medicare Program; Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers.
July 23, 2004	44027		CMS–2202–PN	Medicare and Medicaid Programs; Application by the American Association for Accreditation of Ambulatory Surgery Facilities, Inc., for Continued Deeming Authority for Ambulatory Surgical Centers.
July 23, 2004	44013		CMS–2187–N	State Children's Health Insurance Program (SCHIP); Extended Availability of Unexpended SCHIP Funds From the Appropriation for Fiscal Years 1998 Through 2001; and Provision of Authority for Qualifying States To Use a Portion of SCHIP Funds for Medicaid Expenditures.
July 23, 2004	43956	42 CFR Part 402	CMS–6146–P	Medicare Program; Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures.
July 23, 2004	43926	45 CFR Part 146	CMS–2033–F	Requirements for the Group Health Insurance Market; Non-Federal Governmental Plans Exempt From HIPAA Title I Requirements.
July 23, 2004	43924	45 CFR Part 146	CMS–2152–F2	Amendment to the Interim Final Regulation for Mental Health Parity.
July 30, 2004	45822		CMS–4068–N	Medicare Program; Open Public Meeting Regarding the Development of the Model Guidelines for Categories and Classes of Drugs.
July 30, 2004	45775		CMS–1249–N	Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update.
July 30, 2004	45721		CMS–1360–N	Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Fiscal Year 2005.
July 30, 2004	45640	42 CFR Part 484	CMS–1265–CN	Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2005; Correction Notice.
July 30, 2004	45604	42 CFR Parts 405 and 411	CMS–6014–F	Medicare Program; Interest Calculation.
August 3, 2004	46866	42 CFR Parts 417 and 422	CMS–4069–P	Medicare Program; Establishment of the Medicare Advantage Program.
August 3, 2004	46632	42 CFR Parts 403, 411, 417, and 423.	CMS–4068–P	Medicare Program; Medicare Prescription Drug Benefit.
August 5, 2004	47488	42 CFR Parts 405, 410, 411, 414, 418, 424, 484, and 486.	CMS–1429–P	Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005.
August 5, 2004	47446		CMS–1275–N	Medicare Program; Meeting of the Advisory Panel on Ambulatory Payment Classification Groups—September 1, 2, and 3, 2004.

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

[July 2004 Through September 2004]

Publication date	FR Vol. 69 page No.	CFR parts affected	File code	Title of regulation
August 11, 2004	48916	42 CFR Parts 403, 412, 413, 418, 460, 480, 482, 483, 485, and 489.	CMS–1428–F	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates.
August 16, 2004	50448	42 CFR Parts 410, 411, 419.	CMS–1427–P	Medicare Program; Proposed Changes to the Hospital Outpatient and Prospective Payment System and Calendar Year 2005 Payment Rates.
August 27, 2004	52723	.....	CMS–1279–N2	Medicare Program; Public Meeting of the Program Advisory and Oversight Committee (PAOC) for Quality Standards and Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).
August 27, 2004	52722	.....	CMS–3136–N	Medicare Program; Meeting of the Medicare Coverage Advisory Committee—September 28, 2004.
August 27, 2004	52721	.....	CMS–5025–CN	Medicare Program; Medicare Replacement Drug Demonstration; Correction.
August 27, 2004	52710	.....	CMS–1264–N	Medicare Program; Hospice Wage Index for Fiscal Year 2005.
August 27, 2004	52706	.....	CMS–4067–PN	Medicare and Medicaid Programs; Application by the Utilization Review Accreditation Commission (URAC) for Deeming Authority for Medicare Advantage.
August 27, 2004	52700	.....	CMS–2201–N	State Children's Health Insurance Program; Final Allotments to States, the District of Columbia, and U.S. Territories and Commonwealths for Fiscal Year 2005.
August 27, 2004	52699	.....	CMS–1269–N2	Medicare Program; Second Request for Nominations for Two Specific Categories of Members of the Emergency Medical Treatment and Labor Act (EMTALA) Technical Advisory Group (TAG).
August 27, 2004	52620	42 CFR Parts 431 and 457	CMS–6026–P	Medicaid Program and State Children's Health Insurance Program (SCHIP): Payment Error Rate Measurement.
August 27, 2004	52620	42 CFR Part 402	CMS–6146–CN	Medicare Program; Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures.
September 9, 2004	54674	.....	CMS–8020–N	Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rate, and Annual Deductible Beginning January 1, 2005.
September 9, 2004	54673	.....	CMS–8022–N	Medicare Program; Part A Premium for 2005 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement, Thursday, September 9, 2004.
September 9, 2004	54671	.....	CMS–8021–N	Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 2005, Thursday, September 9, 2004.
September 14, 2004 ..	55440	.....	CMS–6027–N	Medicare Program; September 30, 2004 Open Door Forum: Requirements for Coordination Between Plans Primary or Secondary to Medicare Part D Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).
September 16, 2004 ..	55763	42 CFR Part 414	CMS–1380–F	Medicare Program; Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals.
September 24, 2004 ..	57325	.....	CMS–3141–N	Procedure for Producing Guidance Documents Describing Medicare's Coverage Process.
September 24, 2004 ..	57325	.....	CMS–3137–N	Medicare Program; Meeting of the Medicare Coverage Advisory Committee—November 4, 2004.
September 24, 2004 ..	57324	.....	CMS–2200–N4	Medicare Program; Meeting of the State Pharmaceutical Assistance Transition Commission—October 14, 2004.
September 24, 2004 ..	57312	.....	CMS–9023–N	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—April 2004 Through June 2004.
September 24, 2004 ..	57310	.....	CMS–4077–PN	Medicare and Medicaid Programs; Application by the National Committee for Quality Assurance Preferred Provider Organization for Deeming Authority for Medicare Advantage.
September 24, 2004 ..	57308	.....	CMS–2208–PN	Medicare and Medicaid Programs; Application by the American Osteopathic Association for Continued Approval of Deeming Authority for Hospitals.
September 24, 2004 ..	57307	.....	CMS–2256–PN	Medicare and Medicaid Programs; Application by the Community Health Accreditation Program (CHAP) for Home Health Agencies.

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

[July 2004 Through September 2004]

Publication date	FR Vol. 69 page No.	CFR parts affected	File code	Title of regulation
September 24, 2004 ..	57305	.....	CMS–2204–PN	Medicare and Medicaid Programs; Application by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for Home Health Agencies.
September 24, 2004 ..	57304	.....	CMS–3154–N	Medicare Program; Request for Nominations for Members for the Medicare Coverage Advisory Committee.
September 24, 2004 ..	57244	42 CFR Parts 431 and 457	CMS–6026–CN	Medicaid Program and State Children's Health Insurance Program (SCHIP); Payment Error Rate Measurement; Correction.
September 24, 2004 ..	57226	42 CFR Part 411	CMS–1810–IFC2	Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Correcting Amendment.
September 24, 2004 ..	57224	42 CFR Part 406	CMS–4018–F	Medicare Program; Continuation of Medicare Entitlement When Disability Benefit Entitlement Ends Because of Substantial Gainful Activity.
September 24, 2004 ..	57859	42 CFR Part 493		Laboratory Requirements; OFR Correction.
September 30, 2004 ..	58596	42 CFR Parts 431 and 457	CMS–6026–CN	Medicaid Program and State Children's Health Insurance Program (SCHIP); Payment Error Rate Measurement; OFR Correction.

Addendum V—National Coverage Determinations [July 2004 Through September 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 website at *http://cms.hhs.gov/coverage.*

NATIONAL COVERAGE DETERMINATIONS

[July 2004 Through September 2004]

Title	NCDM section	TN#	Issue date	Effective date
Manualization of Negotiated Clinical Diagnostic Laboratory NCDs	N/A	R17NCD ..	07/02/2004	07/02/2004
Changes to the Laboratory NCD Edit Software for October 2004	N/A	R225CP ...	04/09/2004	10/04/2004
Blood-Derived Products for Chronic Non-Healing Wounds	270.3	R19NCD ..	07/30/2004	07/23/2004
Islet Cell Transplantation	260.3.1	R18NCD ..	07/30/2004	10/04/2004
MRS for Diagnosing Brain Tumors	220.2.1	R21NCD ..	09/10/2004	09/10/2004

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 2nd quarter, July 2004 Through September 2004.

IDE Category
G030093
G030237
G040049
G040052
G040057
G040091
G040092
G040094
G040096
G040098
G040099
G040100
G040102
G040103
G040104
G040105
G040109
G040111
G040112
G040113
G040119
G040122
G040124
G040126
G040128
G040129
G040130
G040134
G040137
G040142
G040143
G040144
G040145
G040146
G040147
G040148
G040149
G040150

G040153
G040154
G040160
G980099

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")
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
0938–0062	431.151, 435.1009, 440.220, 440.250, 442.1, 442.10–442.16, 442.30, 442.40, 442.42, 442.100–442.119, 483.400–483.480, 488.332, 488.400, 498.3–498.5
0938–0065	485.701–485.729
0938–0074	491.1–491.11
0938–0080	406.7, 406.13
0938–0086	420.200–420.206, 455.100–455.106
0938–0101	430.30
0938–0102	413.20, 413.24
0938–0107	413.20, 413.24
0938–0146	431.800–431.865
0938–0147	431.800–431.865
0938–0151	493.1405, 493.1411, 493.1417, 493.1423, 493.1443, 493.1449, 493.1455, 493.1461, 493.1469, 493.1483, 493.1489
0938–0155	405.2470
0938–0170	493.1269–493.1285
0938–0193	430.10–430.20, 440.167
0938–0202	413.17, 413.20
0938–0214	411.25, 489.2, 489.20
0938–0236	413.20, 413.24
0938–0242	488.26, 442.30
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
0938–0328	482.12, 482.13, 482.21, 482.22, 482.27, 482.30, 482.41, 482.43, 482.45, 482.53, 482.56, 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	488.26, 442.30
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	488.26, 442.30
0938–0382	488.26, 442.30
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

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")
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 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	410.38, 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
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
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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
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0938–0872	413.337, 483.20
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0938–0874	*45 CFR* Parts 160 and 162
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0938–0883	*45 CFR* Parts 160 and 164
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0938–0887	*45 CFR* 148.316, 148.318, 148.320
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0938–0921	414.804

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9026–N]

RIN 0938–AN112

Medicare Program; Timeline for Publication of Medicare Final Regulations After Proposed or Interim Final Regulations

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

ACTION: Notice.

SUMMARY: This notice implements section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which establishes a general 3-year timeline for publishing a Medicare final regulation after a proposed regulation or an interim final regulation has been published. In accordance with the statute, this notice permits an extension of a published timeline under exceptional circumstances. The notice also establishes a transition period for publishing Medicare final regulations for previously published interim final regulations.

EFFECTIVE DATE: This notice is effective on December 30, 2004.

FOR FURTHER INFORMATION CONTACT: Renee Swann, (410) 786–4492.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

The general statutory authority for the Department to issue Medicare regulations is found in section 1871 of the Social Security Act (the Act). Specifically, section 1871(a)(1) of the Act authorizes us to publish regulations to administer the Medicare program. Section 1871(a)(2) of the Act states that, with the exception of national coverage determinations, we must publish a regulation ''that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits* * *''

Before issuing a final regulation, section 1871(b)(1) of the Act generally requires us to publish a proposed regulation that solicits comments (for at least 60 days) from the public. There are, however, several exceptions that permit the Secretary to issue final regulations or interim final regulations without first obtaining advance public comments.

Executive Order 12866 (issued on September 20, 1993) requires that all Federal agencies prepare an agenda of all regulations under development or review, at a time and in a manner specified by the Administrator of the Office of Information and Regulatory Affairs, of the Office of Management and Budget.

We announce in the Semi-Annual Unified Regulations Agenda the regulations we plan to publish during the 12-month period following publication of the Agenda in the **Federal Register**. The Agenda is generally published in April and October each year.

In October 2001, to better serve all of our constituencies, including our health care providers, we began publishing regulations on the fourth Friday of every month (except when a statutory deadline demands otherwise), and we began issuing a quarterly publication called the *Quarterly Provider Update* (QPU). The QPU is publicly available on the Internet and lists all of the regulations that we plan to publish in the coming quarter, as well as the publication date and page reference to all regulations published in the previous quarter. The QPU is published on the CMS web site at *http://qa.cms.hhs.gov/providerupdate/main.asp.*

On December 8, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, Pub. L. 108–173) was enacted. Section 902 of the MMA added a new paragraph (a)(3) to section 1871 of the Act. New section 1871(a)(3)(A) of the Act requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish a standardized timeline for the publication of a Medicare final regulation after the