



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-9100-N]

### Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—October through December 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 October through December 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
<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, MPA	(410) 786-7491
<b>V</b> FDA-Approved Category B IDEs	John Manlove	(410) 786-6877
<b>VI</b> Collections of Information	William Parham	(410) 786-4669
<b>VII</b> Medicare –Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786-2749
<b>VIII</b> American College of Cardiology-National Cardiovascular Data Registry Sites	Sarah Fulton, MHS	(410) 786-2749
<b>IX</b> Medicare’s Active Coverage-Related Guidance Documents	JoAnna Baldwin, MS	(410) 786-7205
<b>X</b> One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(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	Linda Gousis, JD	(410) 786-8616
<b>XIII</b> Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
<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: February 16, 2017

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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 4, 2016 (81 FR 6009), May 9, 2016 (81 FR 28072), August 5, 2016 (81 FR 51901) and November 2016 (81 FR 79489). 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 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 Medicare Internet Only Manual Publication Quarterly Update to the Correct Coding Initiative (CCI) Edits, Version 22.3, Effective October 1, 2016 use (CMS-Pub. 100-04) Transmittal No. 3561.

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>	
103	Update to Medicare Deductible, Coinsurance and Premium Rates for 2017 Basis for Determining the Part A Coinsurance Amounts Part B Annual Deductible Part B Premium
<b>Medicare Benefit Policy (CMS-Pub. 100-02)</b>	
228	Internet Only Manual Updates to Pub. 100-01, 100-02 and 100-04 to Correct Errors and Omissions (SNF) Requirements - General Medicare SNF PPS Overview Medicare SNF Coverage Guidelines Under PPS Hospital Providers of Extended Care Services Three-Day Prior Hospitalization Three-Day Prior Hospitalization - Foreign Hospital Effect on Spell of Illness Medical Service of an Intern or Resident-in-Training Medical and Other Health Services Furnished to SNF Patients Services Furnished Under Arrangements With Providers

	Definition of Durable Medical Equipment
229	Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2017
230	Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Updates Index of Acronyms RHC General Information FQHC General Information RHC Staffing Requirements RHC Temporary Staffing Waivers RHC and FQHC Visits Multiple Visits on Same Day Day Payment Window RHC Services FQHC Services Emergency Services Non RHC/FQHC Services Description of Non RHC/FQHC Services RHC Payment Rate Payment Codes for FQHCs Billing Under the PPS FQHC PPS Payment Rate and Adjustments FQHC Payment Codes RHC and FQHC Cost Report Requirements RHC and FQHC Cost Report Forms RHC and FQHC Charges, Coinsurance, Deductible, and Waivers Commingling Dental, Podiatry, Optometry, and Chiropractic Services Graduate Medical Education Transitional Care Management (TCM) Services Chronic Care Management (CCM) Services Services and Supplies Furnished “Incident to” Physician’s Services Provision of Incident to Services and Supplies Incident to Services and Supplies Furnished in the Patient’s Home or Location Other than the RHC or FQHC Payment to Physician Assistants Services and Supplies Furnished Incident to NP, PA, and CNM Services Services and Supplies Incident to CP Services Mental Health Visits Physical Therapy, Occupational Therapy, and Speech Language Pathology Services Requirements for Visiting Nursing Services Treatment Plans Hospice Services Hospice Attending Practitioner Provision of Services to Hospice Patients in a RHC or FQHC Preventive Health Services Preventive Health Services in RHCs Preventive Health Services in FQHCs Copayment for FQHC Preventive Health Services

231	Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2017
<b>Medicare National Coverage Determination (CMS-Pub. 100-03)</b>	
	None
<b>Medicare Claims Processing (CMS-Pub. 100-04)</b>	
3618	Annual Update of HCPCS Codes Used for Home Health Consolidated Billing Enforcement
3619	Table of Chemistry Panels Organ or Disease Oriented Panels
3620	Update to Pub 100-04, Medicare Claims Processing Manual, Chapter 15: Ambulance SNF Billing
3621	Billing of Vaccine Services on Hospice Claims Hospice Claims for Vaccine Services Billing Requirements Claims Submitted to MACs Using Institutional Formats Payment for Pneumococcal Pneumonia Virus, Influenza Virus, and Hepatitis B Virus Vaccines and Their Administration on Institutional Claims Institutional Claims Submitted by Home Health Agencies and Hospices Payment Procedures for Renal Dialysis Facilities (RDF)
3622	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
3623	Issued to a specific audience, not posted to Internet/ Intranet to Confidentiality of Instruction
3624	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
3625	Ambulance Inflation Factor for CY 2017 and Productivity Adjustment Ambulance Inflation Factor (AIF)
3626	Fiscal Year (FY) 2017 Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) PPS Changes
3627	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
3628	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2017
3629	Denial of Home Health Payments When Required Patient Assessment Is Not Received
3630	Correcting Editing for Condition Code 54 and Updating Remittance Advice Messages on Home Health Claims
3631	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3632	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3633	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3634	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3635	Instructions to Process Services Not Authorized by the Veterans Administration (VA) in a Non-VA Facility Reported With Value Code (VC)

	42 Requirements for Processing Non Veterans Administration (VA) Authorized Inpatient Claims
3636	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - January 2017
3637	New Physician Specialty Code for Hospitalist Physician Specialty Codes
3638	Update to the Federally Qualified Health Centers (FQHC) Prospective Payment System (PPS) - Recurring File Updates
3639	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity Instruction
3640	January 2017 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
3641	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3642	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3643	Instructions for Retrieving the 2017 Pricing and HCPCS Data Files through CMS's Mainframe Telecommunications Systems
3644	Therapy Cap Values for Calendar Year (CY) 2017
3645	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3646	Quarterly Update to the Correct Coding Initiative (CCI) Edits, Version 23.0, Effective January 1, 2017
3647	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3648	Calendar Year (CY) 2017 Participation Enrollment and Medicare Participating Physicians and Suppliers Directory (MEDPARD) Procedures
3649	Payment for Oxygen Volume Adjustments and Portable Oxygen Equipment Billing for Oxygen and Oxygen Equipment
3650	Updates to Pub. 100-04, Chapters 8, 13 and 14 to Correct Remittance Advice Messages Physician Billing Requirements to the A/B MAC (B) Noninvasive Studies for ESRD Patients - Facility and Physician Services Medicare Summary Notices (MSN), Reason Codes, and Remark Codes Messages for Noncovered PET Services Coverage for PET Scans for Dementia and Neurodegenerative Diseases Billing and Coverage Changes for PET Scans Effective for Services on or After April 3, 2009 Billing and Coverage Changes for PET Scans for Cervical Cancer Effective for Services on or After November 10, 2009 Metastasis of Cancer Effective for Claims With Dates of Services on or After February 26, 2010 Local Coverage Determination for PET Using New, Proprietary Radiopharmaceuticals for their FDA-Approved Labeled Indications for Oncologic Imaging Only Denial Messages for Noncovered Bone Mass Measurements Ambulatory Surgical Center Services on ASC List Applicable Messages for NTIOLs

	Applicable Messages for ASC 2008 Payment Changes Effective January 1, 2008 Applicable ASC Messages for Certain Payment Indicators Effective for Services Performed on or after January 1, 2009
3651	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3652	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3653	Implementation of the Restructured Clinical Lab Fee Schedule
3654	2017 Annual Update to the Therapy Code List
3655	Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Implementation of Policy Changes for the CY 2017 Home Health Prospective Adjustments of Episode Payment - Outlier Payments Therapy Editing HH PPS Claims Beneficiary-Driven Demand Billing Under HH PPS Input/Output Record Layout Decision Logic Used by the Pricer on Claims Annual Updates to the HH Pricer Medical and Other Health Services Submitted Using Type of Bill 034x Billing Instructions for Disposable Negative Pressure Wound Therapy Services Payment System
3656	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2017
3657	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3658	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3659	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3660	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
3661	Claim Status Category and Claim Status Codes Update
3662	Instructions for Downloading the Medicare ZIP Code File for April 2017
3663	Common Edits and Enhancements Modules (CEM) Code Set Update
3664	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3665	Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): Committee on Operating Rules for Information Exchange (CORE) 360 Uniform Use of Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Claim Adjustment Group Code (CAGC) Rule - Update from Council for Affordable Quality Healthcare (CAQH) CORE
3666	New Waived Tests
3667	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction

3668	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - January 2017
3669	HCPCS Code Update for Preventive Services Table of Preventive and Screening Services Rural Health Clinic (RHC)/Federally Qualified Health Center (FQHC) Special Billing Instructions Deductible and Coinsurance HCPCS Code Advance Beneficiary Notice RHCs/FQHCs Special Billing Instructions RHCs/FQHCs Special Billing Instructions
3670	Update to Editing of Therapy Services to Reflect Coding Changes
3671	CY 2017 Update for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Gap-filling DMEPOS Fees
3672	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3673	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3674	January 2017 Integrated Outpatient Code Editor (I/OCE) Specifications Version 18.0
3675	2017 Healthcare Common Procedure Coding System (HCPCS) Annual Update Reminder
3676	Summary of Policies in the Calendar Year (CY) 2017 Medicare Physician Fee Schedule (MPFS) Final Rule, Telehealth Originating Site Facility Fee Payment Amount and Telehealth Services List, and CT Modifier Reduction List
3677	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3678	Prolonged Services Without Direct Face-to-Face Patient Contact Separately Payable Under the Physician Fee Schedule (Manual Update) Prolonged Services Without Direct Face-to-Face Patient Contact Service (Codes 99358 – 99359)
3679	Payment for Oxygen Volume Adjustments and Portable Oxygen Equipment Billing for Oxygen and Oxygen Equipment
3780	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3681	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
<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>	
273	Notice of New Interest Rate for Medicare Overpayments and Underpayments

	-1 <sup>st</sup> Qtr Notification for FY 2017
274	New Physician Specialty Code for Hospitalist
275	Pub. 100-06, Chapter 3, Section 90 (Provider Liability) Revision Claims Processing Timeliness - All Claims Part E - Interest Payment Data Classification of Claims for Counting Physician/Limited License Physician Specialty Codes
276	New Physician Specialty Code for Hospitalist Part D(1) - Claims Processing Timeliness - All Claims Part E - Interest Payment Data Classification of Claims for Counting Physician/Limited License Physician Specialty Codes
277	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
278	Medicare Financial Management Manual, Chapter 7, Internal Control Requirements OMB Circular A-123 GAO Standards for Internal Controls in the Federal Government Definition and Objectives Contractor Internal Control Review Process and Timeline Risk Assessment Risk Analysis Chart Certification Package for Internal Controls (CPIC) Requirements OMB Circular A-123, Appendix A: Internal Controls Over Financial Reporting (ICOFR) Certification Statement CPIC- Report of Material Weaknesses CPIC- Report of Internal Control Deficiencies Statement on Standards for Attestation Engagements (SSAE) Number 18 (SSAE 18), Reporting on Controls at Service Providers Corrective Action Plans Submission, Review, and Approval of Corrective Action Plans Corrective Action Plan (CAP) Reports CMS Finding Numbers Initial CAP Report Quarterly CAP Report CMS CAP Report Template List of CMS Contractor Control Objectives
279	Instructions to Hospitals on the Election of a Medicare-Supplemental Security Income (SSI) Component of the Disproportionate Share (DSH) Payment Adjustment for Cost Reports that Involve SSI Ratios for Fiscal Year (FY) 2004 and Earlier, or SSI Ratios for Hospital Cost-Reporting Periods for Patient Discharges Occurring Before October 1, 2004
<b>Medicare State Operations Manual (CMS-Pub. 100-07)</b>	
162	Revisions to State Operations Manual (SOM) Appendix J, Part II – Interpretive Guidelines – Responsibilities of Intermediate Care Facilities for Individuals with Intellectual Disabilities
163	Revisions to State Operations Manual (SOM) Appendix W - Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs

164	Revisions to the State Operations Manual (SOM) Chapter 2 Numbering System for CMS Certification Numbers (CCN) CCN for Medicare Providers
165	Revisions to State Operations Manual (SOM) Appendix W - Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs
<b>Medicare Program Integrity (CMS-Pub. 100-08)</b>	
678	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
679	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
680	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
681	Revision to Surety Bond Collection Procedures Claims Against Surety Bonds Model Letters for Claims Against Surety Bonds
682	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
683	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
684	Incorporation of Cycle 2 Revalidation Policies Definitions Timeliness and Accuracy Standards Standards for Initial and Revalidation Applications Form CMS-855 Applications That Require a Site Visit Form CMS-855 Applications That Do Not Require a Site Visit Web-Based Applications - Timeliness Web-Based Applications That Require a Site Visit Web-Based Applications That Do Not Require a Site Visit Paper Applications - Accuracy Web-Based Applications - Accuracy Returns Model Revalidation Letter Model Large Group Revalidation Notification Letter Model Revalidation Pend Letter Model Revalidation Deactivation Letter Model Revalidation Past-Due Group Member Letter Model Deactivation Letter due to Inactive Provider/Supplier Letter Model Return Revalidation Letter Revalidation Lists Mailing Revalidation Letters Phone Calls Pend Status Deactivation Actions Receipt of Revalidation Application Revalidation Received and Development Required Revalidation Received after a Pend is Applied Revalidation Received after a Deactivation Occurs Change of Information Received Prior to Revalidation Letter Mailed Reassignment Applications Received After Revalidation Letter Mailed

	Revalidating Providers Involved in a Change of Ownership (CHOW) Large Group Revalidation Coordination Finalizing the Revalidation Application Revalidation Reporting Revalidation Files Available Online Revalidation Extension Requests
685	Incorporation of Cycle 2 Revalidation Policies Definitions Timeliness and Accuracy Standards Standards for Initial and Revalidation Applications Form CMS-855 Applications That Require a Site Visit Form CMS-855 Applications That Do Not Require a Site Visit Web-Based Applications - Timeliness Web-Based Applications That Require a Site Visit Web-Based Applications That Do Not Require a Site Visit Paper Applications - Accuracy Web-Based Applications - Accuracy Returns Model Revalidation Letter Model Large Group Revalidation Notification Letter Model Revalidation Pend Letter Model Revalidation Deactivation Letter Model Revalidation Past-Due Group Member Letter Model Deactivation Letter due to Inactive Provider/Supplier Letter Model Return Revalidation Letter Revalidation Lists Mailing Revalidation Letters Phone Calls Pend Status Deactivation Actions Receipt of Revalidation Application Revalidation Received and Development Required Revalidation Received after a Pend is Applied Revalidation Received after a Deactivation Occurs Change of Information Received Prior to Revalidation Letter Mailed Reassignment Applications Received After Revalidation Letter Mailed Revalidating Providers Involved in a Change of Ownership (CHOW) Large Group Revalidation Coordination Finalizing the Revalidation Application Revalidation Reporting Revalidation Files Available Online Revalidation Extension Requests
686	Comprehensive Error Rate Testing (CERT) Program: Medicare Administrative Contractor (MAC) Certifying Official Handling Overpayments and Underpayments, MAC Feedback, and Appeals Resulting From the CERT Findings Handling Appeals Resulting From CERT Initiated Denials
687	Extrapolated Overpayments Conduct of Expanded Review Based on Statistical Sampling for Overpayment



	Estimation and Recoupment of Projected Overpayment by Contractors
688	Update to Pub. 100-08, Chapter 15 Medicaid State Agencies Correspondence Address and E-mail Addresses Form CMS-855A and Form CMS-855B Signatories Delegated Officials Supporting Documents Processing Alternatives – Form CMS-855B and Form CMS-855I Processing Alternatives – Form CMS-855O Processing Alternatives – Form CMS-855R Special Program Integrity Procedures Model Revocation Letter for Part B Suppliers and Certified Providers and Suppliers Favorable Corrective Action Plan/Reconsideration Decision –Denials Corrective Action Plans (CAPs) Reconsideration Requests – Non-Certified Providers/Suppliers Additional Appeal Levels Appeals Involving Certified Providers and Certified Suppliers Corrective Action Plans (CAPs) Reconsideration Requests – Certified Providers and Certified Suppliers Additional Appeal Levels HHA Ownership Changes Revocations
689	Medicare Contractor Duties Correspondence Address and E-mail Addresses Contact Persons Certification Statement Signature Requirements Form CMS-855I and CMS-855O Signatories Form CMS-855R Signatories Form CMS-855A, Form CMS-855B and Form CMS-855S Signatories Authorized Officials Delegated Officials Submission of Paper and Internet-based PECOS Certification Statements Certification Statement Development Reserved for Future Use Reserved for Future Use Receipt/Review of Paper Applications Receipt/Review of Internet-Based PECOS Applications Processing Alternatives – Form CMS-855B and Form CMS-855I Processing Alternatives – Form CMS-855A Processing Alternatives – Form CMS- Paper Applications Internet-Based PECOS Applications General Principles – Paper and Internet-Based PECOS Applications Receiving Missing/Clarifying Data/Documentation Paper Applications Internet-Based PECOS Applications Special Program Integrity Procedures Rejections Changes of Information - General Procedures Electronic Fund Transfers (EFT)

	Internet-based PECOS Applications Release of Information Model Letter Guidance Reactivations - Deactivation for Non-Submission of a Claim Reactivations – Miscellaneous Policies
690	Issued to a specific audience, not posted to Internet/ Intranet Confidentiality of Instruction
691	Contacting Non-Responders and Documentation Requests
<b>Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)</b>	
33	Medicare Contractor Beneficiary and Provider Communications Manual Beneficiary Customer Services Pub. 100-09 Chapter 2- Update Beneficiary Customer Services Escalation of Complex Beneficiary Inquiries to the MACs by the Beneficiary Contact Center (BCC) Next Generation Desktop (NGD) Training Disclosure of Information (Adherence to the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule) Screening of Beneficiary Complaints Alleging Fraud or Abuse Medicare Customer Service – Next Generation Desktop (MCSC-NGD) Client Installation and Configuration Requirements Call Center User Group (CCUG) Complex Beneficiary Inquiries Handling Complex Beneficiary Inquiries Controlling Complex Beneficiary Inquiries E-mail and Fax Responses to Complex Written Beneficiary Inquiries Telephone Responses to Complex Beneficiary Inquiries Written Responses to Complex Beneficiary Inquiries Timeliness of Responses to Complex Beneficiary Inquiries Congressional Beneficiary Inquiries Surveys Urgent Need Regional Offices Casework
<b>Medicare Quality Improvement Organization (CMS- Pub. 100-10)</b>	
28	QIO Manual Chapter 5 – “Quality of Care Review
29	QIO Manual Chapter 3 “Memoranda of Agreement for Case Review Authority and Scope for Memoranda of Agreement (MOA) MEMORANDA OF AGREEMENT (MOA) WITH PROVIDERS OF SERVICES Agreements with Providers of Services Hospital Memorandum of Agreement (MOA) Home Health Agencies (HHAs) and Skilled Nursing Facilities (SNFs) Memoranda of Agreement (MOA) AGREEMENTS WITH PAYERS OF HEALTHCARE SERVICES Medicare Administrative Contractor (MAC) Joint Operating Agreements (JOA) Memorandum Of Agreement (MOA) with State Agencies Responsible for Licensing and Certification of Providers and Practitioners
<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>	
123	Chapter 16b, Special Needs Plans
124	Update of Chapter 1 of the Managed Care Manual
<b>Medicare Business Partners Systems Security (CMS-Pub. 100-17)</b>	
	None
<b>Demonstrations (CMS-Pub. 100-19)</b>	
157	Shared System Enhancement 2015: Archive/Remove Inactive Medicare Demonstration Projects
158	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
159	IVIG Demonstration: Payment Update for 2017
160	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
161	Shared System Enhancement 2015: Archive/Remove Inactive Medicare Demonstration Projects
162	Affordable Care Act Bundled Payments for Care Improvement Initiative – Recurring File Updates Models 2 and 4 January 2017 Updates
163	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
164	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
<b>One Time Notification (CMS-Pub. 100-20)</b>	
1723	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1724	Common Working File (CWF) Reorganization of Daily Beneficiary Extract Files
1725	Changes to the End-Stage Renal Disease (ESRD) Facility Claim (Type of Bill 72X) to Accommodate Dialysis Furnished to Beneficiaries with Acute Kidney Injury (AKI)
1726	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
1727	Section 504: Adding a Qualified Reader Preference in Alternate Formats
1728	Part B Detail Line Expansion – MCS Phase 6
1729	Analysis Only - Populate MCS PE Screens from PECOS (Phased Approach)
1730	Part B Detail Line Expansion – MCS Phase 5
1731	Fiscal Intermediary Shared System (FISS) Health Information Technology for Economic and Clinical Health (HITECH) Quarterly Report
1732	Phase Three: Changing Fiscal Intermediary Shared System (FISS) Action on Informational Unsolicited Responses (IURs) From Canceled Claims to Adjustments
1733	Modifications to the National Coordination of Benefits Agreement (COBA) Crossover Process
1734	Phase 3 - Updating the Fiscal Intermediary Shared System (FISS) to Make Payment for Drugs and Biologicals Services for Outpatient Prospective Payment System (OPPS) Providers
1735	System Specific Enhancement 2014: Retaining Most Recent Update for Auxiliary (Aux) File Data in Common Working File (CWF)
1736	Shared System Enhancement 2014 – Identification of Fiscal Intermediary Shared System (FISS) Obsolete On-Request Jobs - Analysis Only File

	(CWF)1693
1737	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1738	Network Fee Reduction for Acute Kidney Injury (AKI) services submitted on Type of Bill 72x
1739	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1740	Shared System Enhancement 2015: National Coverage Determination (NCD) Fiscal Intermediary Shared System (FISS) Implementation
1741	Issued to a specific audience, not posted to Internet/ Intranet Confidentiality of Instruction
1742	Issued to a specific audience, not posted to Internet/ Intranet Confidentiality of Instruction
1743	Modifications to the National Coordination of Benefits Agreement (COBA) Crossover Process
1744	Audit Trail for Reason Code Edit Changes
1745	Part B Detail Line Expansion - Checkpoint Discussion Meetings
1746	Medicare Electronic Health Record (EHR) Incentive Program – Analysis of Meaningful Use Hospital Transition into Hospital Quality Reporting System
1747	Issuing Compliance Letters to Specific Providers and Suppliers Regarding Inappropriate Billing of Qualified Medicare Beneficiaries (QMBs) for Medicare Cost-Sharing
1748	Adding a Foreign Language Tagline Sheet to Medicare Summary Notices (MSNs)
1749	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1750	Increasing the Number of Address Fields in MCS to Match the Address Fields in CWF in Order to Improve the Undeliverable Medicare Summary Notices (uMSNs) Situation: Phase One of Improving FFS9372
1751	Adding a Foreign Language Tagline Sheet to Medicare Summary Notices (MSNs)
1752	System Specific Enhancement 2014: String Testing Automation
1753	Coding Revisions to National Coverage Determination (NCDs)
1754	Common Working File and Fraud Prevention System 2.0 Predictive Modeling and Edits, Data Feed Migration
1755	ICD-10 Coding Revisions to National Coverage Determination (NCDs)
1756	Analysis Only - Modification of Process for Handling the Provider Enrollment Chain Ownership System (PECOS) Extract File
1757	Issuing Compliance Letters to Specific Providers and Suppliers Regarding Inappropriate Billing of Qualified Medicare Beneficiaries (QMBs) for Medicare Cost-Sharing
1758	Updates for the Shared System Maintainers to implement the Social Security Number Removal Initiative (SSNRI)
1759	Changes to the End-Stage Renal Disease (ESRD) Facility Claim (Type of Bill 72X) to Accommodate Dialysis Furnished to Beneficiaries with Acute Kidney Injury (AKI)
1760	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1761	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity

	Instruction
1762	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1763	Shared Savings Program (SSP) Accountable Care Organization (ACO) Qualifying Stay Edits
<b>Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)</b>	
	None
<b>Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)</b>	
	None

**Addendum II: Regulation Documents Published in the Federal Register (October through December 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 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-3Q16QPU.pdf>

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

**Addendum III: CMS Rulings (October through December 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 (October through December 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 website. There were no updates that 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, MPA (410-786-7491).

**Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (October through December 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
G160189	Exablate Model 4000 Type 1	10/01/2016
G160131	EMBOSPHERE MICROSPHERE	10/04/2016
G160191	RETINOIC ACID RECEPTOR ALPHA- INTERFERON RESPONSE FACTOR 8(RARA-IRF8)	10/07/2016
G160149	E-QUIRE Bioelectrical Signal Therapy (BST) Device	10/14/2016
G160200	FENIX Plus Continence Restoration System	10/18/2016
G160197	IMPELLA CP SYSTEM	10/19/2016
G160205	Agili-C	10/20/2016
G160203	BREATHID HP SYSTEM, BREATHID HP LAB SYSTEM	10/21/2016
G160168	TOPS System	10/26/2016
G040175	Relay Thoracic Stend Graft with Transport Delivery System for treatment of thoracic aortic aneurysms.	10/27/2016
G160136	Medtronic Spinal Cord Stimulation Systems	10/28/2016
G160206	Restylane Silk Injectables	10/28/2016
G160207	Cook Zenith TX2 Proximal Component, Cook Zenith TX2 Proximal Extension, Cook Zenith TX2 Proximal Taper	10/28/2016
G160211	BEAT AML MASTER TRIAL CLINICAL TRIAL ASSAY (BEAT AML GENOMIC PROFILING ASSAY)	11/01/2016
G160212	SENSE BRAIN INJURY MONITOR (SDX1)	11/02/2016
G160208	STARSTIM	11/04/2016
G160213	ARTISSE INTRASACCULAR DEVICE, ARTISSE DETACHMENT DEVICE	11/04/2016
G160214	EMBOSPHERE MICROSPHERES	11/04/2016
G160216	Morphology Recurrence Plot Mapping	11/09/2016
G160218	The GORE Cardioform ASD Occuluder	11/10/2016
G160219	ARTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETER	11/10/2016
G160223	Carillon Mitral Contour System	11/17/2016
G160226	Ovation Alto Abdominal Stent Graft System	11/17/2016
G160229	Custom bipolar electrode based on PermaLoc Electrode	11/18/2016
G160234	Embosphere (R) Microspheres	11/21/2016
G160233	Activa Deep Brain Stimulation Therapy System	11/23/2016
G100108	Exablate Model 2100 Type 3.0	12/02/2016
G160238	ALUVRA	12/06/2016
G160106	FemBLOC Permanent Contraceptive System; Component 1) FemBLOC Biopolymer; Component 2) FemBLOC Delivery System; Component 3) FemBLOC FemChec Tubal Occlusion Confirmation Device	12/07/2016
G160232	Zilver Vascular Stent	12/09/2016
G160243	Lynparza HRR Assay	12/13/2016
G160242	IN.PACT AV Access Paclitaxel-Coated PTA Balloon Catheter	12/14/2016

IDE	Device	Start Date
G160250	tRISTAN 624 BIOMAGNETOMETER	12/15/2016
G160172	Ranger Paclitaxel-Coated PTA Balloon Catheter	12/16/2016
G160180	OPTUNE (NovoTTF 100A System)	12/16/2016
G160209	LOTUS Edge Valve System, 23 mm; LOTUS Edge Valve System, 25 mm, LOTUS Edge Valve System, 27 mm	12/16/2016
G160247	Proclaim Elite Implantable Pulse Generator; Triple 16 Paddle Leads	12/16/2016
G160248	A Prospective Pilot Trial for PFO CLOSURE at the Time of ENDOCASCULAR Cardiac Electronic Device Implantation	12/16/2016
G160249	Hydrus Microstent	12/16/2016
G160251	da Vinci SP Surgical System, EndoWrist SP Instruments, and Accessories	12/16/2016
G160265	InPress Technologies Post Partum Hemorrhage Device	12/20/2016
G160253	PERIODONTAL STRUCTURE REPAIR DEVICE	12/20/2016
G160259	Edwards SAPIEN 3 Transcatheter Heart Valve and Accessories	12/20/2016
G100322	TheraSphere	12/21/2016
G130034	BIOFREEDOM Drug Coated Coronary Stent System	12/21/2016
G160256	NUCLEUS C1532 COCHLEAR IMPLANT	12/21/2016
G160263	EXTRACORPOREAL CPR FOR REFRACTORY OUT-OF-HOSPITAL CARDIAC ARREST (EROCA)	12/21/2016
G160265	EMBOZONE MICROSPHERES	12/23/2016
G160121	Implantable Miniature Telescope (IMT) Models Wide Angle 2.2X and Wide Angle 2.7X	12/29/2016

**Addendum VI: Approval Numbers for Collections of Information (October through December 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 William Parham (410-786-4669).

**Addendum VII: Medicare-Approved Carotid Stent Facilities, (October through December 2016)**

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 Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Effective Date	State
<b>The following facilities are new listings for this quarter.</b>			
Baxter Regional Medical Center 624 Hospital Drive Mountain Home, AR 72653	1033147921	10/26/2016	AR
Wellington Regional Medical Center 10101 Forest Hill Boulevard Wellington, FL 33414	1720078702	11/08/2016	FL
St Mark's Hospital 1100 East 3900 South Salt Lake City, UT 84124	470046	11/30/2016	NE
<b>The following facilities have editorial changes (in bold).</b>			
<b>FROM: Peace River Regional Medical Center</b> <b>TO: Bayfront Health Port Charlotte</b> 2500 Harbor Boulevard Port Charlotte, FL 33952	100077	08/24/2009	FL
<b>FROM: Community Heart and Vascular Hospital</b> <b>TO: Community Health Network, Inc</b> 1500 N. Ritter Avenue Indianapolis, IN 46219	15-0074	08/04/2005	IN

**Addendum VIII:**

**American College of Cardiology's National Cardiovascular Data Registry Sites (October through December 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 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 Sarah Fulton, MHS (410 786 2749).

Facility	City	State
<b>The following facilities are new listings for this quarter.</b>		
Sarah Bush Lincoln Health Center	Mattoon	IL
Kaiser Permanente - Vacaville Medical Center	Vacaville	CA
Jersey Community Hospital District	Jerseyville	IL
Roane Medical Center	Harriman	TN
<b>The following facilities are terminations for this quarter.</b>		
Unity Hospital	Fridley	MN
St. Mary's Medical Center	West Palm Beach	FL
Wheaton Franciscan Inc. - Wisconsin Heart Hospital	Milwaukee	WI
Vaughan Regional Medical Center	Selma	AL
Northshore Regional Medical Center	Slidell	LA
TriStar Southern Hills Medical Center	Nashville	TN
St. Elizabeth Boardman	Boardman	OH

Facility	City	State
Tristar Horizon Medical Center	Dickson	TN
Wilcox Memorial Hospital (Hawai'i Pacific)	Lihue	HI
Mercy Tiffin Hospital	Tiffin	OH
Guthrie Corning Hospital	Corning	NY
CHI St. Luke's Health Memorial Livingston	Livingston	TX

**Addendum IX: Active CMS Coverage-Related Guidance Documents (October through December 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, MS (410-786-7205).

**Addendum X:  
List of Special One-Time Notices Regarding National Coverage Provisions (October through December 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, MS (410-786 7205).

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

We are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred 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 Linda Gousis, JD, (410-786-8616).

Facility	Provider Number	Date Approved	State
<b>The following facilities are new listings for this quarter.</b>			
NorthShore University Health System 1301 Central Street, Suite 300 Evanston, IL 60201	14-0010	10/26/2016	IL
St. Francis Hospital 100 Port Washington Boulevard Roslyn, NY 11576	33-0182	11/09/2016	NY
Swedish Medical Center Cherry Hill 500 17th Avenue Seattle, WA 98122	500025	11/09/2016	WA

Facility	Provider Number	Date Approved	State
<b>The following facilities have editorial changes (in bold).</b>			
<b>FROM: UT Southwestern University Hospital</b> <b>TO: UT Southwestern Medical Center</b> 6201 Harry Hines Blvd. Dallas, TX 75390 <b>Other information:</b> <b>Joint Commission certified on 2/3/09. Hospital previously listed as St. Paul Medical Center.</b>	450044	12/10/2003	TX
<b>FROM: Methodist Hospital, The</b> <b>TO: Houston Methodist Hospital</b> 6565 Fannin Street Houston, TX 77030 <b>Other information:</b> <b>DNV GL certified 12/6/16; JCAHO certified 10/29/08</b>	450358	<b>12/06/2016</b>	TX
<b>FROM: Community Heart and Vascular</b> <b>TO: Community Health Network, Inc.</b> 8075 N Shadeland Avenue Indianapolis, IN 46250 <b>Other information:</b> Joint Commission Certified	150074	10/01/2014	IN

**Addendum XIII: Lung Volume Reduction Surgery (LVRS) (October through December 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/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage). For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

**Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (October through December 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/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage). For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

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

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