

Publication date	FR Vol. 68 page No.	CFR parts affected	File code	Title of regulation
September 26, 2003 .....	55566	42 CFR Parts 410 and 414.	CMS-1476-CN .....	Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2004; Correction.
September 26, 2003 .....	55528	42 CFR Parts 483 and 488.	CMS-2131-F .....	Medicare and Medicaid Programs; Requirements for Paid Feeding Assistants in Long Term Care Facilities.
September 26, 2003 .....	55527	42 CFR Part 447 .....	CMS-2175-CN .....	Medicaid Program; Time Limitation on Price Recalculations and Recordkeeping Requirements Under the Drug Rebate Program; Correction
September 29, 2003 .....	55882	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.
September 30, 2003 .....	56478	.....	CMS-1233-N .....	Medicare Program; Hospice Wage Index for Fiscal Year 2004.
September 30, 2003 .....	56383	.....	CMS-1473-NC OFR Correction.	Medicare Program; Home Health Prospective Payment System Rate Update for FY 2004; Correction.

**Addendum V—National Coverage Determinations [July 2003 Through September 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 Decisions [July 2003 Through September 2003]**

**COVERAGE ISSUES MANUAL (CIM) (CMS PUB. 06)**

CIM section	Title	Issue date	Effective date
35-85.1 .....	Implantable Automatic .....	08/22/03 .....	10/01/03
	Defibrillators .....	09/22/03 (correction) .....	10/01/03

**PROGRAM MEMORANDUM (PM)**

PM No.	Title	Issue date	Effective date
AB-03-104 .....	Changes to the Laboratory NCD Edit Software For 10/03 .....	07/25/03	10/01/03

**FEDERAL REGISTER PUBLICATIONS**

Title	Publication date	Effective date
CMS-3062-N—Revised Process for Making National Coverage Determinations .....	09/26/03	N/A

**Addendum VI—Categorization of Food and Drug Administration-Allowed Investigational Device Exemptions**

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c), devices fall into one of three classes. Also, under the new categorization process to assist CMS, the Food and Drug Administration (FDA) assigns each device with an FDA-approved investigational device exemption (IDE) to one of two categories. Category A refers to experimental/investigational device exemptions, and Category B refers to nonexperimental/investigational device exemptions. To obtain more information about the classes or categories, please refer to the **Federal**

**Register** notice published on April 21, 1997 (62 FR 19328).

The following information presents the device number and category (A or B) for the second quarter, July through September 2003.

**INVESTIGATIONAL DEVICE EXEMPTION NUMBERS, 3RD QUARTER 2003**

IDE	Category
G020202 .....	B
G020312 .....	B
G020316 .....	B
G030027 .....	B
G030031 .....	B

**INVESTIGATIONAL DEVICE EXEMPTION NUMBERS, 3RD QUARTER 2003—Continued**

IDE	Category
G030040 .....	B
G030059 .....	B
G030066 .....	B
G030100 .....	B
G030121 .....	B
G030131 .....	B
G030133 .....	B
G030134 .....	B
G030135 .....	B
G030136 .....	B