specifically questioning the government's calculation of the public burden.

Comment: The respondent commented that the extension of the information collection would violate the fundamental purposes of the Paperwork Reduction Act because of the burden it puts on the entity submitting the information and the agency collecting the information. The respondent opposes granting the extension of the information collection requirement.

Response: In accordance with the Paperwork Act (PRA), agencies can request OMB approval of an existing information collection. The PRA requires that agencies use the Federal Register notice and comment process to extend the OMB's approval every three years. This extension to a previously approved information collection pertains to the provision at GSAR 552.211–77, Packing List, which requires contractors to include a packing list that verifies the placement of the order and identifies the items shipped, a normal commercial practice. In addition to the information contractors would normally include on packing lists, the government requires identification of the name of the government credit cardholder, telephone number and the term "Credit Card" on the packing list in supply contracts.

The purpose of the information collection is to facilitate administration of government credit card purchases. Often the government credit cardholder is different from the consignee receiving shipment of the supplies. Providing the additional information ensures the recipient of the packing list, the consignee, notifies the government credit cardholder that the shipment has been received. Once the notification of successful shipment has been received, the cardholder can then authorize payment. This feedback is essential for the cardholder to reconcile his/her monthly statements. This is especially important if the micropurchase threshold is raised to support a contingency operation declaration under FAR subpart 18.2. Not granting this extension would increase costs to the Government during the reconciliation process and may delay payments to contractors for shipments of supplies received.

Comment: The respondent challenged the estimates used by the agency to calculate the public burden, stating that the burden was insufficient and inadequate to reflect the actual total burden. Specifically, the respondent noted that it was unclear as to how the estimated 4,000 information collection

respondents were derived and the estimated number of packing lists in a given year. Therefore, the respondent stated the agency should utilize actual data from the last fiscal year or an estimate of the last three to five fiscal years, reassess the estimated burden, and revise it upwards to be more accurate as was done in FAR Case 2007-006. The respondent also found the "less than one minute per response estimate" to be unrealistically low stating the burden requires creating the packing list.

Response: Serious consideration is given during the open comment period to all comments received and adjustments are made to the paperwork burden estimate when necessary. The burden is prepared taking into consideration the necessary criteria in OMB guidance for estimating the paperwork burden put on the entity submitting the information. Consideration is given to an entity in reviewing the instruction; using technology to collect, process and disclose information; adjusting existing practices to comply with requirements; searching data sources; completing and reviewing the response and transmitting or disclosing information. Estimated burden hours only include those actions that exceed those a company would take in the normal course of business.

Careful consideration went into assessing the burden for this collection. Packing lists accompanying shipments of supplies are customary in the normal course of business, including the information listed in paragraph (a) of clause 552.211-77. The public burden is limited to the annotation on the packing list the name and telephone number of the government credit cardholder and

the phrase "Credit Card."

While there is no centralized database for the collection of the packing lists in a fiscal year, the agency found the respondent's suggestion to use actual data reasonable to calculate the public burden. The annual reporting burden was revised, using actual data from the government-wide Federal Procurement Data System (FPDS) for Fiscal Year (FY) 2012. Two types of actions were analyzed: GSA actions for supplies where the method of payment was made by government credit card; and, non-GSA actions for supplies where both payment was by a government credit card and a GSA indefinite delivery contract for supplies was referenced. Average costs were derived in order for the government to estimate the number of packing slips per order. Thus, an adjustment is made to the annual reporting burden after review of the methodology for computing the number

of respondents and packing lists in a given year and the estimated hours per response.

The government agreed with the respondent that the time per response did not allow for review and transmission of the government credit cardholder's name and telephone number and the phrase "Credit Card" into its packing list system and adjusted the burden accordingly.

Members of the public may submit comments for further consideration and are encouraged to provide data to support their request for an adjustment.

#### C. Annual Reporting Burdens

Respondents: 9,919. Responses per Respondent: 13. Hours per Response: .05. Total Burden Hours: 6447.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417, telephone (202) 501-4755. Please cite OMB Control No. 3090-0246, Packing List Clause, in all correspondence.

Dated: February 8, 2013.

#### Joseph A Neurauter,

Director, Office of Acquisition Policy, Senior Procurement Executive.

[FR Doc. 2013-03558 Filed 2-14-13; 8:45 am] BILLING CODE 6820-61-P

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid** Services

[CMS-9076-N]

Medicare and Medicaid Programs; **Quarterly Listing of Program** Issuances—October Through December 2012

**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 October through December 2012, 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 No.
I CMS Manual Instructions	Ismael Torres	(410) 786–1864
II Regulation Documents Published in the <b>Federal Register</b> III CMS Rulings	Terri Plumb Tiffany Lafferty	(410) 786–4481 (410) 786–7548
IV Medicare National Coverage Determinations	Wanda BelleJohn Manlove	(410) 786–7491 (410) 786–6877
VI Collections of Information	Mitch Bryman Sarah J. McClain	(410) 786–5258 (410) 786–2294
VIII American College of Cardiology-National Cardiovascular Data Registry Sites IX Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin, MS Lori Ashby	(410) 786–7205 (410) 786–6322
X One-time Notices Regarding National Coverage Provisions	Lori Ashby	(410) 786–6322
XI National Oncologic Positron Emission Tomography Registry SitesXII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	Stuart Caplan, RN, MAS JoAnna Baldwin, MS	(410) 786–8564 (410) 786–7205
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	JoAnna Baldwin, MS Kate Tillman, RN, MAS	(410) 786–7205 (410) 786–9252
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials All Other Information	Stuart Caplan, RN, MAS	(410) 786–8564 (410) 786–6580

#### I. Background

Among other things, 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 2011 entitled "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: February 8, 2013.

#### Kathleen Cantwell,

Director, Office of Strategic Operations and Regulatory Affairs.

#### **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: February 21, 2012 (77 FR 9931), May 18, 2012 (77 FR 29648), August 17, 2012 (77 FR 49799) and November 9, 2012 (77 FR 67368). 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 additional information.

### Addendum I: Medicare and Medicaid Manual Instructions (October through December 2012)

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.

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: http://cms.gov/manuals.

#### 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 <a href="http://www.gpo.gov/libraries/">http://www.gpo.gov/libraries/</a>

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 Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) use CMS-Pub. 100-03, Transmittal No. 149.

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 <a href="https://www.cms.gov/Manuals">www.cms.gov/Manuals</a>.

Transmittal Number	Manual/Subject/Publication Number				
	Medicare General Information (CMS-Pub. 100-01)				
80	Manual Updates to Clarify SNF Claims Processing Hospital Insurance				
	(Part A) for Inpatient Hospital, Hospice, Home Health and Skilled Nursing				
	Facility (SNF) Services - A Brief Description				
	Starting a Benefit Period				
	Ending a Benefit Period				
	Definition of Inpatient for Ending a Benefit Period				
81	Update to Medicare Deductible, Coinsurance and Premium Rates for 2013				
	Basis for Determining the Part A Coinsurance Amounts				
	Part B Annual Deductible				
	Part B Premium				
	Medicare Benefit Policy (CMS-Pub. 100-02)				
160	Effect of Beneficiary Agreements Not to Use Medicare Coverage and When				
	Payment May be Made to a Beneficiary for Service of an Opt-Out				
	Physician/Practitioner				
	Requirements of a Private Contract				
	Requirements of the Opt-Out Affidavit				

Failure to Maintain Opt-Out Actions to Take in Cases of Failure to Maintain Opt-Out Physician/Practitioner Who Has Never Enrolled in Medicare Excluded Physicians and Practitioners Relationship between Opt-Out and Medicare Participation Agreements Participating Physicians and Practitioners Maintaining Information on Opt-Out Physicians Informing Medicare Managed Care Plans of the Identity of the Opt-Out Physicians or Practitioners Informing the National Supplier Clearinghouse (NSC) of the Identity of the Opt-Out Physicians or Practitioners System Identification Emergency and Urgent Care Situations Denial of Payment to Employers of Opt-Out Physicians and Practitioners Denial of Payment to Beneficiaries and Others Payment for Medically Necessary Services Ordered or Prescribed by an Opt- out Physician or Practitioner Renewal of Opt-Out Early Termination of Opt-Out Application to the Medicare Advantage Program Claims Denial Notices to Opt-Out Physicians and Practitioners Claims Denial Notices to Beneficiaries  161 Manual Updates to Clarify SNF Claims Processing Three-Day Prior Hospitalization General Daily Skilled Services Defined Definition of Durable Medical Equipment  162 Issued to a specific audience, not posted to Internet/Intranet/ due to Sensitivity of Instruction  163 Implementing the Claims-Based Data Collection Requirement for Outpatient Therapy Services Section 3005(g) of the Middle Class Tax Relief and Jobs Creation Act (MCTRJCA) of 2012  Expansion of Medicare Telehealth Services Medicare National Coverage Determination (CMS-Pub. 100-03)
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	Use of Absolute Words in LCDs
	LCD Requirements That Alternative Item or Service Be Tried First
	LCD Development Process
	Evidence Supporting LCDs
	The Comment Period
	CAC Structure and Process
	LCD Reconsideration Process
	R Challenge of an LCD etired LCDs and The LCD Record
	The Challenge
	Subpoenas
	Dismissals for Cause
	Effectuating the Decision
	Evaluation of Local Coverage Determination (LCD) Topics for National
	Coverage Determination (NCD) Consideration
444	Retirement of the Program Integrity Management Reporting (PIMR) System
Medicare C	Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)
00	None
M	ledicare Quality Improvement Organization (CMS-Pub. 100-10)
00	None
Medicar	re End Stage Renal Disease Network Organizations (CMS Pub 100-14)
00	None
L	

Medicare Managed Care (CMS-Pub. 100-16)			
00	None		
Medicare Business Partners Systems Security (CMS-Pub. 100-17)			
00	None		
	Demonstrations (CMS-Pub. 100-19)		
85	Revisions to the Method of Cost Settlement for Inpatient Services for Rural		
	Hospitals Participating Under Demonstration Authorized by Section 410A of		
	the Medicare Modernization Act. Sections 3123 and 10313 of the Affordable		
	Care Act authorizes an expansion of the demonstration and an extension for		
	an additional 5-year period. This CR makes revisions to CR 7505, which		
	gives instructions for the additional 5-year period		
86	Implementation of the Hospital Value-Based Purchasing Program and		
Hospital Readmission Reduction Program for the Rural Community H			
	Demonstration		
1120	One Time Notification (CMS-Pub. 100-20)		
1128	Recompiling of Application Data Structure Descriptors		
1129	Elimination of the Fiscal Intermediary Shared System (FISS) Off Quarter		
1120	User Releases		
1130	Implementation of the Redesigned MSN		
1131	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity		
1132	of Instruction  Issued to a specific, audience not posted to Internet/Intranet due to		
1132	Confidentiality of Instruction		
1133	New Informational Unsolicited Response (IUR) Process to Identify		
1133	Previously Paid Claims for Services Furnished to Medicare Beneficiaries		
	Classified as "Unlawfully Present" in the United States		
1134	New Informational Unsolicited Response (IUR) Process to Identify		
1134	Previously Paid Claims for Services Furnished to Incarcerated Medicare		
1135	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity		
	of Instruction		
1136	National Correct Coding Initiative (NCCI) Associated Modifier Changes		
	(Additions)		
1137	PWK System Modifications for Processing Days		
1138	Adding Bankruptcy Status Field to the Recovery Audit Contractor Daily and		
	Weekly Reports		
1139	Durable Medical Equipment (DME) National Competitive Bidding (NCB):		
	National Mail Order (NMO) Program Implementation for Diabetic Supplies		
1140	Termination of the Common Working File ELGB Provider Query		
1141	The Supplemental Security Income (SSI)/Medicare Beneficiary Data for		
	Fiscal Year 2010 for Inpatient Prospective Payment System (IPPS)		
	Hospitals, Inpatient Rehabilitation Facilities (IRFs), and Long Term Care		
	Hospitals (LTCHs)		
1142	Editing for Duplicate Payment of Nonphysician Outpatient Services Provided		
	During an Inpatient Hospital Admission		
1143	Issued to a specific, audience not posted to Internet/Intranet due to		
	Confidentiality of Instruction		
1144	MCS/TACs System Edits		
1145	Health Insurance Portability and Accountability Act (HIPAA) EDI Front End		
	Updates for April 2013		

1146	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1147	Implementation of the Revised Health Insurance Claim Form CMS-1500 (02/12) (Analysis Only)
1148	Fee for Service Beneficiary Data Streamlining (FFS BDS)
1149	Multiple Procedure Payment Reduction (MPPR) on the Technical Component (TC) of Diagnostic Cardiovascular and Ophthalmology Procedures
1150	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
1151	Use of Q6 Modifier for Locum Tenens by Providing Performing Provider NPI - Analysis only CR
1152	New Screens and Processes for ICD-9/ICD-10, ICD-10/ICD-9 Diagnosis and Procedure Codes Conversions for Medicare Secondary (MSP) Claims Using the General Equivalence Mappings (GEMS) 2013 Table in CWF
1153	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
1154	Issued to a specific, audience not posted to Internet/Intranet due to Sensitivity of Instruction
1155	Issued to a specific, audience not posted to Internet/Intranet due to Sensitivity of Instruction
1156	Addition of New Common Working File (CWF) Medicare Secondary Payer (MSP) Utilization Edit Codes for CWF to Send the Shared Systems When the Diagnosis Code on the Claim is Considered a Match with the Family of DX Codes in CWF for Non-Group Health Plan (NGHP) MSP Claims
1157	Standardizing the Standard - Phase I

# Addendum II: Regulation Documents Published in the Federal Register (October through December 2012)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register**, contact GPO at <a href="https://www.gpo.gov/fdsys">www.gpo.gov/fdsys</a>. 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 available as an online database through <u>GPO Access</u>. 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) through the present date and can be accessed at <a href="http://www.gpoaccess.gov/fr/index.html">http://www.gpoaccess.gov/fr/index.html</a>. The following website <a href="http://www.archives.gov/federal-register/">http://www.archives.gov/federal-register/</a> provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our website at: <a href="http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-4Q12QPU.pdf">http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-4Q12QPU.pdf</a>

For questions or additional information, contact Terri Plumb (410-786-4481).

#### Addendum III: CMS Rulings

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at <a href="http://www.cms.gov/Rulings/CMSR/list.asp#TopOfPage">http://www.cms.gov/Rulings/CMSR/list.asp#TopOfPage</a>. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

### Addendum IV: Medicare National Coverage Determinations (October through December 2012)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the 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 on our website at: www.cms.gov/medicarecoverage-database/. For questions or additional information, contact Wanda Belle (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Update to Pub. 100-08, Program Integrity Manual, Chapter 13	n/a	R443PI	12/14/2012	01/15/2013
Transcutaneous Electrical Nerve	NCD	R149NCD	11/30/2012	06/08/2012

Stimulation (TENS) Chronic Low Back Pain	160.27			
Transcatheter Aortic Valve Replacement (TAVR) Bariatric Surgery for the Treatment for the Treatment of Morbid Obesity National Coverage Determination, Addition of Laparoscopic Sleeve Gastrostomy (LSG)	NCD 100.1	R148NCD	11/09/2012	06/27/2012

### Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (October through December 2012)

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

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 investigational device exemption (IDE). Category A refers to experimental IDEs, and Category B refers to non-experimental IDEs. To obtain more information about the classes or categories, please refer to the notice published in the April 21, 1997 **Federal Register** (62 FR 19328).

IDE	Device	Start Date
BB15207	Magnetic-Activated Cell Sorter (CliniMACS, Miltenyi)	10/09/12
G100294	Glucose Monitoring System	11/08/12
G110104	Medtronic Activa SC Implantable Neurostimulation System	11/20/12
G110127	Carotid Stent	12/13/12
G110139	Revive SE Thrombectomy Device	11/30/12
G110190	Tandem Heart System	11/08/12
G110228	Zilver Vena Venous Stent	12/13/12
G110238	Cobalt Stage One Acrylic Spacer Cement	10/03/12
G110246	Surgimend PRS Fetal Bovine	11/28/12
G120002	Absorb Bioresorbable Vascular Scaffold	12/14/12
G120090	Libra Implantable Deep Brain Stimulation System for Adjunctive	10/05/12
	Treatment for Treatment Resistance Major Depression	
G120091	Tecnis Multifocal Low-Add 1-Piece Intraocular Lenses (IOLS),	10/17/12

	Modelss ZKB00 and ZLB00	
G120110	Prostate Artery Embolization Device	10/11/12
G120111	Microvention Flow Re-Directional Endoluminal Device (FRED)	11/15/12
G120121	Randomized, Double-Blinded, Sham Controlled Trial of	10/09/12
	Repetitive Transcranial Magnetic Stimulation in Depressed	
G120156	Activa Parkinsons Control Therapy	11/07/12
G120159	Impella RP System	11/08/12
G120168	ESVS Mesh	11/06/12
G120192	IBV Valve System	11/02/12
G120204	Venaseal Sapheon Closure System	12/13/12
G120207	Cool Path Ablation Catheter	11/20/12
G120208	Acrysof IQ Restor +8 Multifocal Intraocular Lens	11/13/12
G120211	Evolution Esophageal Stent System-Fully Covered	10/17/12
G120212	Model 106 With Automatic Stimulation	10/18/12
G120213	Attain Performa Quadripolar Lead	10/19/12
G120214	Nucleus 24 Auditory Brainstem Implant	10/19/12
G120221	Belt Applicator for Non-Invasive Fat Reduction In The Outter	12/28/12
	Thigh	
G120222	Med IC Pharmdx Kit	10/26/12
G120223	Solidalrity Oral Endotracheal Tube Stabilizer	10/26/12
G120226	EENTOVIS MR Conditional System	12/21/12
G120233	Small-Molecule Functional Kinase Inhibitor Screen	11/09/12
G120234	Nucleus CI422	11/14/12
G120237	SIR-Spheres Microspheres	11/14/12
G120238	NRAS Mutation Clinical Trial Assay (CTA)	11/14/12
G120245	Tissuglu	11/20/12
G120246	Exablate Transcranial MRGFUS Thalmotomy Treatment	11/21/12
G120247	Reset-VT	11/20/12
G120249	Durolane 4.5 ML	11/21/12
G120260	Activated HH Pathway Gene Expression Test iD	12/05/12
G120261	NASH/DX Solesta	12/04/12
G120262	Enlite Glucose Sensor	12/05/12
G120265	Lenstec Tetraflex HD Posterior Chamber Intraocular Lens (IOL)	12/07/12
G120267	Zenith T-Branch	12/12/12
G120271	VYSIS CLL CDX FISH KIT (List Number: 07N67-020)	12/19/12
G120273	Sebacia's Acne Treatment System (SATS)	12/20/12
G120277	Heartmate II Left Ventricular Assist System	12/20/12
	· · · · · · · · · · · · · · · · · · ·	12/19/12

### Addendum VI: Approval Numbers for Collections of Information (October through December 2012)

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

www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact Mitch Bryman (410-786-5258).

## Addendum VII: Medicare-Approved Carotid Stent Facilities, (October through December 2012)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. 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 on our website at:

http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage For questions or additional information, contact Sarah J. McClain (410-786-2294).

Facility	Provider Number	Effective Date	State		
The following facilities are new list	ings for this qu	arter.			
Ephraim McDowell Regional Medical Center	180048	09/28/2012	KY		
217 South Third Street Danville, KY 40422					
UC San Diego Sulpizio Cardiovascular Center	050025	10/24/2005	CA		
9434 Medical Center Drive La Jolla, CA 92037					
Monroe Clinic	520028	10/12/2012	WI		
515 22nd Avenue Monroe, WI 53566					
Northside Hospital Forsyth	1376574277	10/31/2012	GA		
1200 Northside Forsyth Drive Cumming, GA 30041					
Spring Valley Hospital Medical Center	1346230323	11/16/2012	NV		
5400 South Rainbow Boulevard					
Las Vegas, NV 89118					
Marian Regional Medical Center	050107	12/28/2012	CA		
1400 East Church Street Santa Maria, CA 93454					
Editorial changes (shown in bold) were made to the facilities listed below.					
FROM: UCSD La Jolla - John M. and Sally B.	050025	10/24/2005	CA		
Thornton Hospital					
TO: UC San Diego Thornton Hospital					
9300 Campus Point Drive La Jolla, CA 92037					

Facility	Provider Number	Effective Date	State
FROM: University of California San Diego Medical Center TO: UC San Diego Medical Center 200 W. Arbor Drive San Diego, CA 92103	050025	10/24/2005	CA
FROM: St. Joseph's Healthcare TO: Henry Ford Macomb Hospitals 15855 Nineteen Mile Road Clinton Township, MI 48038	230047	11/28/2005	MI

#### **Addendum VIII:**

### American College of Cardiology's National Cardiovascular Data Registry Sites (October through December 2012)

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 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 <a href="http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961">http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961</a>

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 <a href="https://www.ncdr.com/webncdr/common">www.ncdr.com/webncdr/common</a>

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: <a href="www.ncdr.com/webncdr/common">www.ncdr.com/webncdr/common</a>. For questions or additional information, contact Joanna Baldwin, MS (410-786-7205).

Facility	City	State
The following facilities are ne	w listings for this quarter.	
Sacred Heart on the Emerald Coast	Miramar Beach	FL
Kennewick General Hospital	Kennewick	WA
Einstein Medical Center Montgomery	East Norriton	PA
Gulf Pointe Surgery Center	Port Charlotte	FL
The following facilities are ter	minated as of this quarter.	
St. Vincent Dunn Hospital	Bedford	IN
Carondelet Heart and Vascular Institute	Tucson	AZ
Northern Louisiana Medical Center	Ruston	LA
Dyersburg Regional Medical Center	Dyersburg	TN

### Addendum IX: Active CMS Coverage-Related Guidance Documents (October through December 2012)

There was one CMS coverage-related guidance documents published in the October through December 2012 quarter. To obtain the document, visit the CMS coverage website at <a href="http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=23">http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=23</a>. For questions or additional information, contact Lori Ashby (410-786-6322).

#### Addendum X:

### List of Special One-Time Notices Regarding National Coverage Provisions (October through December 2012)

There were no special one-time notices regarding national coverage provisions published in the October through December 2012 quarter. This information is available at <a href="https://www.cms.hhs.gov/coverage">www.cms.hhs.gov/coverage</a>. For questions or additional information, contact Lori Ashby (410-786-6322).

### Addendum XI: National Oncologic PET Registry (NOPR) (October through December 2012)

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 October through December 2012 quarter. This information is available at <a href="http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage">http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage</a>. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564)

Facility	Provider Number	Effective Date	State
Editorial changes (shown in bold) were ma	de to the facilit	ies listed below.	
FROM: Hospital of Saint Raphael	070022	03/06/2007	CT
TO: YNHH- St. Raphael Campus			
1450 Chapel Street New Haven, CT 05611			

### Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (October through December 2012)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred to the list of Medicare-approved facilities that meet our standards in the 3-month period. This information is available on our website at

http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

Facility	Provider Number	Date Approved	State
The following facilities	are new listings for thi	s quarter.	
The Medical Center of Central Georgia	110107	11/08/2012	GA
777 Hemlock Street			
Macon GA 31201			
Florida Hospital	100007	10/29/2012	FL
601 East Rollins Street			
Orlando FL 32803			
Scripps Memorial Hospital – La Jolla	050324	11/26/2012	CA
9888 Genesee Avenue			
La Jolla, CA 92037			

## Addendum XIII: Lung Volume Reduction Surgery (LVRS) (October through December 2012)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
  - Medicare approved for lung transplants.

Only the first two types are in the list. There were no additions to the listing of facilities for lung volume reduction surgery published in the October through December 2012 quarter. This information is available on our website at

www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

Facility	Provider Number	Date Approved	State
The following facility is	a new listing for this	quarter.	
Temple University Hospital	3900027	11/17/2012	PA
3401 North Broad Street			

Philadelphia, P	A 19140		

### Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (October through December 2012)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric 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 on our website at

www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Kate Tillman, RN, MAS (410-786-9252).

Facility	Provider Number	Date Approved	State
The following facilities are new list	ings for this qua	rter.	
Duke Raleigh Hospital 3400 Wake Forest Road Raleigh, NC 27609	1013916352	07/16/2012	NC
UC San Diego Health System 200 West Arbor Drive #8401 San Diego, CA 92103	1184722779	09/06/2012	CA
Central Mississippi Medical Center 1850 Chadwick Drive Jackson, MS 39204	1033163092	08/26/2012	MS
Renown South Meadows Medical Center 10101 Double R BoulevardReno, NV 89521	1790789147	03/26/2012	NV

Jackson South Community Hospital	1174601397	07/31/2012	FL
9333 S.W. 152nd Street Miami, FL 33157	11/4001397	07/31/2012	LL
North Mississippi Medical Center	1629049846	09/06/2012	MS
830 South Gloster Street Tupelo, MS 38801	1029049840	09/06/2012	IMS
Huntington Hospital	1508845322	10/06/2012	NY
	1508845522	10/06/2012	INT
270 Park Avenue Huntington, NY 11743	45.0044	05/20/2012	TOTAL .
UT Southwestern Medical Center	45-0044	05/28/2012	TX
5909 Harry Hines Boulevard Dallas, TX 75235		10/11/2010	
St. Vincent's Medical Center	590-62-4449	12/14/2012	FL
1 Shircliff Way Jacksonville, FL 32204			
Center for Surgical Weight Management at Gwinnett	1790715381	11/15/2012	GA
Medical Center – Duluth			
3855 Pleasant Hill Road, Suite 210 Duluth, GA 30096			
Editorial changes (shown in bold) were made			
Grinnell Regional Medical Center	1669420501	10/20/2012	IA
210 Fourth Avenue Grinnell, IA 50112			
FROM: SUNY Upstate Medical University	1578554630	03/27/2009	NY
TO: Upstate Medical University			
750 E. Adams Street, University Hospital			
Syracuse, NY 13210			
FROM: Marshall Medical Center North	01-0005	04/19/2010	AL
TO: Marshall Medical Centers			
11491 US Hwy 431			
Guntersville, AL 35950			
FROM: Charleston Area Medical Center, Women	510022	04/04/2007	WV
and Children's Hospital			''
TO: Charleston Area Medical Center, General			
Hospital			
501 Morris Street Charleston, WV 25301			
Oregon Health & Science University	107708,	06/27/2012	OR
3181 SW Sam Jackson Park Road, L223A	380009:	00/2//2012	010
Portland, OR 97239	1609824010		
Heartland Regional Medical Center	260006	01/20//2012	MO
5325 Faraon Street	200000	01/20/2012	1110
Saint Joseph, MO 64506			
FROM: St. John's Regional Health Center	260065	03/05/2008	МО
TO: Mercy Hospital, Springfield	200003	03/03/2000	MO
1235 E. Cherokee Springfield, MO 65804			
Beth Israel Deaconess Medical Center	04-2103881	02/18/2012	MA
330 Brookline Avenue Boston, MA 02215	04-2103661	02/10/2012	IVIA
University of North Carolina	1932208576	08/23/2010	NC
101 Manning Drive Chapel Hill, NC 27599	1932208370	06/23/2010	INC
Contour Norfells Congred II	4900073	00/20/2012	VA
Sentara Norfolk General Hospital	49000/3	09/30/2012	VA
600 Gresham Drive Norfolk, VA 23507	10005055	10/0/12012	1.74
Newton-Wellesley Hospital	1992737761	10/26/2012	MA
2014 Washington Street Newton, MA 02462			
Our Lady of Lourdes Regional Medical	190102	05/24/2010	LA
4801 Ambassador Caffery Parkway			
Lafayette, Louisiana 70506			L

UMass Memorial Medical Center-Memorial Campus	1831151455	07/27/2012	MA
55 Lake Avenue North; Room H1-760	1831131433	0//2//2012	IVIA
Worcester, MA 01655			
	1336294040;	08/06/2012	CA
Kaiser Permanente South Bay	05-0411	08/06/2012	CA
25825 S. Vermont Avenue Harbor City, CA 90710		10/10/2012	TOT
Cleveland Clinic Florida	100289,	10/19/2012	FL
3100 Weston Road Weston, FL 33331	1083644033		1.55
Sinai Hospital of Baltimore	1285672204	09/25/2012	MD
2435 W. Belvedere Avenue Baltimore, MD 21215			
Highland Hospital	330164	08/30/2012	NY
1000 South Avenue Rochester, NY 14620	NPI#		
	1497941645		
Saint Francis Hospital	370091;	10/24/2012	OK
6161 South Yale Avenue Tulsa, OK 74136	1144228487		
Hackensack University Medical Center	1457456279	12/09/2012	NJ
30 Prospect Avenue Hackensack, NJ 07601			
FROM: Pitt County Memorial Hospital	340040	02/12/2007	NC
TO: Vidant Medical Center			
2100 Stantonsburg Road Greenville, NC 27835			
Princeton Baptist Medical Center	1144312430	07/01/2012	AL
917 Tuscaloosa Avenue, SW Birmingham, AL 35211			
Community Medical Center-Clovis	050492;	06/27/2012	CA
2755 Herndon Avenue Clovis, CA 93611	CMS#		
·	1316027709		
Saint Luke's Hospital of Kansas City	26-0138	01/02/2010	MO
4401 Wornall Road Kansas City, MO			
The following facilities are no longer par	ticipants as of th	his notice.	
River Oaks Hospital Flowood, MS	250138		MS
West Hills Hospital and Medical Center	050481		CA
West Hills, CA			
Phoebe North Campus Albany, GA	110163		GA
AnMed Health Medical Center Anderson, SC	420027		SC
Fletcher Allen Health Care	470003		VT
111 Colchester Avenue Burlington, VT 05401	170003		٧,
Kettering Medical Center Kettering, OH	360079		OH
Rettering Medical Center Rettering, Off	J 300079	<u> </u>	LOH

### Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (October through December 2012)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the October through December 2012 quarter.

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