Dated: November 5, 2013.

### Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–26822 Filed 11–7–13; 8:45 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9081-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July Through September 2013

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

**SUMMARY:** This quarterly notice lists CMS manual instructions, substantive

and interpretive regulations, and other **Federal Register** notices that were published from July through September 2013, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone Number
I CMS Manual Instructions	Ismael Torres	(410) 786-1864
II Regulation Documents Published in the Federal Register	Terri Plumb	(410) 786-4481
III CMS Rulings	Tiffany Lafferty	(410)786-7548
IV Medicare National Coverage Determinations	Wanda Belle	(410) 786-7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786-6877
VI Collections of Information	Mitch Bryman	(410) 786-5258
VII Medicare – Approved Carotid Stent Facilities	Lori Ashby	(410) 786-6322
VIII American College of Cardiology-National Cardiovascular Data Registry Sites	Marie Casey, BSN, MPH	(410) 786-7861
IX Medicare's Active Coverage-Related Guidance Documents	Lori Ashby	(410) 786-6322
X One-time Notices Regarding National Coverage Provisions	Lori Ashby	(410) 786-6322
XI National Oncologic Positron Emission Tomography Registry Sites	Stuart Caplan, RN, MAS	(410) 786-8564
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	Marie Casey, BSN, MPH	(410) 786-7861
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Marie Casey, BSN, MPH	(410) 786-7861
XIV Medicare-Approved Bariatric Surgery Facilities	Kate Tillman, RN, MAS	(410) 786-9252
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	Stuart Caplan, RN, MAS	(410) 786-8564
All Other Information	Annette Brewer	(410) 786-6580

## I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. 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) and Public Health Service Act. We also issue various manuals, memoranda, and

statements necessary to administer and oversee the programs efficiently.

Section 1871(c) 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**.

## II. Revised Format for the Quarterly Issuance Notices

While we are publishing the quarterly notice required by section 1871(c) of the Act, we will no longer republish duplicative information that is available to the public elsewhere. We believe this approach is in alignment with CMS' commitment to the general principles of the President's Executive Order 13563 released January 2011entitled "Improving Regulation and Regulatory Review," which promotes modifying and streamlining an agency's regulatory program to be more effective in achieving regulatory objectives. Section 6 of Executive Order 13563 requires agencies to identify regulations that may be "outmoded, ineffective, insufficient," or excessively burdensome, and to modify, streamline, expand or repeal

them in accordance with what has been learned." This approach is also in alignment with the President's Open Government and Transparency Initiative that establishes a system of transparency, public participation, and collaboration.

Therefore, this quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS Web site or the appropriate data registries that are used as our resources. This information is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the Web site list provides more timely access for beneficiaries, providers, and suppliers. We also believe the Web site offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and "real time" accessibility. In addition, many of the Web sites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the Web site. These listservs avoid the need to check the Web site, as notification of

updates is automatic and sent to the subscriber as they occur. If assessing a Web site proves to be difficult, the contact person listed can provide information.

## III. How To Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice 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 should view the manuals at *http:// www.cms.gov/manuals.* 

Authority: (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: November 1, 2013.

Kathleen Cantwell,

Director, Office of Strategic Operations and Regulatory Affairs.

BILLING CODE 4120-01-P

**Publication Dates for the Previous Four Quarterly Notices** We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: August 17, 2012 (77 FR 49799), November 9, 2013 (77 FR 67368), May 3, 2013 (78 FR 26038) and July 26, 2013 (78 FR 45233). For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or

# Addendum I: Medicare and Medicaid Manual Instructions (July through September 2013)

additional information.

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

## How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool. These wishing to subscribe to old versions of CMS manuals show

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: <u>http://cms.gov/manuals</u>.

# How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information 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. This information is available at <u>http://www.gpo.gov/libraries/</u>

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. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the Medicare National Coverage Determination publication titled Positron Emission Tomography (PET) Scans use CMS-Pub. 100-03, Transmittal No. 156.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. 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 manual. For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

Transmittal	Manual/Subject/Publication Number
Number	
	Medicare General Information (CMS-Pub. 100-01)
00	None
	Medicare Benefit Policy (CMS-Pub. 100-02)
00	None
N	Medicare National Coverage Determination (CMS-Pub. 100-03)
156	Positron Emission Tomography (PET) Scans
	Medicare Claims Processing (CMS-Pub. 100-04)
2737	National Coverage Determination (NCD) for Transcatheter Aortic Valve
	Replacement (TAVR) - Implementation of Mandatory Reporting of Clinical
	Trial Number
	Claims Processing Requirements for TAVR Services on Professional Claims
	Claims Processing Requirements for TAVR Services on Inpatient Hospital
	Claims
2738	Type of Service (TOS) Corrections 2013 Type of Service
2739	New Claim Adjustment Reason Code (CARC) to Identify a Reduction in
	Payment Due to Sequestration Competitive Bidding Durable Medical

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	Requirements for Billing Routine Costs of Clinical Trials
2759	Update to the Claims Processing Internet-Only Manual (IOM) to Add the National Uniform Billing Committee (NUBC) Payer Only Codes Payer Only Codes Utilized by Medicare
2760	Annual Clotting Factor Furnishing Fee Update 2014
2761	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
2762	Annual Clotting Factor Furnishing Fee Update 2014
2763	October 2013 Integrated Outpatient Code Editor (I/OCE) Specifications Version 14.3
2764	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
2765	Diagnosis Code Reporting on Religious Nonmedical Health Care Institution Claims
2766	Update to Hospice Payment Rates, Hospice Cap, Hospice Wage Index, Quality Reporting Program and the Hospice Pricer for FY 2014 Carrier Specific Reminements for Certain Specialties/Spervices
2767	Handling of Incomplete or Invalid Claims once the Phase 2 Ordering and Referring Edits are Implemented Handling Incomplete or Invalid Claims
2768	Update-Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) Fiscal Year (FY) 2014 Annual Update
2769	Inpatient Rehabilitation Facility (IRF) Annual Update: Prospective Payment System (PPS) Pricer Changes for FY 2014 Payment Provisions Linder IRF DPS Onality Reporting Program
2770	October 2013 Update of the Ambulatory Surgery Center (ASC) Payment System
2771	Introduction to Electronic Data Interchange (EDI) for Medicare Fee For
	Services Requirement for EDI Andience for this Chanter
	Scope of this Chapter
	Acronyms and Definitions General EDI
	Legislative Background
	The America Reinvestment and Recovery Act (ARRA) HIPA A and ARRA on Security and Privacy
	Administrative Simplification and Compliance Act (ASCA)
	EDI Enrollment and Registration (AKA Trading Partner Agreements) EDI Enrollment
	New Enrollments and Maintenance of Existing Enrollments Submitter
	Number Network Service Vendor (NSV) Acreement
	Electronic Remittance Advice (ERA) Enrollment Form
	Centers for Medicare and Medicaid Services – Medicare Fee-For-Service
	Transactions Used in the Acknowledgment of Receipt of Inbound Claims
	Change Request (CR) to Communicate Policy Medicare FFS Contractors (A/B MAC, DME MAC, CEDI)/Test Program
	and Annual Recertification Activities

	Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Single Payment Amounts
2740	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
2741	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
2742	Issued to a specific, audience not posted to Internet/Intranet due to Sensitivity of Instruction
2743	Coding Changes to Ultrasound Diagnostic Procedures for Transesophageal Doppler Monitoring
	I ranscophageal Doppler Used for Cardiac Monitoring Coding Requirements for Transcsophageal Doppler Cardiac Monitoring
	rumished Betore January 1, 2013 Coding Requirements for Transesophageal Doppler Cardiac Monitoring
	Furnished On or Atter January 1, 2013 Coding Requirements for Transesophageal Doppler Cardiac Monitoring Furnished On or After January 1, 2013
2744	Type of Service (TOS) Corrections 2013 Type of Service
2745	New Waived Tests
2746	Revision to the ViPS Medicare System Diagnosis Code Editing on the CMS-1500
2747	Additional Data Reporting Requirements for Hospice Claims
2748	Demand Billing of Hospice General Inpatient Level of Care
2749	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
2750	Positron Emission Tomography
	Local Coverage Determination for PET Using New, Proprietary
	Radiopharmaceuticals for their FDA-Approved Labeled Indications for Oncologic Imaging Only
2751	Issued to a specific, audience not posted to Internet/Intranet due to
2752	Issued to a specific, audience not posted to Internet/Intranet due to
2753	Confidentiality of Instruction Instructions for Downloadino the Medicare 71P Code File for January 2014
2754	October Update to the CY 2013 Medicare Physician Fee Schedule Database
2755	Additional States Requiring Payment Edits for DMEPOS Suppliers of Podditional States Requiring Payment Edits for DMEPOS Suppliers of
2756	resonance and commences of the second s
2757	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
2758	Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims-General Billing Requirements for Providers Billing Routine Costs of Clinical Trials
	Involving a Category A IDE Billing Requirements for Providers Billing Routine Costs of Clinical Trials
	Involving a Category B IDE
	Payment for Qualifying Clinical Trial Services Billing Requirements- General
	Controllar

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MAC, DME MACS and CEDI Audit Traits MAC, DME MACS and CEDI Audit Traits Security-Related Requirements for A/B MACs, and CEDI Arrangements With Clearinghouses and Billing Services Release of Medicare Data EDI Enrollment and EDI Claim Record Retention General EDI Outreach Activities MAC and DMF MACMAC Analysis of Internal Information	A /K M/AFS 30/AFFEN FOULKENDEDES
Security-Related Requirements for A/B MACs, and CEDI Arrangements With Clearinghouses and Billing Services Release of Medicare Data EDI Enrollment and EDI Claim Record Retention General EDI Outreach Activities MAC and DMF MACMAC Analysis of Internal Information	Key Shop and Optical Character Recognition
With Clearinghouses and Billing Services Release of Medicare Data EDI Enrollment and EDI Claim Record Retention General EDI Outreach Activities MAC and DMF MACMAC Analysis of Internal Information	Claim Key Shop and Optical Character Recognition (OCR)/Image
Release of Medicare Data EDI Enrollment and EDI Claim Record Retention General EDI Outreach Activities MAC and DMF MACMAC Analysis of Internal Information	Character Recognition (ICR) Mapping to ASC X12N Based Flat File
EDI Enrollment and EDI Claim Record Retention General EDI Outreach Activities MAC and DMF MACMAC Analysis of Internal Information	Key Shop and Image Processing
General EDI Outreach Activities MAC and DMF MACMAC Analysis of Internal Information	Institutional Implementation Guide and Direct Data Entry Edits
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Contact with New Frovincis Development of Information to Increase I lea of FDI	Processional Implementation Unite (TC) Euris National Council for Description Dana Descreen MCDDD) Implementation
Production and Distribution of Material to Market FDI User Guidelines	Remittance Advice and Standard Paner Remittances
Technical Assistance to EDI Trading Partners	Claim Key Shop and Optical Character Recognition (OCR)/Image Character
Training Content and Frequency	Recognition (ICR) Mapping to X12N Based Flat File
Prohibition Against Requiring Use of Proprietary Software or DDE Free	Key Shop and Image Processing Payments
Claim Submission Software	Payment Floor Requirement
Newsletters/Bulletin Board/Internet Publication of EDI Information	Alternative to EFT
Provider Guidelines for Choosing a Vendor	Electronic Funds Transfer (EFT)
Vendor Selection	Tri-Partite Bank Agreement
Provision of EDI User Guidelines	Health Care Provider Taxonomy Code (HPTC) Requirements
Provision and Maintenance of a Directory of Billing Software Vendors and	Payments
Clearinghouses	Payment Floor Requirement
Operating Kules for Electronic Transactions	Alternative to EFI
I elecommunications, Internet and Utal-up Media	Electronic Funds Transfer (EF1)
Terrelations and Transmission Protocols	In-ratue bank Agreement
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CONTINUE BUILD AND EMILAINAMICATION (CENT) - UNICAR DESCRIPTION	Notional function Drug Program (NCDDP) Claim
Claim Numbering	Realitements
Receipt Control and Balancing	Contractor Reporting of Operational and Workload (CROWD) Reporting
Acknowledgements	Common Edits and Enhancement Module (CEM) Reporting
Outbound File Compliance Check	Mandatory Electronic Submission of Medicare Claims
Common Edits and Enhancement Module (CEM) Code Sets Requirements	Small Providers and Full-Time Equivalent Employee Self-Assessments
Handling of Poorly Formed/Invalid Flat Files for a 277CA	Exceptions
Unique Specifications for DME	Unusual Circumstance" Warvers
CEDI Claim Numbering	Unusual Circumstance Waivers Subject to Provider Self-Assessment
Receipt Control and Balancing	Unusual Circumstance Waivers Subject to Evaluation and CMS Decision
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I initiation on Testing of Multiple Providers that Use the Same	Electronic and Daner Claims Imulications of Mandatony Electronic
Clearinghouse Billing Service or Vendor Software/FDI Receiver Testing	Executions and a per statute magneticute of relations of relations for the Submission Enforcement
by A/B MACs and CEDI	Fiscal Intermediary Shared System (FISS) Role in ASCA Enforcement
Changes in Provider's System or Vendor's Software and Use of Additional	MCS & VMS Roles in ASCA Enforcement
	Contractor Roles in ASCA Reviews
Delimiters	Application of Electronic Data Interchange Enrollment Information and
Nulls	ASCA Enforcement Review Decisions from Other Medicare Contractors to
Direct Data Entry (DDE) Screens	the Same Providers When They Bill the Railroad Medicare Carrier
PWK Background	Retirement Board Specially MAC (SMAC) Colorism of Devisions to be Cont Initial I attore for the DMC to Devis an

	ASCA Enforcement Review
	Subsequent Reversal of Decision that a Provider is Not Eligible to Submit
	Paper Claims by a Non-KK Medicare Contractor
	Number of ASCA Enforcement Kevrews to be Conducted by the KMC
	KMC Information in ASCA Enforcement Review Letters RMC Costs Related to Use of ASCA Review Information in SunerPES Files
2772	Issued to a specific, audience not posted to Internet/Intranet due to
	Confidentiality of Instruction
2773	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
2774	Issued to a specific audience not nosted to Internet/Intranet due to
	Confidentiality of Instruction
2775	October 2013 Update of the Hospital Outpatient Prospective Payment System (OPPS)
2776	Remittance Advice Remark and Claims Adjustment Reason Code and Medicare Remit Easy Print and PC Print Update
2777	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
2778	Fiscal Year (FY) 2014 Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) PPS Changes
2779	New Waived Tests
2780	January 2014 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
2781	Home Health Change of Care Notice (HHCCN), Form CMS-10280, Manual
2782	Advance Beneficiary Notice of Noncoverage (ABN). Form CMS-R-131
	Medicare Secondary Payer (CMS-Pub. 100-05)
95	Update the Common Working File (CWF) to not Allow Certain Diagnosis
	Codes on No-Fault Medicare Secondary Payer (MSP) Records
	Certain Diagnosis Codes not Allowed on No-rault Medicare Secondary Payer (MSP) Records
96	ECRS Batch File Layout Changes for ICD-10 Codes COBC Electronic
97	Prevent Electronic Correspondence Referral System (ECRS) Inquiries from
	being submitted with Insurance types other than A, J, K, R, S, or Blank Spaces CODC Plantacio Commenced and Defend Science (PCDS)
	Medicare Financial Management (CMS-Pub. 100-06)
223	Notice of New Interest Rate for Medicare Overpayments and Underpayments 4th or Notification for FY 2013
224	Overpayment (Section 50.3); Chapter 4, Debt Collection (Section 50 - 50.6 and 100.6.4) Related to Extended Repayment Schedules (ERS)
	Establishing an Extended Repayment Schedule (EKS) – (Iormerly known as an Extended Repayment Plan (ERP)
	ERS Required Documentation – Physician is a Sole Proprietor ERS Required Documentation – Provider is an Entity Other than a Sole
	Proprietor ERS Approval Process Sending the FRS Request to the Regional Office (RO)

	Monitoring an Approved Extended Repayment Schedule (ERS) and Reporting Requirements Requests From Terminated Providers or Debts that are Pending Referral to
	Department of 1 reasury Extended Repayment Schedule (ERS) Requests Received on a RAC Initiated Overpayment
225	Removal of POR and PSOR Instructions and the Glossary of Acronyms from the Internet Only Manual, Publication 100.06, Chapter 3
226	Recovery Audit Program Tracking Appeals and Reopenings Tracking Appeals and Reopenings
227	Removal of POR and PSOR Instructions and the Glossary of Acronyms from the Internet Only Manual, Publication 100.06, Chapter 3
	Bankruptcy Bankruptcy Forms Recoupment of the Accelerated Payment Reserved
	Medicare State Operations Manual (CMS-Pub. 100-07)
85	Federally Qualified Health Center (FQHC) Medicare participation
	Description Request to Participate
	Frocessing requests Effective Date
86	Revisions to State Operations Manual (SOM) Chapter 5
87	Revised Appendix A, Interpretive Guidelines for Hospitals, Condition of Particination: Discharee Planning
88	Revisions to State Operations Manual (SOM) Chapter 5
	Post-Survey Procedures
	Substantial Compliance
	Condition-Level, IJ Condition-Level. Non-IJ
	Full Survey after Complaint Survey with Condition-level Deficiencies,
	When Authorized by the RO
	Deemed Provider/ Supplier Retusal of Complaint Investigation Surveys Complaints Involving HIV-Infected Individuals (previously Section 5150)
	Investigating Complaints Involving ESRD Services Provided by Deemed
	Investigating Complaints Against ESRD Suppliers (previously Section
	5170) Hosnital Restraints/Seclusion Death Reporting and Investigation (meviously
	Section 5140)
	Background Responsibilities
	Process
	DUA Multi-Signature Addendum Release of Hospital Restraint/Seclusion
	Reports to Protection and Advocacy
	Medicare Program Integrity (CMS-Pub. 100-08)
474	DUA Multi-Signature Addendum Release of Hospital Restraint/Seclusion Death Reports to Protection and Advocacy
475	PIM Chapter 6 MR Guidelines 6.54-6.5.7 Update

	Review of Procedures Affecting the DRG Reserved for Future 1 ise
	Circumvention of PPS
	Referrals to the Quality Improvement Organization (QIO)
476	Issued to a specific, audience not posted to Internet/Intranet due to
477	Tracking Medicare Contractors' Postpayment Reviews
478	Issued to a specific, audience not posted to Internet/Intranet due to Sensitivity
017	
4/9	Enrollment Denials When an Existing or Delinquent Overpayment Exists
	Delinquent Overpayments Denial Example #6 – Delinquent Overpayments
480	Issued to a specific, audience not posted to Internet/Intranet due to
	Confidentiality of Instruction
481	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
482	Issued to a specific, audience not posted to Internet/Intranet due to
407	Description of the Dark A Critical Assess I familials (CATTA) To dault.
483	Keassignment to Part A Critical Access Hospitals (CAHS), Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs)
484	OMB Collection Number Requesting Additional Documentation During
	Prepayment and Postpayment Review
485	Program Safeguard Contractor (PSC) and Zone Program Integrity Contractor
	(ZPIC) Provider Notification
107	
480	Complex Medical Keview
487	I racking Medicare Contractors' Postpayment Reviews
488	Acceptable Submission Methods for Kesponses to ADKs
	PICURALE CONTRACTOR DEGICIALITY AND LEVENCE COMMUNICATIONS (CM371 ND, 100-07)
00	None B f All 1bbC EAb- FIJb- (CMS Bb-100 11)
	Medicare Programs of All-Inclusive Care for the Elderly (CMS-Fub, 100-11)
0 4	PACE Marketing Universities
	FACE Marketing Outdetitles Medicare End State Renal Disease Network Organizations (CMS Pub 100-14)
00	None
	Medicare Managed Care (CMS-Pub. 100-16)
108	This is the initial release of New Chapter 21, Compliance Program Guidelines
109	This is the initial release of New Chapter 21, Compliance Program Guidelines All Sections/Commliance Program Guidelines
110	Compliance Guidelines Program
011	Compliance Officer
111	Employer/Union-Sponsored Group Health Plans
112	Adding MSP Validity Indicator to the CWF to MBD Feed Working Aged
113	Aujusuitoit Chantar 12-Effect of Chance of Oumerchin Entire Chanter
117	Chapter 12-Effect of Change of Ownership Editie Chapter
114	Clidptet 7-Nisk Aufustulett Chanter 4 Banafits and Banafioium Protoctions
	Ollaptet 4-Detictits allu Deticticaly Florections Modicare Business Partners Systems Security (CMS-Pub. 100-17)
00	None

00	None
	One Time Notification (CMS-Pub. 100-20)
1252	Standardizing the Standard - Phase I
1253	Change in Creation Date for CMS Standard Edit/Audit/Reason Code Reports
1254	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
1255	Issued to a specific, audience not posted to Internet/Intranet due to Sensitivity of Instruction
1256	Issued to a specific, audience not posted to Internet/Intranet due to Sensitivity of Instruction
1257	Medicare Appeals System (MAS) Level 1 Implementation
1258	Redaction of Health Insurance Claim Numbers (HICNs) in Medicare Redetermination Notices (MRNs).
1259	HIPAA 5010 and D.0 2013 Annual Recertification
1260	Issued to a specific, audience not posted to Internet/Intranet due to Sensitivity of Instruction
1261	Fee for Service Beneficiary Data Streamlining (FFS BDS) Local Beneficiary File Analysis
1262	Informational Unsolicited Response (IUR) or Reject for Add-On Codes billed without respective Primary Codes
1263	Issued to a specific audience, not posted to Internet/Intranet due to
1264	Addition of the End Stage Renal Disease (ESRD) Facilities Located in the
	Pacific Rim to the ESRD Prospective Payment System (PPS)
1265	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
1266	Common Working File (CWF) Informational Unsolicited Response (IUR) and Reject for Hospital to Hospital Transfers.
1267	Issued to a specific, audience not posted to Internet/Intranet due to Sensitivity of Instruction
1268	Update to Post Acute Transfer Edit 7272 to Extend Home Health Agency CMS Certification Number (CCN) Range and Add Bypass
1269	Issued to a specific, audience not posted to Internet/Intranet due to Sensitivity of Instruction
1270	Issued to a specific, audience not posted to Internet/Intranet due to Sensitivity of Instruction
1271	Health Insurance Portability and Accountability Act (HIPAA) EDI Front End Updates for January 2014
1272	CEDI Removal of 4010A1 Jobs and Processes
1273	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
1274	The Supplemental Security Income (SSI)/Medicare Beneficiary Data for Fiscal Year 2011 for Innational Prosnective Payment System (IPPS) Hosonials
	Inpatient Rehabilitation Facilities (IRFs), and Long Term Care Hospitals (LTCH)
1275	Issued to a specific, audience not posted to Internet/Intranet due to Sensitivity

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title, the date the publication was issued, and the effective date of the decision An NCD is a determination by the Secretary for whether or not a	particular item or service is covered nationally under the Medicare Program	(title XVIII of the Act), but does not include a determination of the code, if	any, that is assigned to a particular covered item or service, or payment	determination for a particular covered item or service. The entries below	include information concerning completed decisions, as well as sections on	program and decision memoranda, which also announce decisions or, in	some cases, explain why it was not appropriate to issue an NCD.	Information on completed decisions as well as pending decisions has also	been posted on the CMS website. For the purposes of this quarterly notice,	we list only the specific updates that have occurred in the 3-month period.	This information is available at: www.cms.gov/medicare-coverage-	database/. For questions or additional information, contact Wanda Belle	(410-786-7491).	
title, th	particu	(title X	any, th	determ	include	prograi	some c	Inform	been po	we list	This in	databas	(410-78	

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G130160 G130164

G130157

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G130158

G130153 G120184 G130150

G130135

G120087 G130136 G130059 G130145 G130146

DE

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
PET for Cancers	NCD220.6.17 TR156	TR156	08/02/2013	03/07/2013
Ultrasound Diagnostic Procedures Coding	NCD220.5	TN2743	07/25/2013	01/01/2013

# Addendum V: FDA-Approved Category B Investigational Device **Exemptions (IDEs) (July through September2013)**

investigational device exemption (IDE) numbers that the FDA assigns. The updates to the Category B IDEs as of the ending date of the period covered number. For the purposes of this quarterly notice, we list only the specific by this notice and a contact person for questions or additional information. listings are organized according to the categories to which the devices are For questions or additional information, contact John Manlove (410-786assigned (that is, Category A or Category B), and identified by the IDE Addendum V includes listings of the FDA-approved 6877).

G130169 G110165 G130129 G130133 G130177

G130018 G130019 G130106

G120174

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

G130057

G130171 G130180 G130025 G130085 G130128 G130184

Device	Start Date
Optiflow Anastonomic Connector	07/05/2013
Ulthera System Model 8850-0001	07/10/2013
Valiant PS-IDE Stent Graft System With The Captivia Delivery System	07/10/2013
System 2100 Magnetic Resonance Guided Focused Ultrasound Externet System	07/19/2013
ALCON Capsulotomy Device	07/19/2013
MONARCH External Trigeminal Nerve Stimulation (STNS)	07/19/2013
Dako pd-I1 22c3 pharmdx kit	07/25/2013
Alcath LT Gold/ Alcath Flux Extra Gold Catheter	07/25/2013
G7 Ceramic-on-Ceramic Acetabular System	07/26/2013
Endostim Lower Esophageal Sphincter (LES) Stimulation	07/26/2013
System Ventana Anti-Total C-Met (SP44) Rabbit Monoclonal Primary	07/30/2013
Autoooty Assay MCI Risk Assignment Algorithm Companion Diagnostic (CDX)	07/30/21013
System	
Toray Satake Baloon Thermal Ablation System (TSB)	07/31/2013
Roche Cobas EGFR Mutation Test	08/01/2013
Celution One Device (ATHENA-II)	08/01/2013
Fast Visible Flourescent Injectate and Fast Measured Glomerular Filtration Rate Test	08/05/2013
Ventralight, Strattice	08/06/2013
Wearable Cardioverter Defibrillator (WCD)	08/07/2013
Pantheris System	08/08/2013
Autoric Automated Remote Ischemic Conditioning (RIC)	08/09/2013
Device, Control Ontit, Sunan Application Curl, Internation Applicator Cuff	
Prodigy System (Models 3799, 3855, 3730, and 3835)	08/15/2013
Med-El Maestro Cochlear Implant System	08/15/2013
Optical Renal Function Monitor - ORFM	08/15/2013
Gambro Prismaflex HF20	08/22/2013
Prostate Artery Embolization	08/23/2013
Accel Absorbable Hemostat	08/28/2013
Transmedics Organ Care System (OCS)-Lung	08/29/2013
Artefill	08/29/2013
Gammacore Device	08/30/2013
DLBCL Classification IHC Pharmdx Assay	08/30/2013
IRINOTECAN Drug-Eluting Bead (DEBIRI) Therapy for Patients with Liver Metastases Colorectal Cancer	08/30/2013
Propulse 1	08/30/2013
Aegea Vapor System	09/04/2013
Doxorubicin-Eluting LC Bead M1 For Patients With Hepatocellular Carcinoma	09/05/2013
SINOPSYS Lacrimal Stent	09/11/2013

G130159

G130162 G130167

G130161

G120283	Medtronic Active PC+S Implantable Pulse Generator & Sensing	09/13/2013
	Programmer	
G130187	COBAS KRAS Mutation Test	09/17/2013
G130174	Maestro Cochiear Implant	09/18/2013
G130189	Short-Term Use Wearable Defibrillator (SWD)	09/18/2013
G130193	Branched and Fenestrated Stent Graft Device for Treatment of	09/25/2013
	Thoracoabdominal Aortic Aneurysms	
G130198	Ulthera System	09/25/2013
G130140	Serenity System	09/25/2013
G130197	Implant, Dermal, for Aesthetic	09/26/2013
G130163	G-Cath EZ Suture Anchor Delivery Catheter	09/27/2013
G130138	Leadless Cardiac Pacemaker and Delivery Catheter Model	09/27/2013
	SIDLCP. Communications Link Model SILKINK	

# Addendum VI: Approval Numbers for Collections of Information (July through September 2013)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at <u>www.reginfo.gov/public/do/PRAMain</u>. For questions or additional information, contact Mitch Bryman (410-786-5258).

# Addendum VII: Medicare-Approved Carotid Stent Facilities, (July through September 2013)

http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage carotid artery stenting for high risk patients. On March 17, 2005, we issued optimal patient outcomes. We have created a list of minimum standards for only if performed in facilities that have been determined to be competent in facilities modeled in part on professional society statements on competency. carotid artery stenting with embolic protection is reasonable and necessary our decision memorandum on carotid artery stenting. We determined that All facilities must at least meet our standards in order to receive coverage performing the evaluation, procedure, and follow-up necessary to ensure for carotid artery stenting for high risk patients. For the purposes of this Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: For questions or additional information, contact Lori Ashby 410-786-6322)

Facility	Provider	FIICCHVE	olate
	Number	Date	
The following facility is a new listing for this quarter	ing for this qua	rter.	
Florida Hospital Wesley Chapel	100319	07/18/2013	FL
2600 Bruce B. Downs Boulevard			
Wesley Chapel, FL 33544		;	
in bold) were made	e to the faciliti	es listed below.	- N
	29001	04/27/2005	N
TO: Renown Regional Medical Center Facility			
1155 Mill Street Reno, NV 89502			
FROM: Medical College of Ohio	360048	04/27/2005	HO
TO: Medical University of Ohio at Toledo			
3000 Arlington Avenue Toledo, OH 43614			
FROM: MeritCare Hospital	35001	10/04/2005	Q
TO: Sanford Medical Center-Fargo, ND			
801 Broadway North Fargo, ND 58122			
FROM: St. Francis Hospital & Health Centers	15003	04/01/2005	Z
TO: Franciscan St. Francis Health -			
Indianapolis			
1600 Albany Street Beech Grove, IN 46107			
FROM: Lancaster Community Hospital	050204	08/22/2005	CA
<b>TO: Palmdale Regional Medical Center</b>			
43830 10th Street West Lancaster, CA 93534			
Rush University Medical Center	140119	04/20/2005	IL
1653 W Congress Parkway Chicago, IL 60612			
FROM: Gaston Memorial Hospital	340032	12/12/2005	NC
TO: CaroMont Regional Medical Center			
2525 Court Drive Gastonia, NC 28054			
FROM: St. Francis Hospital and Health Center	140118	05/11/2005	IL
TO: MetroSouth Medical Center			
12935 S. Gregory Street Blue Island, IL 60406			
FROM: North Shore Medical Center - FMC	10002900	02/06/2006	FL
Campus			
TO: FLORIDA MEDICAL CENTER – A			
CAMPUS OF NORTH SHORE			
5000 West Oakland Park Boulevard			
Ft. Lauderdale, FL 33313			
	E		

## Addendum VIII: American College of Cardiology's National Cardiovascular Data Registry Sites (July through September 2013) Addendum VIII includes a list of the American College of

Addendum VIII includes a list of the American College of Cardiology's National Cardiovascular Data Registry Sites. We cover implantable cardioverter defibrillators (ICDs) for certain clinical indications, as long as information about the procedures is reported to a central registry. Detailed descriptions of the covered indications are available in the NCD. In January 2005, CMS established the ICD

Abstraction Tool through the Quality Network Exchange (QNet) as a temporary data collection mechanism. On October 27, 2005, CMS announced that the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) ICD Registry satisfies the data reporting requirements in the NCD. Hospitals needed to transition to the ACC-NCDR ICD Registry by April 2006. Effective January 27, 2005, to obtain reimbursement, Medicare

Effective January 27, 2005, to obtain reimbursement, Medicare NCD policy requires that providers implanting ICDs for primary prevention clinical indications (that is, patients without a history of cardiac arrest or spontaneous arrhythmia) report data on each primary prevention ICD procedure. Details of the clinical indications that are covered by Medicare and their respective data reporting requirements are available in the Medicare NCD Manual, which is on the CMS website at http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filt erByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961

A provider can use either of two mechanisms to satisfy the data reporting requirement. Patients may be enrolled either in an Investigational Device Exemption trial studying ICDs as identified by the FDA or in the ACC-NCDR ICD registry. Therefore, for a beneficiary to receive a Medicare-covered ICD implantation for primary prevention, the beneficiary must receive the scan in a facility that participates in the ACC-NCDR ICD registry. The entire list of facilities that participate in the ACC-NCDR ICD registry can be found at <u>www.ncdr.com/webncdr/common</u>

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available by accessing our website and clicking on the link for the American College of Cardiology's National Cardiovascular Data Registry at: www.ncdr.com/webncdr/common. For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

Facility	City State	ate
The following facilities are new listings for this quarter.	s for this quarter.	
Children's Hospital Colorado	Aurora CO	<u> </u>
NorthCrest Medical Center	Springfield TN	-7
Augusta Health	Fisherville VA	ł
St. Joseph Regional Medical Center	Lewiston	
Midtown Surgery Center	New York NY	Y
Doctors Community Hospital	Lanham MD	D
Redlands Community Hospital	Redlands CA	4
St. Lucie Medical Center	Port St. Lucie   FL	
Fleming County Hospital	Flemingsburg KY	Y
St. Claire Regional Medical Center	Morehead KY	Y

Addendum IX: Active CMS Coverage-Related Guidance Documents (July through September 2013)

There are no CMS coverage-related guidance documents published in the July through September 2013 quarter. To obtain the document, visit the CMS coverage website at <u>http://www.cms.gov/medicare-coveragedatabase/details/medicare-coverage-document-details.aspx?MCDId=23</u>. For questions or additional information, contact Lori Ashby (410-786-6322).

## Addendum X: List of Special One-Time Notices Regarding National Coverage Provisions (July through September 2013) There were no special one-time notices regarding national rage provisions published in the July through September 2013 quarter

coverage provisions published in the July through September 2013 quarter. This information is available at <u>www.cms.hhs.gov/coverage</u>. For questions or additional information, contact Lori Ashby (410-786-6322).

## Addendum XI: National Oncologic PET Registry (NOPR) (July through September 2013)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no updates to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the July through September 2013 quarter. This information is available at <u>http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage</u>. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564)

Treatment Trial were also eligible to receive coverage. The following three Until May 17, 2007, facilities that participated in the National Emphysema that are eligible to receive coverage for lung volume reduction surgery.

(ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program

standards and requirements in effect on February 15, 2006).

For the purposes of this quarterly notice, we list only the specific updates to Medicare-approved facilities that meet CMS's minimum facility standards for bariatric surgery and have been certified by ACS and/or
ASMBS in the 3-month period. This information is available at
www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#1opOIPage. For questions or additional information, contact Kate Tillman, RN, MAS
(410-786-9252).

Facility	Provider Number	Date	State
		Approved	
The following facilities are new listings for this quarter.	ew listings for this qua	rter.	
UC Irvine Healthcare 101 The City Drive South Orange, CA 92868	050348	05/25/2013	CA
Kaiser Foundation Hospitals 3288 Moanalua Road Honolulu, HI 96819	NPI#120011	05/20/2013	HI
Bayshore Community Hospital 727 North Beers Street Holmdel, NJ 07733	1831197508	01/15/2013	R
Virtua Memorial Hospital 175 Madison Avenue Mt Holly, NJ 08060	1134125016	05/01/2013	R
West Houston Medical Center 12141 Richmond Avenue Houston, TX 77082	1275580938	04/19/2013	TX
Guthrie Weight Loss Center (Robert Packer Hospital) 1 Guthrie Square Sayre, PA 18840	1982816427	07/11/2013	PA
Sebastian River Medical Center U.S. 1 Sebastian, FL 32958	12386123	07/25/2013	FL
Southern Regional Medical Center 11 Upper Riverdale Road Riverdale, GA 30274	1831190958	05/21/2013	GA
Carle Foundation Hospital 611 West Park Street Urbana, IL 61801	1013071653	04/03/2013	IL
Monmouth Medical Center 300 2nd Avenue Long Branch, NJ 07740	1609983790	06/25/2013	R
Chesapeake Regional Medical Center 736 Battlefield Boulevard Chesapeake, VA 23320	1700896354	08/02/2013	VA
Covenant Healthcare 1447 North Harrison Road Saginaw, MI 48602	1588656946	08/02/2013	MI
Editorial changes (shown in bold) were made to the facilities listed below.	e made to the facilities	s listed below.	
FROM: Central Baptist Hospital/BPSC TO: Baptist Health Lexington 1740 Nicholasville Road Lexington, KY 40503	180103	11/17/2009	КҮ
Carolinas Medical Center Mercy 2001 Vail Avenue Charlotte, NC 28207	NPI#1376985135	04/01/2013	NC
Saint Mary's Regional Medical Center	29-0009	05/29/2012	

235 W 6th Street Reno, NV 89503 ACS; Krystal Flaniken - 775-770-3223			
Northside Hospital 1000 Johnson Ferry Road, NE Atlanta, GA 30342	1457396079	07/01/2013	GA
Lehigh Valley Hospital and Health Network Cedar Crest & I-78 P.O. Box 689 Allentown, PA 18105-1556 ACS; Suzanne Smith - (610) 402-2490	390133;1164400131	05/29/2013	PA
Grinnell Regional Medical Center 210 Fourth Avenue Grinnell, IA 50112	1669420501	10/20/2006	IA
Baystate Medical Center 759 Chestnut Street Springfield, MA 01199 ACS; Janet Adeletti - 413-794-3175	220077	03/13/2007	MA
Upstate Medical University 750 E. Adams Street, University Hospital Syracuse, NY 13210	NP1#1578554630	03/27/2012	λ
Steward Norwood Hospital 3 Edgewater Drive, Suite 102 Norwood, MA 02602 ACS; Dr. Adam Glasgow - (508) 668-4400	1952613416	06/27/2010	MA
St. Vincent Charity Hospital 2351 East 22nd Street Cleveland, OH 44115-3111	# UH3600371, NPI 1710951801	01/20/2006	НО
Huntington Hospital 270 Park Avenue Huntington, NY 11743	1508845322	10/04/2012	ΝΥ
Princeton HealthCare System - University Medical Center of Princeton at Plainsboro One Plainsboro Road Plainsboro, NJ 08536	310010	02/24/2006	ſN
FROM: Middle Tennessee Medical Center TO: Saint Thomas Rutherford Hospital 1700 Medical Center Parkway Murfreesboro, TN 37129	44-0053	11/17/2009	ZI
Pikeville Medical Center 911 S Bypass Road Pikeville, KY 41501	1285621623; <b>180044</b>	01/25/2013	КҮ
Ine following facilities are removed as of this quarter.   DeTar Hospital 45-0147 03   506 E San Antonio Victoria, TX 77902 45-0147 03	emoved as of this quar 45-0147	ter. 03/07/2012	TX
Robert Wood Johnson University Hospital Hamilton 1 Hamilton Health Place Hamilton, NJ 08690	310110	02/12/2010	ſN
Minimally Invasive Surgery Hospital 11217 Lakeview Avenue Lenexa, KS 66219	661021	06/25/2007	KS

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the July through September 2013 quarter.

This information is available on our website at <u>www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOtPage</u>. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).