the individual named within the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Dated: September 24, 2012.

Don Wright,

Director, Office of Disease Prevention and Health Promotion.

[FR Doc. 2012–27425 Filed 11–8–12; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9075–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July through September 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 July through September 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 **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	Sarah J. McClain	(410) 786–2294
VIII American College of Cardiology-National Cardiovascular Data Registry Sites	JoAnna Baldwin, MS	(410) 786–7205
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	JoAnna Baldwin, MS	(410) 786–7205
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	JoAnna Baldwin, MS	(410) 786–7205
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

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 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 5, 2012.

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: December 16, 2011 (76 FR 78267), February 21, 2012 (77 FR 9931), May 18, 2012 (77 FR 29648) and August 17, 2012 (77 FR 49799). 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 (July through September 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 http://www.gpo.gov/libraries/

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. 144.

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 Number	Manual/Subject/Publication Number
Medicare General Information (CMS-Pub. 100-01)	
79	January 2013 Quarterly Updates to the CMS Standard File for Reason Codes for the Fiscal Intermediary Shared System (FISS)
Medicare Benefit Policy (CMS-Pub. 100-02)	
00	None
Medicare National Coverage Determination (CMS-Pub. 100-03)	
144	Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP)
145	National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR)
146	Liver Transplantation for Patients with Malignancies Transcatheter Aortic Valve Replacement (TAVR) Adult Liver Transplantation
Medicare Claims Processing (CMS-Pub. 100-04)	
2494	Pharmacy Billing for Drugs Provided "Incident To" a Physician Service This CR rescinds and fully replaces CR 7109.
2495	Validation of Payment Group Codes for Prospective Payment Systems (PPS)

	Based on Patient Assessments Systematic Validation of Claims Information Using Patient Assessments
2496	New Waived Tests
2497	Update to Hospice Payment Rates, Hospice Cap, Hospice Wage Index and the Hospice Prices for FY 2013
2498	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2499	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2500	Clarification of the Use of the Electronic Claim Format to Indicate Where a Service Was Performed Payment Jurisdiction Among Local B/MACs for Services Paid Under the Physician Fee Schedule and Anesthesia Claims Processing Instructions for Payment Jurisdiction Conditional Data Element Requirements for A/B MACs and DMEMACs
2501	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2502	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2503	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2504	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2505	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2506	Extracorporeal Photopheresis (ICD-10)
2507	Medicare Part A Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Pricer Update FY 2013
2508	Claim Status Category and Claim Status Codes Update
2509	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2510	Payment of Global Surgical Split Care in a Method II Critical Access Hospital (CAH) Submitted with Modifier 54 and/or 55
2511	Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP)
2512	National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) Transcatheter Aortic Valve Replacement (TAVR) Furnished on or After May 1, 2012 Coding Requirements for Requirements for Transcatheter Aortic Valve Replacement (TAVR) Services Furnished On or After May 1, 2012 Claims Processing Requirements for TAVR Services on Professional Claims Claims Processing Requirements for TAVR Services on Inpatient Hospital Claim
2513	Liver Transplantation for Patients with Malignancies Liver Transplants
2514	October 2012 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files Notification for Beneficiaries Exceeding Financial Limitations
2515	Handling Form CMS-1500 Hard Copy Claims Where an ICD-9-CM "E" Code or Where an ICD-10 V00-Y99 Code is Reported as the First Diagnosis on the Claim Conditional Data Element Requirements for A/B MACs and DMEMACs Consolidated Claims Crossover Process Claims Crossover Disposition and Coordination of Benefits Agreement By-Pass Indicators
2516	New Non- Physician Specialty Code for Centralized Flu Nonphysician Practitioner, Supplier, and Provider Specialty Codes
2517	Medicare Claims Processing Pub. 100-04 Chapter 24 Update for Security Requirements
2518	Inpatient Rehabilitation Facility (IRF) Annual Update: Prospective Payment System (PPS) Pricer Changes for FY 2013 Payment Provisions Under IRF PPS
2519	New Fiscal Intermediary Shared System (FISS) Consistency Edit to Validate Attending Physician NPI
2520	Update-Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) Fiscal Year (FY) 2013 Annual Update
2521	Claim Adjustment Reason Code (CARC), Remittance Advice Remark Code (RARC), and Medicare Remit Easy Print (MREP) and PC Print Update
2522	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2523	Revised Medicare Summary Notice (MSN) Message Regarding Outpatient Therapy Caps
2524	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2525	October 2012 Update of the Ambulatory Surgical Center Payment System (ASC)
2526	Annual Update for the Health Professional Shortage Area (HPSA) Bonus Payments
2527	Issued to a specific audience, not posted to Internet/Intranet/ due to Sensitivity of Instruction
2528	Instructions for Downloading the Medicare ZIP Code File for January 2013
2529	Healthcare Common Procedure Coding System (HCPCS) Annual Update Reminder
2530	October Update to the CY 2012 Medicare Physician Fee Schedule Database (MPFSDB)
2531	October 2012 Update of the Hospital Outpatient Prospective Payment System (OPPS) Transitional Outpatient Payments (TOPs) for CY 2010 through CY 2012 Fiscal Intermediary Billing Requirements
2532	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2533	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2534	Healthcare Provider Taxonomy Codes (HPTC) Update, October 2012
2535	Chapter 24 Update to Remove Outdated Information FIs, Carriers, RHHIs, A/B MACs, and CEDI HIPAA Claim Level Edits Institutional Implementation Guide (IG) Edits Institutional Implementation Guide and Direct Data Entry Edits

2536	Indian Health Services (IHS) Hospital Payment Rates for Calendar Year 2012
2537	Expiration of 2012 Therapy Cap Revisions and User-Controlled Mechanism to Identify Legislative Effective Dates S
2538	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2539	Fiscal Year (FY) 2013 Inpatient Prospective Payment System (IPPS), Long Term Care Hospital (LTCH) PPS Changes Medicare Code Editor (MCE) Disproportionate Share Hospital (DSH) Policy Changes Effective for Cost Reporting Periods beginning on or after October 1, 2009 Disproportionate Share Hospital (DSH) Policy Changes Effective for Cost Reporting Periods beginning on or after October 1, 2012 Repeat Admissions Outpatient Services Treated as Inpatient Services Replaced Devices Offered Without Cost or With a Credit Addenda A-Provider Specific File
2540	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2541	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
2542	2013 Annual Update of Healthcare Common Procedure Coding System (HCPCS) Codes for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Update
2543	Extracorporeal Photopheresis (ICD-10) Billing Requirements for Extracorporeal Photopheresis Healthcare Common Procedural Coding System (HCPCS), Applicable Diagnosis Codes and Procedure Code Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RAs) and Claim Adjustment Reason Code
2544	Contractor and Common Working File (CWF) Additional Instructions Related to Change Request (CR) 7633 - Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse
2545	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
2546	Instructions for Retrieving the 2013 Pricing and HCPCS Data Files through CMS' Mainframe Telecommunications Systems
2547	Claim Status Category and Claim Status Codes Update
Medicare Secondary Payer (CMS-Pub. 100-05)	
87	Clarification of Medicare Conditional Payment Policy and Billing Procedures for Liability, No-Fault and Workers' Compensation Medicare Secondary Payer (MSP) Claims.
88	Expanding the Coordination of Benefits (COB) Contractor Numbers to include 11139 and 11142 for the Common Working File (CWF) Definition of MSP/CWF Terms
89	Expanding the Coordination of Benefits (COB) Contractor Numbers to include 11139 and 11142 for the Common Working File (CWF)
Medicare Financial Management (CMS-Pub. 100-06)	
211	Notice of New Interest Rate for Medicare Overpayments and Underpayments – 4th Notification for FY 2011
212	New Non- Physician Specialty Code for Centralized Flu Claims Processing
	Timeliness - All Claims Part E/Interest Payment Data Non-Physician Practitioner/Supplier Specialty Codes
210	Validation of Recovery Audit Program New Issues
Medicare State Operations Manual (CMS-Pub. 100-07)	
82	CMS Certification Numbers for Medicaid-Only Hospitals and New State Code for Foreign Countries
Medicare Program Integrity (CMS-Pub. 100-08)	
00	None
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
00	None
Medicare Quality Improvement Organization (CMS-Pub. 100-10)	
00	None
Medicare End Stage 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
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
00	None
Demonstrations (CMS-Pub. 100-19)	
84	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.
One Time Notification (CMS-Pub. 100-20)	
1101	Reporting of Recoupment for Overpayment on the Remittance Advice (RA) with Patient Control Number
1102	Direction to Modify Institutional Reason Code 39012
1103	Health Insurance Portability and Accountability Act (HIPAA) 5010 and D.0 Execution of the Annual Recertification Program
1104	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1105	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
1106	Posting the Limiting Charge after Applying the e-Prescribing (eRx) Negative Adjustment
1107	The Medicare Secondary Payer Payment Module (MSPPAY) to be Maintained by the Shared System Maintainers for all Future Enhancements
1108	Fee For Service Common Eligibility Services (FFS CES) - Common Working File (CWF) Detail Analysis, Design and Requirements
1109	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
1110	Revision of Medicare Summary Notice (MSN) for Non-Competitive Bid Claims
1111	Expand Place of Service Address to Include Full Address

1112	Health Insurance Portability and Accountability Act (HIPAA) 5010 837 Institutional (8371) Edits and 5010 837 Professional (837P) Edits January 2012
1113	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1114	New Field Established within FISS and MCS
1115	Implement Fraud Prevention Predictive Modeling Prepayment Edits for Shared Systems (xref CR7787)
1116	Implement Fraud Prevention Predictive Modeling Prepayment Edits for Shared Systems (xref CR7787)
1117	Manual Medical Review of Therapy Services
1118	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1119	Implementation of the Award for the Jurisdiction 5 Part A and Part B Medicare Administrative Contractor (J5 A/B MAC) Reprocurment Including a New Workload Number for the Remaining WPS Legacy Workload
1120	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
1121	None
1122	International Classification of Diseases (ICD)-10 Conversion from ICD-9 and Related Code Infrastructure of the Medicare Shared Systems as They Relate to CMS National Coverage Determinations (NCDs) (CR 1 of 3) (ICD-10)

Addendum II: Regulation Documents Published in the Federal Register (July through September 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 www.gpo.gov/fdsys. 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 GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at http://www.gpoaccess.gov/fr/index.html. The following Website http://www.archives.gov/federal-register/ provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our Website at: http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-3Q12QPU.pdf

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 http://www.cms.gov/Rulings/CMSR/list.asp#TopOfPage. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

Addendum IV: Medicare National Coverage Determinations (July through September 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/medicare-coverage-database/. For questions or additional information, contact Wanda Belle (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Liver Transplantation for Malignancies	NCD 260.1	R146NCD	08/03/2012	07/13/2012
Transcutaneous Electrical Nerve Stimulation (TENS) Chronic Low Back Pain	NCD 160.27	R144NCD	08/03/2012	06/08/2012

Transcatheter Aortic Valve Replacement (TAVR)	NCD 20.32	R145NCD	08/03/2012	05/01/2012

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (July through September 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
BB15140	Magellan System	07/06/12
G100021	Stentys Coronary Stent System	09/12/12
G110112	Formula Balloon-Expandable Stent	07/18/12
G110162	Solace Intra Vesical Bladder Control System	08/09/12
G110186	Spinal Modulation Neurostimulator System	09/19/12
G110217	Unify Quadra MP CRT-DS Device	08/08/12
G110221	Siello S Pacing Leads	09/12/12
G110223	Consulta CRT-P Device	09/12/12
G110227	Ingevity Active Fixation and Passive Fixation Pace	07/13/12
G110229	Surpass Intracranial Embolization System	07/11/12
G120008	Pulmonx Zephyr Endobronchial Valve	07/19/12
G120010	NEO Baroreflex Activation Therapy	08/24/12
G120021	Intuitive Surgical Davinci	08/07/12
G120030	Nucleus Cochlear Implant System	07/19/12
G120075	Vercise Deep Brain Stimulation	07/25/12
G120076	Samurai Clinical Study	08/16/12
G120077	Reliance 4-Front Clinical Study	07/10/12
G120092	Non-Invasive Reduction of Fat in the Inner Thighs with the Zeltiq Cool Sculpting System	07/12/12
G120104	Robot-Assisted MRI-Guided Prostate Biopsy	08/09/12
G120133	Allegretto Wave Eye-Q Excimer Laser System	07/03/12
G120135	Deviate-AF	07/06/12
G120136	Zenith P-Branch	07/11/12
G120141	Embosphere Microspheres	09/11/12
G120142	Solitaire FR Revascularization Device	07/18/12
G120143	Michi Neuroprotection System	07/18/12
G120144	Supera Veritas Peripheral Sten System	07/18/12
G120146	Subqstim Study	07/20/12
G120147	Rescue-VT	07/19/12
G120149	Tria Beauty Fan Precision Device	07/18/12
G120150	Implantable Myoelectric Sensors for Upper Extremity Prosthetic Control in Transradial Amputees	07/25/12
G120151	Star S4 Excimer Laser System	07/24/12
G120152	Lifevest Wearable Cardioverter Defibrillator (WDC)	07/25/12
G120155	Prevent	07/26/12
G120162	Star SR IR Excimer Laser System and IDesign Advanced Wavescan Studio for Wavefront-Guided Lasik Treatment of Mixed Astig	08/08/12
G120164	Star SR IR Excimer Laser System and IDesign Advanced Wavescan Studio for Wavefront-Guided Lasik Treatment of Hyperopia	08/08/12
G120166	Ulthera System Model 8850-0001	08/15/12
G120169	Surtavi	08/15/12
G120171	Medtronic Reveal XT Isertable Cardiac Monitor Model 9529	08/24/12
G120175	Native Outflow Tract TPV System	08/30/12
G120176	B-Tevar Device	08/24/12
G120181	Intra-Articular Hyaluronan	08/29/12
G120183	C-Met Immunohistochemistry	09/05/12
G120188	Pulmonary Artery Repair with Covered Cheatham Platinum Stent	09/12/12
G120191	The Lone AFIB Trial	09/19/12
G120194	Nucleus 24 Auditory Brainstem Implant	09/21/12
G120195	The Moe Plasma Treatment System	09/17/12

Addendum VI: Approval Numbers for Collections of Information (July through September 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, (July through September 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 listings for this quarter.			
Carlsbad Medical Center 2430 W. Pierce Street Carlsbad, NM 88220	320065	07/11/2012	NM
Denver Health Medical Center 777 Bannock Street, MC0960 Denver, CO 80204	060011	07/11/2012	CO
Galion Community Hospital 269 Portland Way South Galion, OH 44833	1215907522	07/18/2012	OH
Beaumont Health System – Troy 44201 Dequindre Road Troy, MI 48085	1306825997	07/25/2012	MI
Texoma Medical Center 5016 South US Hwy 75 Denison, TX 75020	1851390967	07/25/2012	TX
McLaren-Lapeer Region 1375 North Main Street Lapeer, MI 48446-1350	230193	08/06/2012	MI
Lutheran Medical Center 150 55th Street Brooklyn, NY 11220-2574	330306	08/20/2012	NY
Southside Regional Medical Center 200 Medical Park Boulevard Petersburg, VA 23805	490067	08/29/2012	VA
Saint Agnes Hospital 900 Caton Avenue Baltimore, MD 21229	210011	09/10/2012	MD
Mercy Hospital Washington 901 E 5th Street Washington, MO 63090	260052	09/13/2012	MO
St. Joseph Regional Medical Center 415 6th Street Lewiston, ID 83501	1225090954	09/24/2012	ID
Editorial changes (shown in bold) were made to the facilities listed below.			
From: Dakota Specialty Institute **To: Innovis Health dba Essentia Health** 3000 32nd Avenue SW Fargo, ND 58104	350070	06/05/2007	ND
Franciscan St. Anthony Health – Michigan City 301 West Homer Street Michigan City, IN 46360	150015	**07/06/2006**	IN
From: Kaleida Health, Millard Fillmore Hospital **3 Gates Circle Buffalo, NY 14209** **To: Buffalo General Medical Center** **100 High Street Buffalo, NY 14203**	330005	05/03/2005	NY
Galichia Heart Hospital 2610 N. Woodlawn Boulevard Wichita, KS 67220-2729	**170123**	05/16/2005	KS
From: Saint Joseph Medical Center **To: Alegent Creighton Health Creighton University Medical Center** 601 North 30th Street Omaha, NE 68131-2197	280030	06/27/2005	NE
The following facility has been removed from the listings of Medicare-approved carotid stent facilities.			
Saint Anthony Memorial 301 W. Homer Street Michigan City, IN 46360	150015	07/06/2006	IN

Addendum VIII:
American College of Cardiology's National Cardiovascular Data Registry Sites (July through September 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
http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=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 www.ncdr.com/webncdr/common

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 Joanna Baldwin, MS (410-786-7205).

Facility Name	City	State
The following facilities are new listings for this quarter.		
Children's Mercy Hospital	Kansas City	MO
Norwegian American Hospital	Chicago	IL
Lake Wales Medical Center	Lake Wales	FL
Thomas Hospital	Fairhope	AL
Ephraim McDowell Regional Medical Center	Danville	KY
Ponca City Medical Center	Ponca City	OK
Northwestern Lake Forest Hospital	Lake Forest	IL
Wentworth-Douglass Hospital	Dover	NH
Oro Valley Hospital	Ora Valley	AZ
Seton Medical Center Harker Heights	Harker Heights	TX
Jupiter Medical Center	Jupiter	FL
Hendricks Regional Health	Danville	IN
St. Anthony's Hospital	Houston	TX
Maine General Medical Center	Augusta	ME
Southeast Georgia Health System	Brunswick	GA
Central Vermont Medical Center Inc	Berlin	VT
Opelousas General Health System	Opelousas	LA
Lodi Memorial Hospital	Lodi	CA
Memorial Hospital of Tampa	Tampa	FL
San Francisco Heart and Vascular Institute	Daly City	CA
Feather River Hospital	Paradise	CA
Mercy Memorial Hospital	Monroe	MI
Palestine Regional Medical Center	Palestine	TX
University Medical Center	Lubbock	TX

Addendum IX: Active CMS Coverage-Related Guidance Documents (July through September 2012)

There were no CMS coverage-related guidance documents published in the July through September 2012 quarter. To obtain full-text copies of these documents, visit the CMS Coverage website at http://www.cms.gov/mcd/index_list.asp?list_type=mcd_1 and click on the archives link. 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 2012)

There were no special one-time notices regarding national coverage provisions published in the July through September 2012 quarter. This information is available at www.cms.hhs.gov/coverage. For questions or additional information, contact Lori Ashby (410-786-6322).

Addendum XI: National Oncologic PET Registry (NOPR) (July through September 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 July through September 2012 quarter. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage.

For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564)

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (July through September 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 this quarter.			
Abington Memorial Hospital 1200 Old York Road Abington, PA 19001	390231	07/10/2012	PA
Froedtert Memorial Lutheran Hospital 9200 West Wisconsin Avenue Milwaukee, WI 53226	520177	08/01/2012	Wi
Maimonides Medical Center 4802 Tenth Avenue Brooklyn, NY 11219	330194	08/24/2012	NY

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (July through September 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 Commision 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 July through September 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).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (July through September 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 listings for this quarter.			
Greater Baltimore Medical Center (GBMC) Comprehensive Obesity Management Program 6535 North Charles Street Physicians Pavilion North, Suite 125 Baltimore, MD 21204	1396774238	06/07/12	MD
The Bryn Mawr Hospital 130 South Bryan Mawr Avenue Bryn Mawr, PA 19010	24371	03/16/12	PA
Hurley Medical Center One Hurley Plaza Flint, MI 48503-5993	230132	04/14/12	MI
Surgical Weight Loss Program at Eastern Maine Medical Center 905 Union Street, Suite 11 Bangor, ME 4401	1790789147	06/10/12	ME
Saint Vincent Hospital 123 Summer Street Worcester, MA 01608	220176	06/10/10	MA
Mount Sinai Hospital 5 East 98th Street, 15th Floor New York, NY 10029	1932103413	07/15/11	NY
Editorial changes (shown in bold) were made to the facilities listed below.			
St. Francis Hospital & Health Centers 1600 Albany Street Beech Grove, IN 46107	**1386749893**	05/30/2007	IN
MetroWest Medical Center, Leonard Morse Hospital 67 Union Street, Fair 4 Natick, MA01760	**220175**	07/14/2010	MA
SSM DePaul Health Center 12266 DePaul Drive, Suite 310 Bridgeton, MO 63044	**260104**	02/24/2006	MO
Silver Cross Hospital and Medical Centers **1900 Silver Cross Boulevard New Lenox, IL. 60451-9508**	140213	03/10/2006	IL
Brigham and Women's Hospital 75 Francis Street ASBII-3 Boston, MA 02115-619	MPI-1790717650; PI-220110	**08/14/2012**	MA
Albany Medical Center 47 New Scotland Avenue Albany, NY 12208	330013	**06/02/2012**	NY
The following facilities are no longer participants as of this notice.			
Northeast Alabama Regional Medical Center 400 East 10th Street Anniston, AL 36207	010078	07/30/2007	AL
Parkway Medical Center 1854 Beltline Road SW Decatur, AL 35601	01-0054	12/18/2009	AL
Allegheny General Hospital 320 East North Avenue Pittsburgh, PA 15212	390050	11/21/2006	PA

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (July through September 2012)

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

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

[FR Doc. 2012–27422 Filed 11–08–12; 8:45 am]
BILLING CODE 4120–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1057]

Draft Guidance for Industry and Food and Drug Administration Staff; Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices.'' This draft guidance is to provide industry and Agency staff with recommendations for studies to establish the analytical and clinical performance of highly multiplexed microbiological/medical countermeasures in vitro nucleic acid based diagnostic devices (HMMDs) intended to simultaneously detect and identify multiple pathogen nucleic acids extracted from a single appropriate human specimen or culture. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 7, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: John Hobson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5555, Silver Spring, MD 20993–0002, 301–796–5892.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance is to provide industry and Agency staff with recommendations for studies to establish the analytical and clinical performance of HMMDs intended to simultaneously detect and identify multiple pathogen nucleic acids extracted from a single appropriate human specimen or culture. For the purposes of this draft guidance document the multiplex level that is used to define HMMDs is the capability to detect ≥20 different organisms/targets, in a single reaction, using a nucleic acid based technology and involves testing multiple targets through a common process of specimen preparation, amplification and/or detection, and result interpretation. HMMDs are used to aid in the diagnosis of infection.

The scope of this draft guidance includes nucleic acid based devices that employ technologies such as polymerase chain reaction, reverse-transcriptase polymerase chain reaction, bead-based liquid arrays, microarrays, re-sequencing approaches as well as the measurement of individual targets determined by ≥20 separate assays that are reported out simultaneously through the use of a diagnostic algorithm. This draft guidance is not intended to address devices that utilize detection mechanisms other than nucleic acid based approaches. The document does not apply to devices that are intended to screen donors of blood and blood components, and donors of human cells, tissues, and cellular and tissue-based products for communicable diseases.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on highly multiplexed microbiological/medical countermeasure in vitro nucleic acid based diagnostic devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* To receive ''Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1803 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

V. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*