

thus make Commission operations more efficient and effective.

To better align the terms of service with Commission operations, the terms of all current members are hereby extended for 4 months. The following members' terms will expire on April 30, 2017: Sharon Carte, Andrea Cohen, Herman Gray, Norma Martinez Rogers, and Sara Rosenbaum. The following members' terms will expire on April 30, 2018: Gustavo Cruz, Leanna George, Marsha Gold, Charles Milligan, Sheldon Retchin, and Peter Szilagyi. The following members' terms will expire on April 30, 2019: Brian Burwell, Toby Douglas, Christopher Gorton, Stacey Lampkin, Penny Thompson, and Alan Weil.

Subsequent appointments will be for 3 years.

**Gene L. Dodaro,**  
*Comptroller General of the United States.*  
[FR Doc. 2016-10535 Filed 5-6-16; 8:45 am]  
**BILLING CODE 1610-02-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-9097-N]

### Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—January Through March 2016

**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 January through March 2016, relating to the Medicare and Medicaid programs and other programs administered by CMS.

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

Addenda	Contact	Phone number
I CMS Manual Instructions .....	Ismael Torres .....	(410) 786-1864
II Regulation Documents Published in the <b>Federal Register</b> .....	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 Fulton .....	(410) 786-2749
VIII American College of Cardiology-National Cardiovascular Data Registry Sites .....	Sarah Fulton .....	(410) 786-2749
IX Medicare's Active Coverage-Related Guidance Documents .....	JoAnna Baldwin .....	(410) 786-7205
X One-time Notices Regarding National Coverage Provisions .....	JoAnna Baldwin .....	(410) 786-7205
XI National Oncologic Positron Emission Tomography Registry Sites .....	Stuart Caplan, RN, MAS .....	(410) 786-8564
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities .....	Linda Gousis .....	(410) 786-8616
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities .....	Sarah Fulton .....	(410) 786-2749
XIV Medicare-Approved Bariatric Surgery Facilities .....	Sarah Fulton, MHS .....	(410) 786-2749
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials .....	Stuart Caplan, RN, MAS .....	(410) 786-8564
All Other Information .....	Annette Brewer .....	(410) 786-6580

## I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871,

1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

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

## II. 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 Web site 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 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>.

Dated: April 29, 2016.

**Kathleen Cantwell,**

*Director, Office of Strategic Operations and Regulatory Affairs.*

#### **Publication Dates for the Previous Four Quarterly Notices**

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: April 24, 2015 (80 FR 23013) August 3, 2015 (80 FR 45980) November 13, 2015 (80 FR 70218) and February 4, 2016 (81 FR 6009). 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 Web site to access this information and a contact person for questions or additional information.

#### **Addendum I: Medicare and Medicaid Manual Instructions (January Through March 2016)**

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 Web site at [www.cms.gov/Manuals](http://www.cms.gov/Manuals).

Transmittal No.	Manual/subject/publication No.
<b>Medicare General Information (CMS-Pub. 100–01)</b>	
97 .....	<p>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.</p> <p>Standardized Terminology for Claims Processing Systems.</p> <p>Standard Terminology Chart.</p> <p>Release Software.</p> <p>Implementing Validated Workarounds for Shared System Claims Processing by All Medicare DME MACs.</p> <p>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).</p> <p>Shared System Testing Requirements for Shared System Maintainers, Single Testing Contractor (STC), and DME MACs.</p> <p>Minimum Testing Standards for Shared System Maintainers and the Single Testing Contractor (STC)/Beta Testers.</p> <p>Testing Standards Applicable to all Beta Testers.</p> <p>Part A/Part B (A/B) Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) (User) Testing Requirements 7/40.3.6/Testing Requirements Applicable to all CWF Data Centers (Hosts).</p> <p>Timeframe Requirements for all Testing Entities.</p> <p>Testing Documentation Requirements.</p> <p>Definitions.</p> <p>Test Case Specification Standard.</p> <p>Next Generation Desktop (NGD) Requirements.</p>

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Transmittal No.	Manual/subject/publication No.
	Reserved.
	Reserved.
	Reserved.
	Reserved.
3442 .....	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3443 .....	Manual Update to Pub. 100–04, Chapter 20, to Include Used Rental Equipment.
3444 .....	Payment for Purchased Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Furnished to Medicare Beneficiaries Residing Outside the U.S.—Expatriate Beneficiaries.
3445 .....	Off-Cycle Update to the Long Term Care Hospital (LTCH) Prospective Payment System (PPS) Fiscal Year (FY) 2016 Pricer Budget Neutrality Offset.
3446 .....	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3447 .....	New Physician Specialty Code for Dentist Physician Specialty Codes.
3448 .....	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3449 .....	Off-Cycle Update to the Inpatient Prospective Payment System (IPPS) Fiscal Year (FY) 2016 Pricer.
3450 .....	April 2016 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files.
3451 .....	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3452 .....	Additional Fields Added to the Outlier Reconciliation Lump Sum Utility Procedure for Medicare Contractors to Perform and Record Outlier Reconciliation Adjustments.
3453 .....	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3454 .....	Correction to Applying Therapy Caps to Maryland Hospitals and Billing Requirement for Rehabilitation Agencies and Comprehensive Outpatient Rehabilitation Facilities (CORFs). Payments on the MPFS for Providers With Multiple Service Locations. Part B Outpatient Rehabilitation and Comprehensive Outpatient Rehabilitation Facility (CORF) Services—General.
3455 .....	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3456 .....	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3457 .....	New Condition Code for Reporting Home Health Episodes With No Skilled Visits.
3458 .....	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3459 .....	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
3460 .....	Screening for Cervical Cancer With Human Papillomavirus (HPV). Testing—National Coverage Determination (NCD). Screening for Cervical Cancer with Human Papillomavirus Testing. Screening Pap Smears: Healthcare Common Procedure Coding System (HCPCS) Codes for Billing. Screening Pap Smears: Diagnoses Codes. TOB and Revenue Codes for Form CMS–1450. MSN Messages. Remittance Advice Codes.
3461 .....	Screening for the Human Immunodeficiency Virus (HIV) Infection. Healthcare Common Procedure Coding System (HCPCS) for HIV Screening Tests. Billing Requirements. Payment Method. Types of Bill (TOBs) and Revenue Code. Diagnosis Code Reporting.
3462 .....	Medicare Summary Notice (MSN) and Claim Adjustment Reason Codes (CARCs).
3463 .....	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3464 .....	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
3465 .....	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3466 .....	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
3467 .....	Common Edits and Enhancements Modules (CEM) Code Set Update.
3468 .....	Healthcare Provider Taxonomy Codes (HPTCs) April 2016 Code Set Update.
3469 .....	Medicare Internet Only Manual (IOM) Publication 100–04 Chapter 27 Contractor Instructions for CWF.
3470 .....	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB)—April CY 2016 Update.
3471 .....	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3472 .....	April 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS). Billing Instructions for IMRT Planning Billing for Multi-Source Photon (Cobalt 60-Based) Stereotactic Radiosurgery (SRS) Planning and Delivery.
3473 .....	July Quarterly Update to 2016 Annual Update of HCPCS Codes Used for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Enforcement.
3474 .....	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3475 .....	Updates to Pub. 100–04, Chapters 4 and 5 to Correct Remittance Updates to Pub. 100–04, Chapters 4 and 5 to Correct Remittance. Advice Messages. Remittance Advice Coding Used in this Manual. Editing Of Hospital Part B Inpatient Services: Reasonable and Necessary Part A Hospital Inpatient Denials. Editing Of Hospital Part B Inpatient Services: Other Circumstances in Which Payment Cannot Be Made under Part A. Assistant at Surgery Medicare Summary Notice (MSN) and Remittance Advice (RA) Messages. Co-surgeon Services Medicare Summary Notice (MSN) and Remittance Advice (RA) Messages. Codes. Claims Processing Requirements for Financial Limitations/Multiple Procedure Payment Reductions for Outpatient Rehabilitation Services.

Transmittal No.	Manual/subject/publication No.
3476 .....	<p>Coding Guidance for Certain CPT Codes—All Claim Advice Messages.</p> <p>Telehealth Services.</p> <p>List of Medicare Telehealth Services.</p> <p>Payment for ESRD-Related Services as a Telehealth Service.</p> <p>Payment for Subsequent Hospital Care Services and Subsequent Nursing Facility Care Services as Telehealth Services.</p> <p>Payment for Diabetes Self-Management Training (DSMT) as a Telehealth Service.</p> <p>Originating Site Facility Fee Payment Methodology.</p> <p>Payment Methodology for Physician/Practitioner at the Distant Site.</p> <p>Submission of Telehealth Claims for Distant Site Practitioners.</p>
3477 .....	April 2016 Integrated Outpatient Code Editor (I/OCE) Specifications Version 17.1.
3478 .....	April 2016 Update of the Ambulatory Surgical Center (ASC) Payment System.
3479 .....	New Waived Test.
3480 .....	Instructions for Downloading the Medicare ZIP Code File for July 2016.
3481 .....	<p>Updates to Pub. 100–04, Chapters 3, 6, 7 and 15 to Correct Remittance Advice Messages.</p> <p>Payment for Blood Clotting Factor Administered to Hemophilia.</p> <p>Inpatients.</p> <p>Pancreas Transplants Kidney Transplants.</p> <p>Pancreas Transplants Alone (PA).</p> <p>Intestinal and Multi-Visceral Transplants.</p> <p>Billing for Abortion Services.</p> <p>Remittance Advices.</p> <p>Remittance Advice Impact.</p> <p>Recording Determinations of Excepted/Nonexcepted Care on Claim Records.</p> <p>Reject and Unsolicited Response Edits.</p> <p>Edit for Clinical Social Workers (CSWs).</p> <p>Editing of Skilled Nursing Facilities Part B Inpatient Services.</p> <p>Additional Introductory Guidelines.</p> <p>ZIP Code Determines Fee Schedule Amounts.</p> <p>Coding Instructions for Paper and Electronic Claim Forms.</p>
3482 .....	Quarterly Update to the Correct Coding Initiative (CCI) Edits, Version 22.2, Effective July 1, 2016.
3483 .....	April 2016 Integrated Outpatient Code Editor (I/OCE) Specifications Version 17.1.
3484 .....	Medicare Internet Only Manual Publication 100–04 Chapter 26—Completing and Processing Form CMS–1500 Data Set.
3485 .....	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for July 2016.
3486 .....	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
3487 .....	Corrections to Recoding in the Home Health (HH) Pricer Program.
3488 .....	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP)—July 2016.
<b>Medicare Secondary Payer (CMS-Pub. 100–05)</b>	
00 .....	None.
<b>Medicare Financial Management (CMS-Pub. 100–06)</b>	
258 .....	Notice of New Interest Rate for Medicare Overpayments and Underpayments 2nd Qtr Notification for FY 2016.
259 .....	<p>Internet Only Manual Pub. 100–06, Chapter 4 Revisions to Reflect the New Debt Referral Requirements Mandated by the Digital Accountability and Transparency Act of 2014 (DATA Act).</p> <p>Requirements for Collecting Part A and B Non-MSP Provider Overpayments.</p> <p>Required Timeframes for Debt Collection Process for Provider Non-MSP Overpayments.</p> <p>Referral Requirements.</p> <p>Debts RTA by Treasury as paid in Full (RP), Satisfied Payment Agreement (RS) or Satisfied Compromise (RC)—Exhibit 1 Intent to Refer Letter (IRL).</p>
260 .....	Revision to Chapter 3 Section 200: Limitation on Recoupment—Medicare Overpayments Manual.
261 .....	Monitoring Accounts Receivable that are in a Redetermination or Reconsideration Status.
262 .....	New Physician Specialty Code for Dentist Physician/Limited License Physician Specialty Codes.
263 .....	Contractor Reporting of Operational and Workload Data (CROWD) Form 5.
264 .....	<p>Update with Revisions to Pub. 100–06 Medicare Financial Management Manual, Chapter 6.</p> <p>Extended Repayment Schedule (ERS) Manual Updates.</p> <p>Establishing an Extended Repayment Schedule (ERS)—(formerly known as an Extended Repayment Plan (ERP)).</p> <p>ERS Required Documentation—Physician is a Sole Proprietor.</p> <p>ERS Required Documentation—Provider is an Entity Other Than a Sole Proprietor.</p>
265 .....	<p>Contractor Reporting of Operational and Workload Data (CROWD) Form 5.</p> <p>Update with Revisions to Pub. 100–06 Medicare Financial Management Manual, Chapter 6.</p> <p>Medicare Contractor Transaction Report (CROWD Form 5).</p> <p>Heading.</p> <p>Body of Report.</p>
<b>Medicare State Operations Manual (CMS-Pub. 100–07)</b>	
152 .....	Revisions to the State Operations Manual (SOM) Chapter 2 Numbering System for CMS Certification Numbers (CCN).

Transmittal No.	Manual/subject/publication No.
153 .....	CCN for Medicare Providers. Revisions to the State Operations Manual (SOM) Chapter 9 Exhibits.
<b>Medicare Program Integrity (CMS-Pub. 100–08)</b>	
635 .....	Clarification to Language Regarding Proof of Delivery Requirements in Pub. 100–08, Chapter 4, Section 4.26.1.
636 .....	Proof of Delivery and Delivery Methods. Update to Pub. 100–08, Chapter 15. Medicare Contractor Duties. Correspondence Address and E-mail Addresses. Tax Identification Numbers (TINs) of Owning and Managing. Organizations and Individuals. Form CMS–855A and Form CMS–855B Signatories. Delegated Officials. Technicians. Supervising Physicians. Processing Form CMS–855R Applications. Inter-Jurisdictional Reassignments. Form CMS–855 Applications That Require a Site Visit. Form CMS–855 Applications That Do Not Require a Site Visit. General Timeliness Principles. Receipt/Review of Internet-Based PECOS Applications. Verification of Data/Processing Alternatives. Special Program Integrity Procedures. Tie-In/Tie-Out Notices and Referrals to the State/RO. Ambulatory Surgical Centers (ASCs)/Portable X-ray Suppliers (PXRS). Tie-In/Tie-Out Notices and Referrals to the State/RO. Processing of Registration Applications. Disposition of Registration Applications. Revocation of Registration. Registration Letters. Returns. Denials. Non-Certified Suppliers and Individual Practitioners. Existing or Delinquent Overpayments. Contractor Communications. Application Fees. Movement of Providers and Suppliers into the High Level. Web Sites. Release of Information. Model Letter Guidance. Approval Letter Guidance. Appeals Process. Corrective Action Plans (CAPs). Reconsideration Requests—Non-Certified Providers/Suppliers. Corrective Action Plans (CAPs). Reconsideration Requests—Certified Providers and Certified Suppliers. HHA Ownership Chang. Revocations. Other Identified Revocations. External Reporting Requirements. Reserved for Future Use.
637 .....	Comprehensive Error Rate Testing (CERT) program Treatment of Claims in the Prior Authorization Model.
638 .....	Issued to a specific audience, not posted to Internet/Intranet to Confidentiality of Instruction.
639 .....	Issued to a specific audience, not posted to Internet/Intranet to Confidentiality of Instruction.
640 .....	Issued to a specific audience, not posted to Internet/Intranet to Confidentiality of Instruction.
641 .....	Proof of Delivery in Nursing Facilities.
642 .....	Medicare Program Integrity Changes—Pub. 100–08 Chapter 7.
<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.

Transmittal No.	Manual/subject/publication No.
<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>	
133 .....	Issued to a specific audience, not posted to Internet/Intranet to 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.
136 .....	Issued to a specific audience, not posted to Internet/Intranet to Confidentiality of Instruction.
137 .....	Implementation of the Part B Drug Payment Model (Phase 1).
138 .....	Issued to a specific audience, not posted to Internet/Intranet to Confidentiality of Instruction.
139 .....	Oncology Care Model (OCM) Monthly Enhanced Oncology Services (MEOS) Payment Implementation.
140 .....	Comprehensive Care for Joint Replacement Model (CJR) Provider Education.
141 .....	Medicare Care Choices Model (MCCM)—Per Beneficiary per Month Payment (PBPM)—Implementation.
<b>One Time Notification (CMS-Pub. 100–20)</b>	
1590 .....	Implementation of Procedures for Undeliverable Medicare Summary Notices (uMSNs).
1591 .....	Changes to the Medicare Electronic Health Record (EHR) Incentive Program Payment Adjustment beginning January 1, 2016.
1592 .....	Award of Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Contract for Jurisdiction D.
1593 .....	Health Insurance Portability and Accountability Act (HIPAA) EDI Front End Updates for July 2016.
1594 .....	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
1595 .....	Issuing Continuing Compliance Letters to Specific Providers and Suppliers.
1596 .....	Required Billing Updates for Rural Health Clinics.
1597 .....	System Specific Enhancement 2014: Create A Single Trailer-Generating Module in Common Working File (CWF).
1598 .....	Shared System Enhancement 2015 Resolve Operating Report (ORPT) Issues, Analysis and Design.
1599 .....	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
1600 .....	Award of Medicare Administrative Contractor (MAC) Contract for Jurisdiction 15.
1601 .....	Payment Clarification for the Purchase of Used Inexpensive and Routinely Purchased Durable Medical Equipment (DME) when Previously Rented.
1602 .....	Part B Detail Line Expansion—MCS Phase 4.
1603 .....	Part B Detail Line Expansion—MCS Phase.
1604 .....	Part B Detail Line Expansion—MCS Phase 1.
1605 .....	Common Working File (CWF) Daily Beneficiary Extract Files Reaching Maximum Record Size, Analysis and Design for Possible Data Reorganization.
1606 .....	Shared System Enhancement 2015 Edit Control/Override Table, Analysis and Design.
1607 .....	Shared System Enhancement 2015 Improve Efficiency of Drug Code Provider, and Procedure and Diagnosis Codes Processing, Analysis and Design.
1608 .....	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
1609 .....	Accredited Standards Committee (ASC) X12 Healthcare Claims Acknowledgement (277CA) Flat File Update.
1610 .....	System Specific Enhancement 2014: Fiscal Intermediary Standard System (FISS) Edit/Rules Engine Analysis and Design.
1611 .....	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
1612 .....	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
1613 .....	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
1614 .....	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
1615 .....	Advance Care Planning (ACP) Services furnished by Rural Health Clinics (RHCs).
1616 .....	Updating the Fiscal Intermediary Shared System (FISS) to Make Payment for Drugs and Biologicals Services for Outpatient Prospective Payment System (OPPS) Providers.
1617 .....	System Specific Enhancement 2014: String Testing Automation.
1618 .....	System Specific Enhancement 2015: Replace FISS ACS/Development Letters with HP Exstream, Analysis Only.
1619 .....	Revision to Fiscal Intermediary Shared System (FISS) Lab Travel Allowance Editing to Include New Specimen Collection Code G0471.
1620 .....	Shared System Enhancement 2015: National Coverage Determination (NCD) Analysis Process.
1621 .....	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
1622 .....	Shared System Enhancement 2015 Analysis and Design HUOPCUT Hospice Period and Health Maintenance Organization (HMO) Processing.
1623 .....	Using scrubbed Medicare beneficiary/legal rep address data within the Fee-For-Service (FFS) systems—Analysis and Design.

Transmittal No.	Manual/subject/publication No.
1624 .....	System Specific Enhancement 2015: Fiscal Intermediary Standard System (FISS) Enhanced Purge Process.
1625 .....	Identifying "No Documentation" Medical Necessity Denials for Claims Flagged for Recovery Auditor Review.
1626 .....	Reclassification of Certain Durable Medical Equipment HCPCS Codes Included in Competitive Bidding Programs (CBP) from the Inexpensive and Routinely Purchased Payment Category to the Capped Rental Payment Category.
1627 .....	Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP): Implementation of Round 2 Recompete of the DMEPOS CBP Program and National Mail Order (NMO) Recompete.
1628 .....	Identification of Obsolete Shared System Maintainer (SSM) On-Request Jobs—VMS.
1629 .....	Identification of Obsolete Shared System Maintainer (SSM) Reports—VMS.
1630 .....	Coding Revisions to National Coverage Determinations.
1631 .....	Shared System Enhancement 2015 Edit Control/Override Table, Analysis and Design.
1632 .....	Shared System Enhancement 2015 Resolve Operating Report (ORPT) Issues, Analysis and Design.
1633 .....	Settlement Effectuation Instructions for the Department of Health and Human Services' (DHHS) Office of Medicare Hearings and Appeals (OMHA) Settlement Conference Facilitation (SCF) Pilot Related to Part A Appeals (Phase 3).
1634 .....	Implementation of the Award for Jurisdiction A Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Workload.
1635 .....	VIPS Medicare System (VMS), Analysis and Design for Jurisdiction A (JA) and Jurisdiction B (JB) Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs) Transitions.
1636 .....	Implementation of the Award for Jurisdiction B Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Workload.
1637 .....	Required Billing Updates for Rural Health Clinics.
1638 .....	Reclassification of Certain Durable Medical Equipment HCPCS Codes Included in Competitive Bidding Programs (CBP) from the Inexpensive and Routinely Purchased Payment Category to the Capped Rental Payment Category.
1639 .....	Reporting Principal and Interest Amounts When Refunding Previously Recouped Money on the Remittance Advice (RA).
1640 .....	End Stage Renal Disease (ESRD) Cost Audits.
<b>Medicare Quality Reporting Incentive Programs (CMS-Pub. 100–22)</b>	
53 .....	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
54 .....	Fiscal Year 2017 and After Payments to Inpatient Rehabilitation Facilities (IRFs) That Do Not Submit Required Quality Data—This CR Rescinds and Fully Replaces CR 9106.
55 .....	Fiscal Year 2017 and After Payments to IRFs That Do Not Submit Required Quality Data.
<b>Information Security Acceptable Risk Safeguards (CMS-Pub. 100–25)</b>	
.....	None.

## Addendum II: Regulation Documents Published in the Federal Register (January through March 2016)

### 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 Web site <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 Web site at: <http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-1Q16QPU.pdf>

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

### Addendum III: CMS Rulings (January through March 2016)

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 (January through March 2016)

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 Web site. 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:

[www.cms.gov/medicare-coverage-database/](http://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
Screening for the Human Immunodeficiency Virus (HIV) Infection.	NCD 210.7 .....	R190	02/05/2016	04/13/2015
Screening for Cervical Cancer With Human Papillomavirus (HPV) Testing—National Coverage Determination (NCD).	NCD 210.2.1 .....	R189	02/02/2016	07/09/2015

#### Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (January through March 2016)

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
BB16806 .....	MarrowStim P.A.D. Kit: Concentration of autologous bone marrow aspirate (cBMA)	01/22/2016
G130034 .....	BIOFREEDOM Drug Coated Coronary Stent System .....	02/10/2016
G150002 .....	Silhouette Instalift .....	01/08/2016
G150154 .....	RA-308 Excimer Laser System and DABRA Catheter Model 101 .....	01/08/2016
G150269 .....	Sodium Hyaluronate (1%) Ophthalmic Viscoelastic Devices (OVD), Sodium Hyaluronate (2.3%) Ophthalmic Viscoelastic Devices (OVD).	01/06/2016
G150270 .....	Embozene Microspheres .....	01/08/2016
G150273 .....	Medtronic Activa PC+S Deep Brain Stimulation System .....	01/15/2016
G150275 .....	Optune (Novocure's Tumor Treating Electric Fields [TTFIELDS] Therapy) .....	03/24/2016
G150278 .....	SAPIEN 3 Transcatheter Heart Valve and Accessories .....	01/14/2016
G150282 .....	Berlin Heart EXCOR Pediatric Ventricular Assist Device .....	01/28/2016
G160002 .....	FlowTrieve Retrieval/Aspiration System .....	02/03/2016
G160004 .....	Embosphere Microspheres .....	02/04/2016
G160008 .....	Investigational LabCorp MGMT Methylation-Specific PCR Companion Diagnostic Assay.	02/10/2016
G160009 .....	Medtronic PC+S Deep Brain Stimulation system .....	02/11/2016
G160011 .....	CP950 Sound Processor (Kanso) .....	02/17/2016
G160015 .....	JetStream (Boston Scientific) Atherectomy .....	02/19/2016
G160018 .....	Deep brain stimulation (DBS) in patients with refractory chronic neuropathic pain ....	03/23/2016
G160019 .....	CT-DBS for Traumatic Brain Injury using the Medtronic Activa PC+S System .....	02/26/2016
G160021 .....	A Feasibility Study to Evaluate Safety and Initial Effectiveness of MR-Guided Focused Ultrasound Ablation Therapy in the Treatment of Subcortical Lesional Epilepsy.	03/02/2016
G160022 .....	CoreValve Evolut R System, Medtronic CoreValve System .....	02/17/2016
G160023 .....	NeuroStar TMS Therapy System with the NeuroStar XPLORE Clinical Research System.	03/04/2016
G160025 .....	Medtronic DBS Lead Model 3387 .....	03/04/2016
G160028 .....	NeuroBlate System .....	03/09/2016
G160029 .....	VENTANA HA CDx Assay .....	03/10/2016
G160033 .....	Veterans Administration Lung Cancer Surgery or Stereotactic Radiotherapy (VALOR).	03/09/2016
G160035 .....	Misago RX Self-expanding Peripheral Stent .....	03/17/2016
G160038 .....	MYELOTec VIDEO GUIDED CATHETER; MYELOTec MYELOSOCPE .....	03/17/2016
G160039 .....	Medtronic TAVR 2.0 System .....	03/16/2016
G160041 .....	The Ulthera System; DS 4-4.5S, Simulines Transducer; DS 4-3.0S, Simulines Transducer; DS 4-4.5, Standard Transducer; DS 7-3.0, Standard Transducer.	03/18/2016
G160042 .....	LUMENATI SYSTEM .....	03/18/2016
G160043 .....	Senza Spinal Cord Stimulation (SCS) System .....	03/23/2016
G160045 .....	NeuroStar TMS Therapy System with the NeuroStar XPLORE Clinical Research System.	03/24/2016

**Addendum VI: Approval Numbers for Collections of Information (January through March 2016)**

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/MedicareApprovedFacilities/CASF/list.asp#TopOfPage> For questions or additional information, contact Lori Ashby (410-786-6322).

Facility	Provider No.	Effective date	State
<b>The following facilities are new listings for this quarter</b>			
Community Medical Center Barnabas Health, 99 Highway 37 West Toms River, NJ 08755.	310041	01/07/2016	NJ.
Las Palmas Medical Center, 1801 North Oregon, El Paso, TX 79902 .....	1770536120	01/07/2016	TX.
Sky Ridge Medical Center, 10101 Ridgeway Parkway, Lone Tree, CO 80124 .....	060112	01/04/2016	CO.
McLaren Port Huron, 1221 Pine Grove Port, Huron, MI 48061 .....	1982685384	01/04/2016	MI.
DMC Huron Valley—Sinai Hospital, 1 Williams Carls Drive, Commerce, MI 48382 .....	1922310200	01/04/2016	MI.
Valley Baptist Medical Center—Brownsville, PO Box 450028, 1040 West Jefferson, Brownsville, TX 78520.	450028	03/09/2016	TX.
Manchester Memorial Hospital, 71 Haynes Street, Manchester, CT 06040 .....	1457399198	03/09/2016	CT.
Grand Stand Medical Center, 809 82nd Parkway, Myrtle Beach, SC 29572 .....	1083668669	03/23/2016	SC.
Ben Taub Hospital, 1504 Taub Loop, Houston, TX 77030 .....	450289	03/30/2016	TX.
<b>The following facilities have editorial changes (in bold)</b>			
FROM: Saint Joseph Medical Center, TO: St. Joseph Medical Center, 2500 Bernville Road, Reading, PA 19605.	390096	04/01/2005	PA.
FROM: Helen Ellis Memorial Hospital, TO: Florida Hospital North Pinellas, 1395 South Pinellas Avenue, Tarpon Springs, FL 34689.	100055	01/20/2009	FL.
<b>The following facility has been removed from the listing of approved facilities</b>			
Rockingham Memorial Hospital, 235 Cantrell Avenue, Harrisonburg, VA 22801 .....	490004	06/30/2010	VA.

**Addendum VIII: American College of Cardiology's National Cardiovascular Data Registry Sites (January through March 2016)**

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 Web site 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 Web site 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>		
Saint Francis Hospital .....	Columbus	GA.
CGH Medical Center .....	Sterling	IL.
Longmont United Hospital .....	Longmont	CO.
La Paz Regional Hospital .....	Parker	AZ.
Carlsbad Medical Center .....	Carlsbad	NM.
Pacific Surgery Center .....	Costa Mesa	CA.
Memorial Care Outpatient Surgical Center of Long Beach .....	Long Beach	CA.
Pearland Medical Center (HCA) .....	Pearland	TX.
Alaska Native Medical Ctr .....	Anchorage	AK.
Bronx-Lebannon Hospital Center .....	Bronx	NY.
Kentuckiana Medical Center .....	Clarksville	IN.
Wheaton Franciscan Healthcare—Franklin, Inc .....	Milwaukee	WI.
Andalusia Regional Hospital .....	Andalusia	AL.
Parkway Surgical & Cardiovascular Hospital .....	Fort Worth	TX.
Bay Area Regional Medical Center .....	Webster	TX.
Sanford Bemidji Medical Center .....	Bemidji	MN.
Flushing Hospital Medical Center .....	Flushing	NY.
Garden Park Medical Center .....	Gulfport	MS.
Silicon Valley Interventional Surgery Center .....	Houston	TX.
Surgery Center of Enid, Inc. ....	Enid	OK.
UPMC East .....	Monroeville	PA.
Straith Hospital For Special Surgery .....	Southfield	MI.
Bay Area Hospital .....	Coos Bay	OR.
Kaiser Permanente Irvine Medical Center .....	Irvine	CA.
Cohen Children's Medical Center .....	New Hyde Park	NY.
<b>The following facilities are terminated</b>		
St. Elizabeth Healthcare Florence .....	Florence	KY.
Lakewood Hospital .....	Lakewood	OH.
Mease Dunedin Hospital .....	Dunedin	FL.
Baylor All Saints Medical Center .....	Dallas	TX.
Regional Medical Center of Acadiana .....	Lafayette	LA.
CHI Health St. Elizabeth .....	Lincoln	NE.
Ochsner North Shore Covington .....	Covington	LA.
Central Carolina (LifePoint) .....	Sanford	NC.
Mohammed Bin Khalifa Cardiac Centre .....	Riffa	International.
Rockdale Medical Center .....	Conyers	GA.

#### **Addendum IX: Active CMS Coverage-Related Guidance Documents (January through March 2016)**

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 (January through March 2016)**

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) (January through March 2016)**

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/MedicareApprovedFacilities/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 (January through March 2016)**

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, there were no 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/MedicareApprovedFacilities/VAD/list.asp#TopOfPage>. For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

**Addendum XIII: Lung Volume Reduction Surgery (LVRS) (January through March 2016)**

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/MedicareApprovedFacilities/LVRS/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilities/LVRS/list.asp#TopOfPage). For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

**Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (January through March 2016)**

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 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/MedicareApprovedFacilities/BSF/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilities/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 (January through March 2016)**

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

This information is available on our Web site at [www.cms.gov/MedicareApprovedFacilities/PETDT/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilities/PETDT/list.asp#TopOfPage). For questions or

additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

[FR Doc. 2016-10819 Filed 5-6-16; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2015-N-4602]

**Streamlining Regulations for Good Manufacturing Practices for Hearing Aids; Public Workshop; Extension of Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or we) is extending the comment period for the document entitled "Streamlining Regulations for Good Manufacturing Practices for Hearing Aids; Public Workshop" that appeared in the **Federal Register** of January 7, 2016. In the document, FDA requested comments on the appropriate level of good manufacturing practices (GMPs) regulation to ensure the safety and effectiveness of air-conduction hearing aid devices. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments. **DATES:** FDA is extending the comment period on the document published January 7, 2016 (81 FR 784). Submit either electronic or written comments by June 30, 2016.

**ADDRESSES:** You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your