



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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**Centers for Medicare & Medicaid Services**

[CMS-9094-N]

**Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—**

**October through December 2015**

**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 2015, 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.

<b>Addenda</b>	<b>Contact</b>	<b>Phone Number</b>
<b>I</b> CMS Manual Instructions	Ismael Torres	(410) 786-1864
<b>II</b> Regulation Documents Published in the <b>Federal Register</b>	Terri Plumb	(410) 786-4481
<b>III</b> CMS Rulings	Tiffany Lafferty	(410)786-7548
<b>IV</b> Medicare National Coverage Determinations	Wanda Belle	(410) 786-7491
<b>V</b> FDA-Approved Category B IDEs	John Manlove	(410) 786-6877
<b>VI</b> Collections of Information	Mitch Bryman	(410) 786-5258
<b>VII</b> Medicare –Approved Carotid Stent Facilities	Lori Ashby	(410) 786-6322
<b>VIII</b> American College of Cardiology-National Cardiovascular Data Registry Sites	Marie Casey, BSN, MPH	(410) 786-7861
<b>IX</b> Medicare’s Active Coverage-Related Guidance Documents	JoAnna Baldwin	(410) 786-7205
<b>X</b> One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin	(410) 786-7205
<b>XI</b> National Oncologic Positron Emission Tomography Registry Sites	Stuart Caplan, RN, MAS	(410) 786-8564
<b>XII</b> Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	Marie Casey, BSN, MPH	(410) 786-7861
<b>XIII</b> Medicare-Approved Lung Volume Reduction Surgery Facilities	Marie Casey, BSN, MPH	(410) 786-7861
<b>XIV</b> Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
<b>XV</b> Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	Stuart Caplan, RN, MAS	(410) 786-8564
<b>All Other Information</b>	Annette Brewer	(410) 786-6580

**I. Background**

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance.

Administration and oversight of these programs involves the following: (1) furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining

effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

## **II. Format for the Quarterly Issuance Notices**

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 website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website 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 websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website 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>.

Dated January 28, 2016

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**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: February 2, 2015 (80 FR 5537), April 24, 2015 (80 FR 23013) August 3, 2015 (80 FR 45980) and November 13, 2015 (80 FR 70218). 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 2015)**

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 manual for Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - January 2016 (CMS-Pub. 100-04)Transmittal No. 3377.

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](http://www.cms.gov/Manuals).

Transmittal Number	Manual/Subject/Publication Number
<b>Medicare General Information (CMS-Pub. 100-01)</b>	
93	Internet Only Manual (IOM) Publication 100-01 - General Information, Eligibility, and Entitlement, Chapter 7 - Contract Administrative Requirements, Section 40 – Shared System Maintainer Responsibilities for Systems Releases
94	Internet Only Manual Updates to Pub. 100-01, 100-02 and 100-04 to Correct Errors and Omissions (2015)
95	Internet Only Manual (IOM) Publication 100-01 - General Information, Eligibility, and Entitlement, Chapter 7 - Contract Administrative Requirements, Section 40 – Shared System Maintainer Responsibilities for Next Generation Desktop (NGD) Requirements Standardized Terminology for Claims Processing Systems Standard Terminology Chart Release Software Implementing Validated Workarounds for Shared System Claims Processing by All Medicare DME MACs Shared System Testing Requirements for Shared System Maintainers, Single

	Testing Contractor (STC)/Beta Testers, and Part A/Part B (A/B) Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs) Shared System Testing Requirements for Shared System Maintainers, Single Testing Contractor (STC), and DME MACs Definitions Test Case Specification Standard Shared System Maintainer and Part A/Part B (A/B)/Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) and the Single Testing Contractor (STC) Responsibilities for Systems Releases Systems Releases
<b>Medicare Benefit Policy (CMS-Pub. 100-02)</b>	
211	Internet Only Manual Updates to Pub. 100-01, 100-02 and 100-04 to Correct Errors and Omissions (2015) Three-Day Prior Hospitalization
212	Update to the List of Compendia as Authoritative Sources for Use in the Determination of a “Medically-Accepted Indication” of Drugs and Biologicals Used Off-label in an Anti-Cancer Chemotherapeutic Regimen Update to the List of Compendia as Authoritative Sources for Use in the Determination of a “Medically-Accepted Indication” of Drugs and Biologicals Used Off-label in an Anti-Cancer Chemotherapeutic Regimen
213	Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for Calendar Year (CY) 2016
<b>Medicare National Coverage Determination (CMS-Pub. 100-03)</b>	
185	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
186	National Coverage Determination (NCD) for Single Chamber and Dual Chamber Permanent Cardiac Pacemakers - This CR rescinds and fully replaces CR 8525 Single Chamber and Dual Chamber Permanent Cardiac Pacemakers
187	National Coverage Determination (NCD) for Single Chamber and Dual Chamber Permanent Cardiac Pacemakers Single Chamber and Dual Chamber Permanent Cardiac Pacemakers
<b>Medicare Claims Processing (CMS-Pub. 100-04)</b>	
3363	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction Uniform Use of CARCs and RARCs Rule
3364	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October CY 2015 Update
3365	2016 Healthcare Common Procedure Coding System (HCPCS) Annual Update Reminder
3366	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2016
3367	Applying Therapy Caps to Maryland Hospitals Part B Outpatient Rehabilitation and Comprehensive Outpatient Rehabilitation Facility (CORF) Services - General Determining Payment Amounts – Institutional Claims Exceptions to Therapy Caps – General Exceptions Process Use of the KX Modifier for Therapy Cap Exceptions Therapy Cap Manual Review Threshold Identifying the Certifying Physician

	MSN Messages Regarding the Therapy Cap Application of Financial Limitations
3368	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3369	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3370	2016 Annual Update for the Health Professional Shortage Area (HPSA) Bonus Payments
3371	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3372	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3373	Fiscal Year (FY) 2016 Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) PPS Changes Provider-Specific File IPPS Transfers Between Hospitals Addendum A/Provider Specific File Prospective Payment Changes for Fiscal Year (FY) 2004 and Beyond
3374	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3375	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3376	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3377	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - January 2016
3378	Additional G-Codes Differentiating RNs and LPNs in the Home Health and Hospice Settings
3379	Internet Only Manual Updates to Pub. 100-01, 100-02 and 100-04 to Correct Errors and Omissions (2015) Decision Logic Used by the Pricer on Claims Outpatient Surgery and Related Procedures – INCLUSION Dialysis and Dialysis Related Services to a Beneficiary With ESRD Screening and Preventive Services Other Excluded Services Beyond the Scope of a SNF Part A Benefit
3380	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3381	Instructions for Retrieving the 2016 Pricing and HCPCS Data Files through CMS' Mainframe Telecommunications Systems
3382	Instructions for Retrieving the 2016 Pricing and HCPCS Data Files through CMS' Mainframe Telecommunications Systems
3383	Home Health Prospective Payment System (HH PPS) Rate Update for Calendar Year (CY) 2016
3384	National Coverage Determination (NCD) for Single Chamber and Dual Chamber Permanent Cardiac Pacemakers - This CR rescinds and fully replaces CR 8525.
3385	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction

3386	Medicare Internet Only Manual (IOM) Publication 100-04 Chapter 27 Contractor Instructions for CWF
3387	Billing of the Transportation Fee by Portable X-ray Suppliers Transportation Component (HCPCS Codes R0070 - R0076)
3388	Manual Updates to Clarify IRF Claims Processing Verification Process Used To Determine If The Inpatient Rehabilitation Facility Met The Classification Criteria
3389	Outpatient Mental Health Treatment Limitation Split Claims Fix Splitting Claims for Processing
3390	Off-Cycle Update to the Inpatient Prospective Payment System (IPPS) Fiscal Year (FY) 2016 Pricer
3391	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3392	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3393	Reporting of Type of Bill (TOB) 014x for Billing Screening of Hepatitis Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Institutional Billing Requirements C Virus (HCV) in Adults
3394	Implementation Instructions to Operationally Process the Claims of a Subclause (II) Long Term Care Hospital (LTCH) in a Manner that is Generally Consistent with the Claims Processing of Non-Prospective Payment System (PPS) Hospitals
3395	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3396	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2016
3397	Calendar Year (CY) 2016 Participation Enrollment and Medicare Participating Physicians and Suppliers Directory (MEDPARD) Procedures
3398	Processing Hospice Denials When Face-to-Face Encounter is Not Received Timely
3399	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3400	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3401	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3402	Payment Reduction for Computed Tomography (CT) Diagnostic Imaging Services Services That Do Not Meet the National Electrical Manufacturers Association (NEMA) Standard XR-29-2013
3403	New Influenza Virus Vaccine Code CWF Crossover Edits for A/B MAC (B) Claims Healthcare Common Procedure Coding System (HCPCS) and Diagnosis Codes CWF Edits on AB MAC (A) Claims CWF Edits on AB MAC (B) Claims

	Table of Preventive and Screening Services
3404	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3405	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3406	New Waived Tests
3407	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October CY 2015 Update Quarterly Update to the Correct Coding Initiative (CCI) Edits
3408	Version 22.1, Effective April 1, 2016
3409	Instructions for Downloading the Medicare ZIP Code File for April 2016
3410	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3411	Implement Operating Rules - Phase III ERA EFT: CORE 360 Uniform Use of Claim Adjustment Reason Codes (CARC) and Remittance Advice Remark Codes (RARC) Rule - Update from CAQH CORE
3412	Common Edits and Enhancements Modules (CEM) Code Set Update
3413	Claim Status Category and Claim Status Codes Update
3414	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3415	Payment for Grandfathered Tribal Federally Qualified Health Centers (FQHCs) that were Provider-Based Clinics on or Before April 7, 2000 Payer Only Codes Utilized by Medicare
3416	CY 2016 Update for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Gap-Filling DMEPOS Fees Intermediary Format for Durable Medical Equipment, Prosthetic, Orthotic, Supply Fee Schedule
3417	Therapy Cap Values for Calendar Year (CY) 2016
3418	Remittance Advice Remark and Claims Adjustment Reason Code and Medicare Remit Easy Print and PC Print Update
3419	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3420	Calendar Year (CY) 2016 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
3421	National Coverage Determination (NCD) for Single Chamber and Dual Chamber Permanent Cardiac Pacemakers
3422	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3423	Summary of Policies in the Calendar Year (CY) 2016 Medicare Physician Fee Schedule (MPFS) Final Rule and Telehealth Originating Site Facility Fee Payment Amount
3424	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP)-April 2016
3425	January 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS) Comprehensive APCs Packaging Use of Modifiers for Discontinued Services

	<p>Use of HCPCS Modifier – CT</p> <p>Transitional Pass-Through Payments for Designated Devices</p> <p>Billing for Devices Eligible for Transitional Pass-Through Payments and Items Classified in “New Technology” APCs</p> <p>Categories for Use in Coding Devices Eligible for Transitional Pass Through Payments Under the Hospital OPPS</p> <p>Devices Eligible for Transitional Pass-Through Payments</p> <p>General Coding and Billing Instructions and Explanations</p> <p>Services Eligible for New Technology APC Assignment and Payments</p> <p>Edits for Claims on Which Specified Procedures are to be Reported</p> <p>Device Codes and For Which Specific Devices are to be Reported With Procedure Codes</p> <p>Inpatient-only Services</p> <p>Billing for Corneal Tissue</p> <p>Billing Instructions for IMRT Planning</p> <p>Separately Billable ESRD Laboratory Tests Furnished by Hospital-Based Facilities</p> <p>Billing and Payment for Observation Services Furnished Between January 1, 2008 and December 31, 2015</p> <p>Billing and Payment for Direct Referral for Observation Care Furnished Beginning January 1, 2008</p> <p>Billing and Payment for Observation Services Furnished Beginning January 1, 2016</p> <p>Method of Payment for Clinical Laboratory Tests - Place of Service Variation</p> <p>Billing for Multi-Source Photon (Cobalt 60-Based) Stereotactic Radiosurgery (SRS) Planning and Delivery</p>
3426	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3427	January 2016 Integrated Outpatient Code Editor (I/OCE) Specifications Version 17.0
3428	Advance Care Planning (ACP) as an Optional Element of an Annual Wellness Visit (AWV) 140.8 Advance Care Planning (ACP) as an Optional Element of an Annual Wellness Visit (AWV)
3429	New Influenza Virus Vaccine Code
<b>Medicare Secondary Payer (CMS-Pub. 100-05)</b>	
115	Electronic Correspondence Referral System (ECRS) Web Updates to Claims Processing Medicare Secondary Payer (MSP) Policy and Procedures Regarding Ongoing Responsibility for Medicals (ORM)
116	Instructions on Using the Claim Adjustment Segment (CAS) for Medicare Secondary Payer (MSP) Part A CMS-1450 Paper Claims, Direct Data Entry (DDE), and 837 Institutional Claims Transactions
<b>Medicare Financial Management (CMS-Pub. 100-06)</b>	
255	Notice of New Interest Rate for Medicare Overpayments and Underpayments - 1st Qtr Notification for FY 2016
256	Medicare Financial Management Manual, Chapter 7, Internal Controls
<b>Medicare State Operations Manual (CMS-Pub. 100-07)</b>	
147	Revisions to State Operation Manual (SOM), Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services

148	Revisions and Deletion to the State Operations Manual (SOM) Chapter 9 Exhibits
149	State Operations Manual (SOM) for All Types of Providers and Suppliers Subject to Certification
150	Revisions to State Operations Manual (SOM), Chapter 2, Clarification of Requirements for Off-Premises Activities and Approval of Extension Locations for Providers of Outpatient Physical Therapy and Speech-Language Pathology Services
151	Revisions to State Operations Manual (SOM), Appendix A -Survey Protocol, Regulations and Interpretive Guidelines for Hospitals
<b>Medicare Program Integrity (CMS-Pub. 100-08)</b>	
615	Signature Requirements, Amendments, Corrections and Delayed Entries in Medical Documentation
616	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
617	Update to Chapter 3 of Pub. 100-08
618	<p>Written Orders Prior to Delivery (WOPD)</p> <p>Items and Services Having Special DME Review Considerations</p> <p>Refills of DMEPOS Items Provided on a Recurring Basis</p> <p>Detailed Written Orders</p> <p>Written Orders Prior to Delivery</p> <p>Face-to-Face Encounter Requirements</p> <p>Face-to-Face Encounter Conducted by the Physician</p> <p>Face-to-Face Encounter Conducted by a Nurse Practitioner, Physician Assistant or Clinical Nurse Specialist</p> <p>Date and Timing Requirements</p> <p>Requirements of New Orders</p> <p>Billing for Refills of DMEPOS Items Provided on a Recurring Basis</p> <p>Verbal and Preliminary Written Orders</p>
619	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
620	<p>Pub. 100-08 Chapter 3 Updates: Section 3.2.3.2 Timeframes for Submission and Section 3.2.3.8 - No response to Additional</p> <p>No Response or Insufficient Response to Additional Documentation Requests</p> <p>Timeframes for Submission</p> <p>Verifying Potential Errors and Taking Corrective Actions</p> <p>Documentation Requests</p>
621	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
622	<p>Program Integrity Manual Chapter 12 Revision</p> <p>The Comprehensive Error Rate Testing Program</p> <p>Annual Improper Payment Reduction Strategy (IPRS)</p>
623	<p>Written Orders Prior to Delivery (WOPD)</p> <p>Items and Services Having Special DME Review Considerations</p> <p>Verbal and Preliminary Written Orders</p> <p>Detailed Written Orders</p> <p>Written Orders Prior to Delivery</p> <p>Face-to-Face Encounter Conducted by the Physician</p> <p>Refills of DMEPOS Items Provided on a Recurring Basis</p>



	Face-to-Face Encounter Requirements Date and Timing Requirements Requirements of New Orders Billing for Refills of DMEPOS Items Provided on a Recurring Basis Face-to-Face Encounter Conducted by a Nurse Practitioner, Physician Assistant or Clinical Nurse Specialist
624	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
625	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
626	Update to Surety Bond Collection Requirements Claims against Surety Bonds Model Letters for Claims against Surety Bonds
627	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
628	Update to CMS Publication 100-08, Chapter 3, Section 3.2.3.2 (Time Frames for Submission)
629	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
630	Medicare Program Integrity Data Analysis—Update
<b>Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)</b>	
	None
<b>Medicare Quality Improvement Organization (CMS- Pub. 100-10)</b>	
	None
<b>Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)</b>	
	None
<b>Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)</b>	
	None
<b>Medicare Managed Care (CMS-Pub. 100-16)</b>	
	None
<b>Medicare Business Partners Systems Security (CMS-Pub. 100-17)</b>	
	None
<b>Demonstrations (CMS-Pub. 100-19)</b>	
121	Medicare Care Choices Model (MCCM) - Per Beneficiary per Month Payment (PBPM) - Implementation
122	Termination of the Rural Community Hospital Demonstration, Mandated by Section 410A of the Medicare Modernization Act and Extended by Sections 3123 and 10313 of the Affordable Care Act
123	Implementing Payment Changes for FCHIP (Frontier Community Health Integration Project), Mandated by Section 123 of MIPPA 2008 and as Amended by Section 3126 of the ACA of 2010 (This CR Rescinds and Replaces CR 8683
124	Affordable Care Act Bundled Payments for Care Improvement Initiative – Recurring File Updates Models 2 and 4 January 2016 Updates
125	Medicare Care Choices Model (MCCM) - Per Beneficiary per Month Payment (PBPM) – Implementation
126	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
127	Oncology Care Model (OCM) Monthly Enhanced Oncology Services

	(MEOS) Payment Implementation
128	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
129	Oncology Care Model (OCM) Monthly Enhanced Oncology Services (MEOS) Payment Implementation
130	Demonstration: Payment Update for 2016
131	Implementing Payment Changes for FCHIP (Frontier Community Health Integration Project), Mandated by Section 123 of MIPPA 2008 and as Amended by Section 3126 of the ACA of 2010 (This CR Rescinds and Replaces CR 8683)
132	Oncology Care Model (OCM) Monthly Enhanced Oncology Services (MEOS) Payment Implementation
133	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
134	Medicare Care Choices Model (MCCM) - Per Beneficiary per Month Payment (PBPM) – Implementation
135	Affordable Care Act Bundled Payments for Care Improvement Initiative - Recurring File Updates Models 2 and 4 April 2016 Updates
<b>One Time Notification (CMS-Pub. 100-20)</b>	
1546	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1547	ICD-10 Conversion/Coding Infrastructure Revisions to National Coverage Determinations (NCDs)--3rd Maintenance CR
1548	Analysis Only: To Obtain the Level of Effort (LOE) from Medicare Administrative Contractors (MACs) to Implement Multifactor Authentication (MFA) as an Option for Non-Organization Users and to also Obtain the Level of Effort (LOE) from Medicare Administrative Contractors (MACs) to Implement Multifactor Authentication (MFA) as a Requirement for Non-Organization Users
1549	Shared System Enhancement 2014 - Removal of Railroad Board (RRB) obsolete reports identified by Multi-Carrier System (MCS) Shared System Maintainer (SSM)
1550	System Specific Enhancement 2014: Process Health Maintenance Organization (HMO) edits in a single module in Common Working File (CWF)
1551	System Specific Enhancements 2014: Move PAP smear Risk Indicator (PAPRI) and Technical (TECH)/Professional (PROF) Dates to Screening Auxiliary file
1552	Medicare Remit Easy Print (MREP) Upgrade
1553	New State Code for CT, MA, NJ, PR, GA, NC, SC, TN, AR, OK, CO, CA, OR, LA, NM, TX and WA
1554	System Specific Enhancements 2014: Retaining Most Recent Update for Auxiliary (Aux) File Data in Common Working File (CWF)
1555	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
1556	Shared System Enhancement 2015: Eliminate Remaining Uses of AREAFILE and CUSTCHRG Virtual Storage Access Method Files
1557	System Specific Enhancement 2015: Archive Competitive Bidding Demonstration Logic in ViPS Medicare System (VMS)

1558	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
1559	Shared System Enhancement 2015: Modify Purged Claim History to Improve Efficiency
1560	Instruction to Apply the Part A Deductible on a Medicare Secondary Payer (MSP) Inpatient Same Day Transfer Claim
1561	Part B Detail Line Expansion - Trailer 08 Update
1562	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1563	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
1564	Health Insurance Portability and Accountability Act (HIPAA) EDI Front End Updates for April 2016
1565	System Specific Enhancement 2015: Fiscal Intermediary Standard System (FISS) Extend Hard Segregation of Security
1566	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1567	System Specific Enhancements 2014: Retaining most recent update for Auxiliary (Aux) file data in Common Working File (CWF) Analysis Only
1568	Implementation of Procedures for Undeliverable Medicare Summary Notices (uMSNs)
1569	Shared System Enhancement 2015: Combined Common Edits/Enhancements Module (CCEM) Claim Tracking and Logging.
1570	Reporting Principal and Interest Amounts When Refunding Previously Recouped Money on the Remittance Advice (RA)
1571	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1572	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1573	Shared System Enhancement 2014 - Removal of Obsolete Reports and On-Request Jobs from the ViPS Medicare System (VMS) – Implementation
1574	Shared System Enhancement 2015: Technical Improvements to the Redesigned Medicare Summary Notice (MSN) process.
1575	Shared System Enhancement 2015: Identify Inactive Medicare Demonstration Projects (Analysis Only)
1576	Chronic Care Management (CCM) services for Rural Health Clinics (RHCs) and Federal Qualified Health Centers (FQHCs)
1577	System Specific Enhancement 2015: Remove Direct Claim Updates within the Daily Batch Cycle Analysis and Design CR
1578	Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction
1579	None
1580	ICD-10 Conversion/Coding Infrastructure Revisions to National Coverage Determinations (NCDs)--3rd Maintenance CR
1581	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1582	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1583	Settlement Effectuation Instructions for the Department of Health and Human

	Services' (DHHS) Office of Medicare Hearings and Appeals (OMHA) Settlement Conference Facilitation (SCF) Pilot
1584	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1585	Modifications to the National Coordination of Benefits Agreement (COBA) Crossover Process
1586	Eliminate Two Case-mix Payment Adjustments (Monoclonal Gammopathy and Bacterial Pneumonia) Available Under the End State Renal Disease (ESRD) Prospective Payment System (PPS) in Accordance With Section 632 of the American Taxpayer Relief Act (ATRA)
1587	Instruction to Apply the Part A Deductible on a Medicare Secondary Payer (MSP) Inpatient Same Day Transfer Claim
1588	Settlement Effectuation Instructions for the Department of Health and Human Services' (DHHS) Office of Medicare Hearings and Appeals (OMHA) Settlement Conference Facilitation (SCF) Pilot
<b>Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)</b>	
49	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
50	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
51	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
52	Fiscal Year 2017 and After Payments to Hospice Agencies That Do Not Submit Required Quality Data - This CR Rescinds and Fully Replaces CR9091
<b>Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)</b>	
	None

**Addendum II: Regulation Documents Published in the Federal Register (October through December 2015)**  
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](http://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-3Q15QPU.pdf>

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

**Addendum III: CMS Rulings  
(October through December 2015)**

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/Regulations-and-Guidance/Guidance/Rulings>. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

**Addendum IV: Medicare National Coverage Determinations  
(October through December 2015)**

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, there were no additions in the 3-month period. This information is available at: [www.cms.gov/medicare-coverage-database/](http://www.cms.gov/medicare-coverage-database/). For questions or additional information, contact Wanda Belle (410-786-7491).

**Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (October through December 2015)**

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
G150121	SurVeil Drug Coated Balloon Catheter	10/02/15
G150191	Restylane; Restylane - L; Perlane; Restylane Lyft; Restylane Silk	10/02/15
G150192	Prostate Embolization for Massive Benign Prostatic Hypertrophy (BPH) Using Embosphere Microspheres	10/02/15
G150194	SYNERGYTM Everolimus-Eluting Platinum Chromium Coronary Stent System	10/02/15
G150198	Multichannel Vestibular Implant	10/09/15
G150201	VOCARE Bladder System	10/09/15
G150208	EPIFLO (Spinal Fusion)	10/16/15
G150209	EPIFLO (Colo-Rectal Surgery)	10/16/15
G150210	Corvia Medical InterAtrial Shunt Device (IASD) System II	10/22/15
G150035	JenaValve Pericardial THV System	10/22/15
G130173	CELSTAT	10/29/15
G150211	MET Exon 14 Deletion Test	10/29/15
G150214	HAC Coil Transcranial Magnetic Stimulation (DTMS) Device	10/29/15
G150218	Halo Craniofacial Nerve Stimulator; Earpiece Wearable Antenna	11/06/15
G150220	Edwards SAPIEN 3 Transcatheter Heart Valve [sizes 20mm, 23mm, 26mm, 29mm], Edwards Commander Delivery System, Edwards Balloon Catheter, Crimper	11/06/15
G150222	Penumbra Apollo System	11/12/15
G150223	High Resolution Microendoscope (HRME). Portable Screening System (PS2.1/PS3)	11/12/15
G150224	Thorflex Hybrid	11/13/15
G150225	Venous External Support (VEST) Device	11/13/15
G150226	BreathID MCS System <sup>13</sup> C-Methacetin Breath Test (MBT)	11/13/15
G150207	Low surgical risk transcatheter aortic valve replacement (TAVR)	11/19/15
G150228	Panpac Vaginal Pessary [distributed in the US under the	11/19/15

IDE	Device	Start Date
	company name Bioteque America Inc.	
G150227	Precision Spinal Cord Stimulator	11/20/15
G150232	Vessix Renal Denervation System	11/20/15
G150212	Espiner Tissue Retrieval System	11/24/15
G150230	Prosigna Breast Cancer Gene Signature Assay for use on nCounter Dx Analysis System	11/24/15
G150233	Roche cobas ADCY9 Genotype Test; Roche cobas 4800 system Sample Preparation Kit [240 tests, 960 tests]; Roche cobas 4800 System Lysis Kit 1 [240 tests, 960 tests]; Roche	11/24/15
G150235	FGFR-CTA Clinical Trial Assay (FGFR-CTA)	11/25/15
G150234	Intergrated Diagnostics Driven Diuretic and Chronic Medication Management for Heart Failure (INTERVENE-HF)	12/02/15
G150139	CarboClear Pedicle Screw System	12/02/15
G150101	ROX COUPLER	12/04/15
G150236	Halo Migraine System (HMS), Halo Stimulator, Earpiece Wearable Antenna	12/04/15
G150237	Vercise DBS System; MagPro R30 Magnetic Stimulator, MCF-B65 coil	12/04/15
G150185	WallFlex Pancreatic RX Fully Covered Soft Stent System	12/10/15
G140249	ROADSAVER Carotid Artery Stent System and NANOPARASOL Embolic Protection Device	12/11/15
G150238	Safety and efficacy of remote programming of Nucleus cochlear implants	12/11/15
G150200	WATCHMAN FLX Left Atrial Appendage Closure (LAAC) Device	12/14/15
G150246	Brainsway Deep Transcranial Magnetic Stimulation (TMS) Machine	12/16/15
G150243	The Spanner Temporary Prostatic Stent	12/16/15
G150144	RECOR PARADISE RENAL DENERVATION SYSTEM (PARADISE SYSTEM)	12/17/15
G150252	The Edwards SAPIEN 3 Transcatheter Heart Valve	12/17/15
G150248	Venovo Venous Stent System	12/18/15
G150251	Valiant Evo Thoracic Stent Graft System	12/18/15
G150253	Restylane Silk	12/18/15
G150216	dEEG-guided rTMS for treatment of epileptic seizures	12/18/15
G150260	Self-Centering Guide Catheter	12/21/15
G150264	Dexcom G5 Mobile Continuous Glucose Monitoring System	12/22/15
G150181	ImageReady MR Conditional Defibrillation System	12/22/15
G150196	Neocis Guidance System (NGS)	12/22/15
G150164	Cordis Precise Pro Rx Nitinol Stent System	12/23/15
G150254	PINPOINT Endoscopic Fluorescence Imaging System (PINPOINT)	12/23/15
G150255	Visualase Thermal Therapy System (VTTS), Visualase Cooled Laser Applicator System (VCLAS), Visualase Software, PHOTEX 15 W DIODE LASER SERIES 980, 810, 940, Peristaltic Pump	12/23/15
G150262	OL-1000	12/25/15

IDE	Device	Start Date
G150128	MED SYSTEM MODEL MED-WS1, MED-MB1	12/27/15
G150265	InPress Technologies Post Partum Hemorrhage Device	12/30/15

**Addendum VI: Approval Numbers for Collections of Information (October through December 2015)**

All approval numbers are available to the public at [Reginfo.gov](http://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](http://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 2015)**

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 at: <http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage> For questions or additional information, contact Lori Ashby (410-786-6322).

Facility	Provider Number	Effective Date	State
<b>The following facilities are new listings for this quarter.</b>			
Valley View Hospital Association 1906 Blake Avenue Glenwood Springs, CO 81601	060075	10/09/2015	CO
St. Rita’s Medical Center 730 West Market Street Lima, OH 45801	1811939887	11/09/2015	OH
White Plains Hospital 41 East Post Road White Plains, NY 10601	330304	11/09/2015	NY

**Addendum VIII:**

**American College of Cardiology’s National Cardiovascular Data Registry Sites (October through December 2015)**

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](http://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](http://www.ncdr.com/webncdr/common). For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

Facility	City	State
<b>The following facilities are new listings for this quarter.</b>		
The Mount Sinai Hospital of Queens	Long Island	NY
Patients’ Hospital of Redding	Redding	CA
Johnston Memorial Hospital	Abingdon	VA
Saint Joseph East	Lexington	KY
Brownwood Hospital, LP	Brownwood	TX
Lucile S Packard Children’s Hospital at Stanford U	Palo Alto	CA

**Addendum IX: Active CMS Coverage-Related Guidance Documents (October through December 2015)**

CMS issued a guidance document on November 20, 2014 titled “Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document”. Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS’s implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27>. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin (410-786-7205).

**Addendum X:**

**List of Special One-Time Notices Regarding National Coverage Provisions (October through December 2015)**

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at [www.cms.hhs.gov/coverage](http://www.cms.hhs.gov/coverage). For questions or additional information, contact JoAnna Baldwin (410-786 7205).

**Addendum XI: National Oncologic PET Registry (NOPR) (October through December 2015)**

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 additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. 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 (October through December 2015)**

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 at <http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage>. For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

Facility	Provider Number	Date Approved	State
<b>The following facilities are new listings for this quarter.</b>			
Advocate Christ Medical Center 4440 W. 95th Street Oak Lawn, IL 60505	140208	9/28/2015	IL
Hackensack University Medical Center 30 Prospect Avenue Hackensack, NJ 07601	31001	10/20/2015	NJ
University of California, Davis Medical Center (UCDMC) 2315 Stockton Blvd Sacramento, CA 95817	050599	11/25/2015	CA

**Addendum XIII: Lung Volume Reduction Surgery (LVRS) (October through December 2015)**

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 updates to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at [www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage). For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

**Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (October through December 2015)**

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).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS's minimum facility standards [FR Doc. 2016-02108 Filed: 2/3/2016 8:45 am; Publication Date: 2/4/2016]

for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at [www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage). For questions or additional information, contact Sarah Fulton, MPH (410-786-2749).

**Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (October through December 2015)**

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

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