DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9020–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—October 2003 Through December 2003

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

ACTION: Notice.

SUMMARY: This notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from October 2003 through December 2003, relating to the Medicare and Medicaid programs. This notice provides information on national coverage determinations affecting specific medical and health care services under Medicare. Additionally, this notice identifies certain devices with investigational device exemption (IDE) numbers approved by the Food and Drug Administration (FDA) that potentially may be covered under Medicare. Finally, this notice also includes listings of all approval numbers from the Office of Management and Budget for collections of information in CMS regulations.

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

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may have a specific information need and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing information contact persons to answer general questions concerning these items. Copies are not available through the contact persons. (*See* Section III of this notice for how to obtain listed material.)

Questions concerning items in Addendum III may be addressed to Karen Bowman, Office of Strategic Operations and Regulatory Affairs, Centers for Medicare & Medicaid Services, C5–16–03, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–5252.

Questions concerning national coverage determinations in Addendum V may be addressed to Patricia Brocato-Simons, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244–1850, or you can call (410) 786–0261.

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

SUPPLEMENTARY INFORMATION:

I. Program Issuances

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

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

II. How To Use the Addenda

This notice is organized so that a reader may review the subjects of manual issuances, memoranda, substantive and interpretive regulations, national coverage determinations (NCDs), and Food and Drug Administration (FDA)-approved investigational device exemptions (IDEs) published during the subject quarter to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals may wish to review Table I of our first three notices (53 FR 21730, 53 FR 36891, and 53 FR 50577) published in 1988, and the notice published March 31, 1993 (58 FR 16837). Those desiring information on the Medicare National Coverage Determination Manual (NCDM, formerly the Medicare Coverage Issues Manual (CIM)) may wish to review the August 21, 1989, publication (54 FR 34555). Those interested in the revised process used in making NCDs under the Medicare program may review the September 26, 2003, publication (68 FR 55634).

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

- Addendum I lists the publication dates of the most recent quarterly listings of program issuances.
- Addendum II identifies previous **Federal Register** documents that contain a description of all previously published CMS Medicare and Medicaid manuals and memoranda.
- Addendum III lists a unique CMS transmittal number for each instruction in our manuals or Program Memoranda and its subject matter. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in

conjunction with information currently in the manuals.

- Addendum IV lists all substantive and interpretive Medicare and Medicaid regulations and general notices published in the **Federal Register** during the quarter covered by this notice. For each item, we list the—
- Date published;
- **Federal Register** citation;
- Parts of the Code of Federal Regulations (CFR) that have changed (if applicable);
- Agency file code number; and
- Title of the regulation.
- Addendum V includes completed NCDs, or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCDM (or CIM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision.
- Addendum VI includes listings of the FDA-approved IDE categorizations, using the IDE numbers the FDA assigns. The listings are organized according to the categories to which the device numbers are assigned (that is, Category A or Category B), and identified by the IDE number.
- Addendum VII includes listings of all approval numbers from the Office of Management and Budget (OMB) for collections of information in CMS regulations in title 42; title 45, subchapter C; and title 20 of the CFR.

III. How To Obtain Listed Material

A. Manuals

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

In addition, individual manual transmittals and Program Memoranda listed in this notice can be purchased from NTIS. Interested parties should identify the transmittal(s) they want. GPO or NTIS can give complete details on how to obtain the publications they sell. Additionally, most manuals are available at the following Internet address: *http://cms.hhs.gov/manuals/default.asp.*

B. Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. Interested individuals may purchase individual copies or subscribe to the **Federal Register** by contacting the GPO at the address given above. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is also available on 24x microfiche and as an online database through *GPO Access*. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) forward. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using the World Wide Web; the Superintendent of Documents home page address is *http://www.gpoaccess.gov/fr/index.html*, by using local WAIS client software, or by telnet to *swais.gpoaccess.gov*, then log in as guest (no password required). Dial-in users should use communications software and modem to call (202) 512–1661; type swais, then log in as guest (no password required).

C. Rulings

We publish rulings on an infrequent basis. Interested individuals can obtain copies from the nearest CMS Regional Office or review them at the nearest regional depository library. We have, on occasion, published rulings in the **Federal Register**. Rulings, beginning with those released in 1995, are available online, through the CMS Home Page. The Internet address is *http://cms.hhs.gov/rulings.*

D. CMS's Compact Disk-Read Only Memory (CD–ROM)

Our laws, regulations, and manuals are also available on CD–ROM and may be purchased from GPO or NTIS on a subscription or single copy basis. The Superintendent of Documents list ID is HCLRM, and the stock number is 717–139–00000–3. The following material is on the CD–ROM disk:

- Titles XI, XVIII, and XIX of the Act.
- CMS-related regulations.
- CMS manuals and monthly revisions.
- CMS program memoranda.

The titles of the Compilation of the Social Security Laws are current as of January 1, 1999. (Updated titles of the Social Security Laws are available on the Internet at *http://www.ssa.gov/OP_Home/ssact/comp-toc.htm.*) The remaining portions of CD–ROM are updated on a monthly basis.

Because of complaints about the unreadability of the Appendices (Interpretive Guidelines) in the State Operations Manual (SOM), as of March 1995, we deleted these appendices from CD–ROM. We intend to re-visit this issue in the near future and, with the aid of newer technology, we may again be able to include the appendices on CD–ROM.

Any cost report forms incorporated in the manuals are included on the CD–ROM disk as LOTUS files. LOTUS software is needed to view the reports once the files have been copied to a personal computer disk.

IV. How To Review Listed Material

Transmittals or Program Memoranda can be reviewed at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL.

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most Federal Government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library.

For each CMS publication listed in Addendum III, CMS publication and transmittal numbers are shown. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the Medicare Benefit Policy Manual, Inpatient Hospital Services publication, use CMS-Pub. 100–02, Transmittal No. 01.

(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: March 9, 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.

November 2, 1999 (64 FR 59185)
December 7, 1999 (64 FR 68357)

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

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 2003 through December 2003]

Transmittal No.	Manual/Subject/Publication No.
	Manual System (CMS-Pub. 100–00)
01	Introduction.
	Medicare Benefit Policy (CMS-Pub. 100–02)
01	Inpatient Hospital Services. Inpatient Psychiatric Hospital Services. Duration of Covered Inpatient Services. Inpatient Psychiatric Benefit Days Reduction and Lifetime Limitation. Lifetime Reserve Days. Hospital Services Covered Under Part B. Home Health Services. Coverage of Extended Care Skilled Nursing Facility Services Under Hospital Coverage of Hospice Services Under Hospital Insurance. Ambulance Services. End-Stage Renal Disease. Comprehensive Outpatient Rehabilitation Facility Coverage. Rural Health Clinic and Federally Qualified Health Center Services. Medical Devices. Covered Medical and Other Health Services. General Exclusions from Coverage.
02	Provider Education Article Stopping Abuse of the Power Wheelchair Benefit.
03	Fecal-Occult Blood Tests.
	Medicare National Coverage Determinations (CMS-Pub. 100–03)
02	Artificial Hearts and Related Devices.
03	Lung Volume Reduction Surgery (Reduction Pneumoplasty).
04	Provider Education Article Ventricular Assist Devices for Destination Therapy.
05	Colorectal Cancer Screening Test.
	Medicare Claims Processing (CMS-Pub. 100–04)
01	General Billing Requirements. Admission and Registration Requirements. Inpatient Part A Hospital. Part B Hospital (Including Inpatient Hospital Part B and Outpatient Prospective Payment System). Part B Outpatient Rehabilitation and Comprehensive Outpatient Rehabilitation Facility Services. Skilled Nursing Facility Inpatient Part A Billing. Skilled Nursing Facility Part B (Including Inpatient Part B and Outpatient Fee Schedule). Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims. Rural Health Clinics and Federal Qualified Health Centers. Home Health Agency Billing. Hospice. Physician/Practitioner Billing. Radiology Services. Ambulatory Surgical Centers. Ambulance. Laboratory Services from Independent Labs, Physicians, and Providers. Drugs and Biologicals. Preventive and Screening Services. Indian Health Services (not yet available). Durable Medical Equipment, Prosthetics, Orthotics and Supplies Parenteral and Enteral. Medicare Summary Notices. Remittance Notices to Providers. Fee Schedule Administration and Coding Requirements. EDI Support Requirements. Completing and Processing UB–92 (CMS–1450) Data Set. Completing and Processing Form CMS–1500 Data Set. Contractor Instructions for Common Working File. Coordination With Medigap, Medicaid, and Other Complementary Insurers.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October 2003 through December 2003]

Transmittal No.	Manual/Subject/Publication No.
	Appeals of Claims Decisions.
	Financial Liability Protections.
02	File Descriptions for Retrieving the 2004 Pricing and Health Common Coding Data Files through Centers for Medicare & Medicaid Services.
	Mainframe Telecommunications System.
03	New Effective Data for CR2112 (Revisions to the Outpatient Prospective Payment System Pricer Software and Outpatient Code Editor).
04	October 2003 Update to the Health Care Provider Taxonomy Code.
05	Type of Service.
06	Implementation of the Coding, Testing, and Implementation Phase and Provider Education for Change Request 2631, Revisions to the Medicare.
	Carrier Manual for Jurisdiction and Unprocessable Claims.
07	Correction of Duplicate Editing in Common Working File for Immunosuppressive Drug Claims at the Durable Medical Equipment Regional Carrier.
08	Annual Update of Healthcare Common Procedure Coding System Codes Used for Home Health Consolidated Billing Enforcement.
09	Reasonable Charge Update for 2004 for Splints, Casts, Dialysis Supplies, Dialysis Equipment, Therapeutic Shoes, and Certain Intraocular Lenses.
10	Billing Instructions for Claims for Ventricular Assist Devices for Beneficiaries in a Medicare+Choice Plan.
11	Use of GY Modifier to Identify Clinical Diagnostic Laboratory Services That Are Not Covered by Medicare.
12	Certificate for Physician-Performed Microscopy Procedures.
13	Confirming Outcome & Assessment Information Set Assessment Items.
	Therapy Threshold.
	Hospitalization Within 14 Days of Start Care.
14	Modifier for Transportation of Portable X-rays.
15	Implementation Guide Edits.
16	Payment Limit for Purchased Service.
17	Billing and Payment Procedures Regarding Ownership and Provider Numbers.
	Payment Procedures for Terminated Home Health Agency.
18	Expansion of Beneficiary History and Claims In Process Files in the Viable Information Processing System Medicare System.
19	Annual Update of Healthcare Common Procedure Coding System Codes Used For Skilled Nursing Facility Consolidated Billing Enforcement.
20	Updated Skilled Nursing Facility to Pay File Available for Download.
21	Update to Medicare Deductible, Coinsurance, and Premium Rates for Calendar Year 2004.
22	Schedule Release for January Updates to Software Programs and Pricing/Coding Files.
23	Claims Information and Claims Forms and Formats.
	Paper Claim Submission to Carriers.
	Electronic Claim Submission to Carriers.
24	Billing Non-Covered Charges to Fiscal Intermediaries ''Summary and New Instructions.
25	Billing Non-Covered Charges to Fiscal Intermediaries.
26	Lung Volume Reduction Surgery.
27	CPT Code for Lung Volume Reduction Surgery and Instructions for Processing Claims for Beneficiaries in a Risk Medicare+Choice Plan.
28	Consolidation of the Claims Crossover Process & the Adding of Common Working File.
	Crossover Disposition Indicators.
29	Consolidation of Claims Crossover.
30	The Financial Limitation.
	Discipline Specific Outpatient Rehabilitation Modifiers—All Claims.
31	Dialysis Provider Number Series.
32	Remittance Advice Remark Code and Claim Adjustment Reason Code Update.
33	Mammography Quality Standards Act of 1992 File.
34	ANSIX12 Transaction 835 Companion Document and Flat File Change for.
	Durable Medical Equipment Regional Carriers, and Correction in the Companion Document for Fiscal Intermediaries.
35	Minimum Number of Pricing Files that Must be Maintained Online for Single Drug Pricer.
36	Revenue Code 068X.
37	Medicare Physician Fee Schedule Data Base.
38	Revised Skilled Nursing Facility No Pay/File—Effective January 1, 2004.
39	The Supplemental Security Income Medicare Beneficiary Data for Fiscal Year 2002 for Inpatient Rehabilitation Facility Paid Under the Prospective Payment System.
40	Healthcare Common Procedure Coding System and Diagnosis Codes.
	Roster Claims Submitted to Carriers for Mass Immunization.
	Claims Submitted to Fiscal Intermediaries for Mass Immunizations of Influenza and Pneumococcal Pneumonia Vaccine.
41	Payment for Anesthesia in a Critical Access Hospital.
42	Financial Limitation on Therapy Services.
43	Displaying Material With CDT–4 Code.
	American Dental Association's Copyright Notice.
	Point and Click License, and Shrink Wrap License.
44	Mandatory Electronic Submission of Claims.
	Small Providers and Full-Time Equivalent Employee Assessments Exceptions.
	Electronic and Paper Claims Implications Of Mandatory Electronic Submission.
45	Outpatient Provider Specific File.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October 2003 through December 2003]

Transmittal No.	Manual/Subject/Publication No.
46	Outpatient Prospective Payment System Outpatient Code Editors.
47	Carriers Specific Requirements for Certain Specialties/Services.
48	National Council for Prescription Drug Programs.
49	Fiscal Intermediaries Health Insurance Portability and Accountability Act. Claim Level Edits.
50	Description of Healthcare Common Procedure Coding System.
51	January Medicare Outpatient Code Editor (OCE) Specifications Version 19.1 For Bills From Hospitals That Are Not Paid Under the Outpatient Prospective Payment System.
52	Colorectal Cancer Screening.
53	January Outpatient Code Editor Specifications Version 5.0.
54	Payment Allowance Limit for Drugs and Biologicals Not Paid on a Cost or Prospective Payment Basis.
55	Calculation of the Payment Allowance Limit for Durable Medical Equipment Regional Carrier Drugs.
56	Ambulance Inflation Factor.
	Medicare Secondary Payer (CMS–Pub. 100–05)
01	Background and Overview. Medicare Secondary Payer Provisions. Medicare Secondary Providers Billing Requirements. Coordination of Benefits Contractor Requirements. Contractor Prepayment Processing Requirements. Medicare Secondary Payer Common Working File Process. Contractor MSP. Recovery Rules.
02	Individuals Not Subject to the Limitation on Payment.
03	Non-Employer Group Health Plan ''Send to Common Working File''. Switch Error.
04	Data Center Testing Production.
05	Data Center Testing Production.
06	Auto Notice of Change to Medicare Secondary Payer. Medicare Financial Management.
	Medicare Financial Management. (CMS–Pub. 100–06)
23	Clarification of Existing Instructions to Chapters 1 and 2 of the Medicare Financial Management.
24	Installation of Version 32.0 of the Provider Statistical and Reimbursement Reporting Stem.
25	Initial Interest Rate Manual Instruction and Business Requirement.
26	Incremental Cost Budgeting and Reporting for Productivity Investment Projects.
27	Revision to Chapters 8, 9 and 10 of the Medicare Financial Management Manual.
28	Uncollectible Accounts Forms.
29	Revisions to Chapters 3 and 4.
	Medicare Program Integrity (CMS-Pub. 100–08)
52	The Report of Benefit Saving.
53	Informing Beneficiaries About Which Local Medical Review Policy and/or National Determination Is Associated With Their Claims Denial.
54	Informing Beneficiaries About Which Lab Negotiated National Coverage.
55	Quarterly Update To Correct Coding Initiative Edit, Version 10.0, Effective January 1, 2004.
56	Update of Codes in the Program Integrity Management Reporting System and the Contractor Administrative Cost and Financial Management System.
57	Quarterly Update to Correct Coding Initiative Edits, Version 10.0, Effective January 1, 2004.
58	Provider Enrollment Manual Section 20.
59	Documentation Specifications for Areas Selected for Prepayment or Postpayment. Medicare Review.
60	Provider Enrollment, Chain and Ownership System.
	Medicare Contractor Beneficiary and Provider Communications (CMS Pub. 100–09)
1	Contains General Instructions and Requirements for Medicare Carriers, Including Durable Medical Equipment Regional Carrier and Intermediaries, for Processing Correspondence.
2	Revised Disclosure Desk Reference for Call Centers (Fourth Version).
3	Corrections and Reorganization of Material.
	Medicare Quality Improvement Organizations (CMS–Pub. 100–10)
11	Medicare+Choice Organizations.
12	Quality Improvement Organization.
13	Hospital Self-Generated Data

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October 2003 through December 2003]

Transmittal No.	Manual/Subject/Publication No.
	Medicare End-Stage Renal Disease Network Organizations (CMS Pub. 100–14)
4	Confidentiality and Disclosure.
	Medicare Managed Care (CMS Pub. 100–16)
32	Contacts With Medicare+Choice Organizations.
33	Contacts With Medicare+Choice Organizations.
34	Medicare+Choice Beneficiary Grievances.
35	Contacts With Medicare+Choice Organizations.
36	Medicare+Choice Organizations.
37	Revisions to Chapter 15.
38	Medicare Cost Plan Enrollment and Disenrollment Instructions.
39	Quality Assessment.
40	Manualization of the Plan Communication Guide.
	End-Stage Renal Disease (CMS-Pub. 100–14)
1	Forward.
	Purpose of the Network Manual.
	Statutes and Regulations.
	End-Stage Renal Disease Network Organizations Manual Revisions.
	Acronyms and Glossary.
	Purpose of End-Stage Renal Disease Network Organization.
	Requirements for End-Stage Renal Disease Network Organization.
	Responsibilities of End-Stage Renal Disease Network Organization.
	Health Care Quality Improvement Program Goals.
	Network Organization's Role in Health Care Quality Improvement Program.
2	Forward.
	Purpose of the Network Manual.
	Statutes and Regulations.
	Revision to the End-Stage Renal Disease Organizations Manual.
	Purpose of End-Stage Renal Disease Network Organization.
	Requirements for End-Stage Renal Disease Network Organizations.
	Responsibilities of End-Stage Renal Disease Network Organizations Goals.
	Network Organization's Role in Health Care Quality Improvement Program.
3	Organizational Structure.
	Establishing the Network Computer.
	Board of Directors.
	Other Committees.
	Network Staff.
	Required Administrative Reports/Activities.
	Quarterly Progress and Status Reports.
	Annual Report.
	Semi Annual Report of Network Operating Costs.
	New End Stage Renal Disease Patient Orientation Package Activities.
	Internal Quality Control Program.
	Internal Quality Control Program Requirements.
	Managed Care Manual (CMS Pub. 100–16)
26	Alternate Employer Group Enrollment Election.
	Optional Employer Group Medicare+Choice Enrollment Election.
	Request Submitted via Internet.
	Request Signature and Data.
	Effective Dates.
	Notice Requirements.
	Optional Employer Group Medicare+Choice Disenrollment Election.
	Medigap-Guaranteed Issue Notification Requirements.
	General Rule.
	Effective Date.
	Researching and Acting on a Change of Address.
	Clarified the Notice Requirements for Out of Area Permanent.
27	Noncontracted Provider Appeals.
	Storage of Appeal Case Files by the Independent Review Entity.
	Representative Filing on Behalf of the Enrollee.
	Storage of Hearing Files.
28	Streamlined Marketing Review Process.
	Introduction.
	Marketing Review Process.
	Guidelines for Advertising Material.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October 2003 through December 2003]

Transmittal No.	Manual/Subject/Publication No.
	Guidelines for Advertising (Pre-enrollment) Material.
	Guidelines for Beneficiary Notification Materials.
	Model Annual Notice of Change.
	General Guidance on Dual Eligibility.
	Guideline for Outreach Program.
	Submission Requirements.
	Center for Medicare+Medicaid Services Review/Approval Process.
	Model Direct Mail Letter.
	Summary of Benefits for Medicare+Choice Organizations.
	Referral Programs.
	Allowable Actions for Medicare+Choice Organizations.
	Specific Guidance About the Use of Independent Insurance Agents.
	Answers to Frequently Asked Questions About Promotional Marketing of Multiple Lines of Business.
29	Introduction.
	Quality Assessment and Performance Improvement Program.
	Administration of the Quality Assessment and Performance Improvement Program.
	Medicare+Choice Organizations Using Physician Incentive Plans.
	Health Information System.
	Quality Assessment and Performance Improvement.
	Centers for Medicare & Medicaid Services Directed Special Projects.
	Reporting Time Frames.
	Communication Process.
	Quality Assessment and Performance Improvement.
	Process for Centers for Medicare & Medicaid Services Multi-Year Quality Assessment and Performance Improvement Program Project Approvals.
	Evaluation of Quality Assessment and Performance Improvement Program Projects.
	The Medicare+Choice Deeming Program.
	Terminology.
	General Rule.
	Obligations of Deemed Medicare & Medicaid Organizations.
	Oversight of Accrediting Organizations.
	Application Requirements.
	Reporting Requirements.
	Informal Hearing Procedures.
30	Reasonable Cost-Based Payments—General.
	Reasonable Cost Payments.
	Bill Processing.
	Principles of Payments.
	Budget and Enrollment Forecast.
	Interim Per Capita Rate.
	Interim Payment for Health Care Prepayment Plans.
	Electronic Transfer of Funds.
	Payment Report.
	Interim and Final Cost and Enrollment Report.
	Adjustment of Payments.
	Final Cost Report.
	Final Settlement Process for Medicare Health Care Prepayment Plans.
	Final Settlement Payment for Medicare Health Care Prepayment Plans.
	Recovery of Overpayment.
	Interest Charges for Medicare Overpayments/Underpayments.
	The Basic Rules.
	Definition of Final Determination.
	Rate of Interest.
	Accrual of Interest.
	Waiver of Interest.
	Rules Applicable to Partial Payments.
	Exception to Applicability.
	Nonallowable Interest Cost.
	Centers for Medicare & Medicaid Services General Payment Principles.
	Medicare Payments to Health Care Prepayment Plans.
	Prudent Buyer Principle.
	Allowable Costs.
	Costs Not Reimbursable Directly to the Health Care Prepayment Plans.
	Deductible and Coinsurance.
	Hospice Care Costs.
	Medicare as Secondary Payer.
31	Overview of Enrollment and Payment Process.
	Purpose of the Chapter.
	Medicare+Choice Organization Data Processing Responsibilities.
	Centers for Medicare & Medicaid Services Group Health Plan System.
	Enrollment/Disenrollment Requirements and Effective Dates.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October 2003 through December 2003]

Transmittal No.	Manual/Subject/Publication No.
	General. Enrollments. Disenrollments. Cost Based Medicare+Choice Organizations Only. Medicare+Choice Organizations Only. Cost Based Medicare+Choice Organizations Only—Employer Group Health Plan. Retroactive Enrollment. Medicare Membership Information. The Centers for Medicare & Medicaid Services Medicare+Choice. Organizations Only Interface. Submitting Medicare Membership Information to Centers for Medicare & Medicaid Services. Submission of Enrollment/Disenrollment Transaction Records. Submission of Correction Transaction Records. Health Insurance Claim Number. Transaction Type Code and the Prior Commercial Indicator. Transaction Type Codes. Prior Commercial Months Field. Special Status Beneficiaries—Medicare+Choice Organizations. Special Status Beneficiaries. Special Status—Hospice. Special Status—End-Stage Renal Disease. Special Status—Institutionalized. Special Status—Medicaid/Medical Assistance Only. Special Status—Working Aged. When to Submit ''Special Status'' Information (Medicare+Choice Organizations Only). Other Medicare Membership Information. Risk Adjustment Payment. Bonus Payment. Extra Payment in Recognition of Quality Congestive Heart Failure. Outpatient Care. Benefit Stabilization Fund. Electronic Submission of Membership Records to Centers for Medicare & Medicaid Services. Timeliness Requirements. Record Submission Schedule. Sending the Transaction File to Centers for Medicare & Medicaid Services. Electronic Data Transfer. Centers for Medicare & Medicaid Services Data Center Access. Data Processing Vendor. Receiving Medicare Membership Information From Centers for Medicare & Medicaid Services. General. Centers for Medicare & Medicaid Services Transaction Reply/Monthly Activity Report. Transaction Reply Field Information. Plan Payment Report. Demographic Report-Medicare+Choice Organizations Only. Medicare Fee-For-Service Bill Itemization and Summary Report. Monthly Membership Report. Bonus Payment Report. Working Aged Transaction Status Report. Retroactive Payment Adjustment Policy. Standard Operating Procedures for State and County Code Adjustments. Standard Operating Procedures for Processing of Institutional Adjustments. Standard Operating Procedures for Medicaid Retroactive Adjustments. Standard Operating Procedures for End-Stage Renal Disease Retroactive Adjustments. Processing of Working Aged Retroactive Adjustments. Standard Operating Procedures for Retroactive Adjustment Plan Elections. Centers for Medicare & Medicaid Services, Social Security Act. Administration, and Customer Service Center Disenrollments. General. Medicare Customer Service Center Disenrollments. Centers for Medicare & Medicaid Services Disenrollments. Coordination With the Medicare Fee-For-Services Program. Pro-Rate Deductible. Duplicate Payment Prevention by Cost-Based Medicare+Choice Organizations.
	One Time Notification (CMS Pub. 100–20)
06	Either Impact Multiple Manuals or Have No Manual Impact.
07	Common Working File Edits for Inserts for Therapeutic Shoes.
08	Revised X12N 4010A1 837 Professional Flat File.
09	Shared System Maintainer Hours for Resolution of Problems Detected During Health Insurance Portability and Accountability Act Transaction Release Testing.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October 2003 through December 2003]

Transmittal No.	Manual/Subject/Publication No.
10	Changes to the Laboratory National Coverage Determination Edit Software for January 1, 2004.
11	Calendar Year 2004 Participation Enrollment and Medicare Participating Physicians and Suppliers Directory Procedures.
12	New Waived Tests—January 1, 2004.
13	Program Integrity Management Reporting System for Part A—Phase 3.
14	Comprehensive Error Rate Testing Program—Requirements Update for Medicare Part A Provider Address File and Sample Claims Resolution File.
15	Changes in Transitional Outpatient Payment (TOP) for 2004.
16	Implementation of Correction to: Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2004 Rates; as Published in the October 6, 2003, **Federal Register** (68 FR 57732); and Extension of the Provision Equalizing the Urban and Rural Standardized Medicare Inpatient Hospital Payments as Required by Public Law 108–89.
17	Fee Schedule Update for 2004 for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies.
18	Change in Coding on Medicare Claims for Darbepoetin Alfa (Trade Name Aranesp) and Epoetin Alfa (Trade Name Epogen) of Treatment of Anemia in End-Stage Renal Disease Patients on Dialysis.
19	Change in Payment for Darbepoetin Alfa (Trade Name Aranesp) for Treatment of Anemia In End-Stage Renal Disease Patients on Dialysis.
20	2004 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services to Reasonable Charge Payment.
21	Indian Health Service (IHS) Hospital Payment Rates for Calendar Year 2003.
22	Clarification to Transmittal B–03–059 (CR 2755)—Minimum Number of Pricing Files That Must Be Maintained Online for Medicare Single Drug Pricer.
23	Payment for Ambulance Services Furnished by New Suppliers.
24	Instructions for Fiscal Intermediary Standard System (FISS) and Multi-Carrier System Healthcare Integrated General Ledger Accounting System Changes.
25	Clarification of Mammography Annual Screening Examination.
26	Coding and Billing Instructions for Velcade™ (Bortezomib).
27	Emergency Correction to the 2004 Healthcare Common Procedure Coding System File.
28	2004 Medicare Physician Fee Schedule Increase and Extension of the Annual Participation Enrollment Period.
29	Revised American National Standards Institute X12N 837 Professional Health Care Claim Companion Document.
30	Changes in Transitional Outpatient Payment (TOP) for 2004.
31	Emergency Revised 2004 Update of the Durable Medical Equipment Provider of Services and Clinical Laboratory Fee Schedules.
32	January 2004 Update of the Hospital Outpatient Prospective Payment System.
33	Change of Medicare Part A Plan Under Contract With the Blue Cross/Blue Shield Association and Change of Part B Carrier in the State of Rhode Island From Blue Cross/Blue Shield of Rhode Island to Arkansas Blue Cross/Blue Shield.
34	2004 Medicare Physician Fee Schedule Annual Changes.
35	Emergency Correction to the Fee Schedule Update for 2004 for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
36	Additional Modification Regarding Change Request 2963: Change in Coding on Medicare Claims for Darbepoetin Alfa (Trade Name Aranesp) and Epoetin Alfa (Trade Name Epogen) for Treatment of Anemia In End-Stage Renal Disease Patient on Dialysis.
37	Home Health Cost Reporting Processes.

ADDENDUM IV.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER

[October 2003 through December 2003]

Publication date	FR Vol. 68 page no.	CFR parts affected	File code	Title of regulation
October 6, 2003	57732	42 CFR Parts 412 and 413	CMS–1470–CN	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2004 Rates; Correction.
October 10, 2003	58756	42 CFR Parts 409, 411, 413, 440, 483, 488, and 489.	CMS–1469–CN	Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Correction.
October 24, 2003	61005		CMS–1253–N	Medicare Program; November 17, 2003, Meeting of the Practicing Physicians Advisory Council.
October 24, 2003	61004		CMS–4061–N	Medicare Program: Meeting of the Advisory Panel on Medicare Education-November 20, 2003.
October 24, 2003	61002		CMS–8018–N	Medicare Program; Part A Premium for 2004 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement.
October 24, 2003	60997		CMS–8017–N	Medicare Program; Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Beginning January 1, 2004.
October 24, 2003	60995		CMS–8016–N	Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 2004.
November 7, 2003	63398	42 CFR Parts 410 and 4419.	CMS–1471–FC	Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates.

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

[October 2003 through December 2003]

Publication date	FR Vol. 68 page no.	CFR parts affected	File code	Title of regulation
November 7, 2003	63692	42 CFR Parts 400, 405, and 426.	CMS–3063–F	Medicare Program: Review of National Coverage Determinations and Local Coverage Determinations.
November 7, 2003	63196	42 CFR Parts 410, and 414	CMS–1476–FC	Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2004.
November 19, 2003 ...	65346	42 CFR Part 426	OFR Correction	Medicare Program; Review of National Coverage Determinations and Local Coverage Determinations.
November 28, 2003 ...	66920	42 CFR Parts 412, 413, and 424.	CMS–1213–P	Medicare Program; Prospective Payment System for Inpatient Psychiatric Facilities.
November 28, 2003 ...	66721	42 CFR Part 408	CMS–6016–F	Medicare Program; Reduction in Medicare Part B Premiums as Additional Benefits Under Medicare+Choice Plans.
November 28, 2003 ...	66710	42 CFR Parts 403, 489, and 498.	CMS–1909–F	Medicare Program; Religious Nonmedical Health Care Institutions and Advance Directives.
December 5, 2003	67960	42 CFR Part 414	CMS–1232–FC	Medicare Program; Coverage and Payment of Ambulance Services; Inflation Update for CY 2004.
December 5, 2003	67955	42 CFR Parts 412, 413, 476, and 484.	CMS–3055–F	Medicare Program; Photocopying Reimbursement Methodology.
December 15, 2003 ...	69928	.....	CMS–4063–N	Medicare Program; Medicare Prescription Drug Discount Card.
December 15, 2003 ...	69840	42 CFR Parts 403 and 408.	CMS–4063–IFC	Medicare Program, Prescription Drug Discount Card.
December 15, 2003 ...	69707	.....	CMS 1370–N	Medicare Program; The Practicing Physicians Advisory Council's Request for Nominations.
December 24, 2003 ...	74792	42 CFR Parts 405 and 491.	CMS–1910–F	Medicare Program; Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions; and Establishment of a Quality Assessment and Performance Improvement Program.
December 24, 2003 ...	74622	.....	CMS–1247–N	Medicare Program; Town Hall Meeting in Calendar Year 2004 for Ambulance Condition Codes.
December 24, 2003 ...	74621	.....	CMS–1254–N	Medicare Program, Meeting of the Advisory Panel on Ambulatory Payment Classification Groups—February 18, 19, and 20, 2004.
December 24, 2003 ...	74613	.....	CMS–1226–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 2004.
December 24, 2003 ...	74607	.....	CMS–3119–PN	Medicare Program; Procedures for Maintaining Code Lists in the Negotiated National Coverage Determinations for Clinical Diagnostic Laboratory Services.
December 24, 2003 ...	74590	.....	CMS–9019–N	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July 2003 Through September 2003.
December 24, 2003 ...	74491	42 CFR Part 411.	CMS–18089–F4	Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Extension of Partial Delay of Effective Date.
December 31, 2003 ...	75442	42 CFR Parts 410 and 419.	CMS–1471–CN	Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates; Final Rule; Correction.

Addendum V—National Coverage Determinations [October 2003 Through December 2003]

A national coverage determination (NCD) is a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under Title XVIII of the Social Security Act, but does not include a determination of what code, if any, is assigned to a particular item or service covered under this title, or determination with respect to the amount of payment made for a particular item or service so covered. We include below all of the NCDs that 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 (or CIM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. Information on completed decisions as well as pending decisions has also been posted on the CMS Web site at *http://cms.hhs.gov/coverage.*

NATIONAL COVERAGE DETERMINATIONS

[October 2003 Through December 2003]

100–03	Title	Issue date	Effective date
20.9	Ventricular Assist Devices (VADs)	10/17/03	10/01/03
240.1	Lung Volume Reduction Surgery (LVRS)	11/04/03	10/01/03
210.3	Fecal Occult Blood Tests (FOBT)	12/19/03	01/01/04

MEDICARE CLAIMS PROCESSING MANUAL

100–04	Title	Issue date	Effective date
AB03–104	Changes to the Laboratory NCD Edit Software for 01/01/04	10/24/03	01/01/04

ONE-TIME NOTIFICATION

100–20	Title	Issue date	Effective date
AB03–127	2004 Annual Update for Clinical Lab Fee Schedule	11/07/03	01/01/04

Addendum VI—FDA-Approved Category B IDEs

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c), devices fall into one of three classes. To assist CMS under this categorization process, the FDA assigns one of two categories to each FDA-approved IDE. Category A refers to experimental IDEs, and Category B refers to nonexperimental IDEs. To obtain more information about the classes or categories, please refer to the **Federal Register** notice published on April 21, 1997 (62 FR 19328).

The following list includes all Category B IDEs approved by FDA during the 4th quarter, October through December 2003.

G020078
G020185
G020237
G030132
G030149
G030156
G030161
G030178
G030180
G030182
G030185
G030186
G030187
G030189
G030190
G030191
G030195
G030197
G030198
G030200
G030201
G030202
G030204
G030205
G030206
G030207
G030208
G030209
G030210
G030214
G030216
G030217
G030219
G030220
G030221
G030222
G030224
G030225
G030226
G030229
G030230
G030232
G030236
G030238
G030239
G030240
G030246
G030248
G030249
G030250
G030255
G030259
G939227

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
0938–0034	405.821
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

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'')
0938–0101	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	416.44, 418.100, 482.41, 483.270, 483.470
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
0938–0300	431.800
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	418.1–418.405
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
0938–0338	486.104, 486.106, 486.110
0938–0354	441.60
0938–0355	484.10–484.52
0938–0357	409.40–409.50, 410.36, 410.170, 411.4–411.15, 421.100, 424.22, 484.18, 489.21
0938–0358	412.20–412.30
0938–0359	412.40–412.52
0938–0360	405.2100–405.2184
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
0938–0386	405.2100–405.2171
0938–0391	488.18, 488.26, 488.28
0938–0426	476.104, 476.105, 476.116, 476.134
0938–0429	447.53
0938–0443	473.18, 473.34, 473.36, 473.42
0938–0444	1004.40, 1004.50, 1004.60, 1004.70
0938–0445	412.44, 412.46, 431.630, 456.654, 466.71, 466.73, 466.74, 466.78
0938–0447	405.2133
0938–0449	440.180, 441.300–441.310
0938–0454	424.20
0938–0456	412.105
0938–0463	413.20, 413.24
0938–0465	411.404, 411.406, 411.408
0938–0467	431.17, 431.306, 435.910, 435.920, 435.940–435.960
0938–0469	417.107, 417.478
0938–0470	417.143, 417.408, 417.800–417.840, 422.6
0938–0477	412.92
0938–0484	424.123
0938–0486	498.40–498.95
0938–0501	406.15
0938–0502	433.138
0938–0512	486.301–486.325
0938–0526	462.102, 462.103, 475.100, 475.106, 475.107
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
0938–0567	Part 498 Subparts D and E, and 20 CFR 404.933
0938–0573	412.230, 412.256

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
0938–0612	493.1–493.2001
0938–0618	433.68, 433.74, 447.272
0938–0653	493.1771, 493.1773, 493.1777
0938–0655	493.1840
0938–0657	405.2110, 405.2112
0938–0658	405.2110, 405.2112
0938–0667	482.12, 488.18, 489.20, 489.24
0938–0673	430.10
0938–0679	410.38
0938–0685	410.32, 410.71, 413.17, 424.57, 424.73, 424.80, 440.30, 484.12
0938–0686	493.551–493.557
0938–0688	486.301–486.325
0938–0690	488.4–488.9, 488.201
0938–0691	412.106
0938–0692	466.78, 489.20, 489.27
0938–0700	417.479, 417.500; 422.208, 422.210; 434.44, 434.67, 434.70; 1003.100, 1003.101, 1003.103, 1003.106
0938–0701	422.152
0938–0702	45 CFR 146.111, 146.115, 146.117, 146.150, 146.152, 146.160, 146.180
0938–0703	45 CFR 148.120, 148.124, 148.126, and 148.128
0938–0714	411.370–411.389
0938–0717	424.57
0938–0721	410.33
0938–0722	422.370–422.378
0938–0723	421.300–421.318
0938–0730	405.410, 405.430, 405.435, 405.440, 405.445, 405.455, 410.61, 415.110, 424.24
0938–0732	417.126, 417.470
0938–0734	45 CFR 5b
0938–0739	413.337, 413.343, 424.32, 483.20
0938–0742	422.300–422.312
0938–0749	424.57
0938–0753	422.000–422.700
0938–0754	441.152
0938–0758	413.20, 413.24
0938–0760	Part 484 Subpart E, 484.55
0938–0761	484.11, 484.20
0938–0763	422.1–422.10, 422.50–422.80, 422.100–422.132, 422.300–422.312, 422.400–422.404, 422.560–422.622
0938–0768	417.800–417.840
0938–0770	410.2
0938–0778	422.64, 422.111, 422.560–422.622
0938–0779	417.126, 417.470, 422.64, 422.210
0938–0781	411.404–411.406, 484.10
0938–0786	438.352, 438.360, 438.362, 438.364
0938–0787	406.28, 407.27
0938–0790	460.12, 460.22, 460.26, 460.30, 460.32, 460.52, 460.60, 460.70, 460.71, 460.72, 460.74, 460.80, 460.82, 460.98, 460.100, 460.102, 460.104, 460.106, 460.110, 460.112, 460.116, 460.118, 460.120, 460.122, 460.124, 460.132, 460.152, 460.154, 460.156, 460.160, 460.164, 460.168, 460.172, 460.190, 460.196, 460.200, 460.202, 460.204, 460.208, 460.210
0938–0792	491.3, 491.8, 491.11
0938–0798	413.24, 413.65, 419.42
0938–0802	419.43
0938–0810	482.45
0938–0819	45 CFR 146.121
0938–0823	420.410
0938–0824	440.10, 482.13
0938–0827	45 CFR 146.141
0938–0829	422.568
0938–0832	Part 489
0938–0833	483.350–483.376
0938–0841	431.636, 457.50, 457.60, 457.70, 457.340, 457.350, 457.431, 457.440, 457.525, 457.560, 457.570, 457.740, 457.750, 457.810, 457.940, 457.945, 457.965, 457.985, 457.1005, 457.1015, 457.1180
0938–0842	412, 413
0938–0846	411.1, 411.350–411.357, 424.22
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 Subparts F and G

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'')
0938–0883	45 CFR Parts 160 and 164
0938–0887	45 CFR 148.316, 148.318, 148.320
0938–0897	412.22, 412.533
0938–0907	412.30, 412.304, 413.65
0938–0913	414.707

[FR Doc. 04–6350 Filed 3–25–04; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2062–N]

RIN 0938–AJ74

Medicaid Program; Disproportionate Share Hospital Payments

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

ACTION: Notice.

SUMMARY: This notice announces the final Federal share disproportionate share hospital (DSH) allotments for Federal fiscal years (FFYs) 2001 and 2002, and the preliminary Federal share DSH allotments for FFYs 2003 and 2004. It also announces the final FFYs 2000, 2001, and 2002, and the preliminary FFYs 2003 and 2004, limitations on aggregate DSH payments that States may make to institutions for mental disease (IMDs) and other mental health facilities. In addition, this notice describes the methodologies for determining the amounts of States' FFY DSH allotments for FFY 2001 and thereafter. It also republishes the Federal share DSH allotments for FFYs 1998 through 2000, and the final FFYs 1998 and 1999 limitations on aggregate DSH payments that States may make to IMDs and other mental health facilities. Additionally, the notice specifies a format to be used by States when submitting their annual DSH report to ensure that Federal funds provided for DSH adjustments are made in accordance with the Medicaid statutory requirements.

FOR FURTHER INFORMATION CONTACT: Richard Strauss, (410) 786–2019 (DSH Allotments and IMD DSH Limits); Jonas Eberly, (410) 786–6232 (Annual DSH report for DSH payments).

SUPPLEMENTARY INFORMATION:

I. Background

A. DSH Allotments and IMD DSH Limits Published in October 8, 1998 ***Federal Register****.*

We published a notice in the October 8, 1998 **Federal Register** (63 FR 54142) that announced the Federal share DSH allotments for FFYs 1998 through 2002 and the IMD DSH limits for FFYs 1998 and 1999. The DSH allotments and IMD DSH limits published in that notice specified and were determined in accordance with the sections 1923(f) and (1923(h) of the Social Security Act (the Act), as amended by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted on August 5, 1997). The notice also reflected the FFY 1998 DSH allotment for one State, specified in accordance with section 601 of Pub. L. 105–78 (enacted on November 13, 1997).

Additional legislative changes relating to the amounts or methodologies for calculating the States' DSH allotments or IMD DSH limits have been made to the Act since the publication of the October 8, 1998 notice. In this section and in Section II of this notice, we describe each of the legislative changes related to the DSH allotments and IMD DSH limits for fiscal years that were not included in the October 8, 1998 notice.

B. DSH Allotments For FFYs 1998 Through 2000

Section 4721(a) of the BBA amended section 1923(f) of the Act to require that Federal Medicaid DSH expenditures be limited by the statutorily defined Federal share DSH allotments for FFYs 1998 through 2002 specified in a chart in section 1923(f)(2) of the Act. Section 601 of Pub. L. 105–78 amended the DSH allotment contained in this chart for the State of Minnesota for FFY 1998. The October 8, 1998 notice published the statutorily prescribed DSH allotments for all States for FFYs 1998 through 2002, in accordance with the amounts specified in the chart at section 1923(f)(2) of the Act, as established by the BBA and as amended by Pub. L. 105–78. Subsequent to the publication of the DSH allotments for these years, a number of legislative actions revised the DSH allotments specified in the chart at section 1923(f)(2) of the Act, for certain States. Specifically, sections 702, 703, and 704 of Pub. L. 105–277 (enacted on October 21, 1998) amended the FFY 1999 DSH allotments for Minnesota, New Mexico, and Wyoming, respectively, and section 601(a) of the Medicare, Medicaid, SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113, enacted on November 29, 1999) amended the FFYs 2000, 2001, and 2002 DSH allotments for the District of Columbia, Minnesota, New Mexico, and Wyoming.

C. DSH Allotments For FFYs 2001 and 2002

Section 701(a) of the Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554, enacted on December 21, 2000) added a new section 1923(f)(4) of the Act that provided for a ''Special Rule For Fiscal Years 2001 and 2002,'' under which States' DSH allotments for FFY 2001 and 2002 would be determined through the application of a methodology. The DSH allotments for these fiscal years, calculated under this methodology, supercede the DSH allotments for the years that are specified in the chart at section 1923(f)(2) of the Act. Under section 1923(f)(4) of the Act, the DSH allotments for FFY 2001 and FFY 2002 are determined by increasing the States' prior FFY DSH allotments by the Consumer Price Index for all Urban Consumers (CPI–U) for the prior fiscal year, subject to the limitation that an increase to a State's DSH allotment for a fiscal year could not result in the DSH allotment exceeding 12 percent of the State's total Federal medical assistance expenditures for the allotment year (referred to as the 12-percent limit). The application of this special rule for FFY 2001 and FFY 2002 had the effect of increasing States' DSH allotments for those years, as compared to the allotments they would have received under the chart at section 1923(f)(2) of the Act. In fact, the chart contained at section 1923(f)(2) of the Act would have provided for a decrease in States' DSH allotments over the fiscal years.

The BIPA also added a new section 1923(f)(5) of the Act, which established a ''Special Rule For Extremely Low DSH States.'' Under this rule, States with FFY 1999 DSH expenditures that were