

Dated: April 21, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9091-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—January through March 2015

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive

and interpretive regulations, and other **Federal Register** notices that were published from January through March 2015, relating to the Medicare and Medicaid programs and other programs administered by CMS.

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

| Addenda | Contact | Phone number |
|--|-------------------------|----------------|
| I CMS Manual Instructions | Ismael Torres | (410) 786-1864 |
| II Regulation Documents Published in the Federal Register | Terri Plumb | (410) 786-4481 |
| III CMS Rulings | Tiffany Lafferty | (410)786-7548 |
| IV Medicare National Coverage Determinations | Wanda Belle | (410) 786-7491 |
| V FDA-Approved Category B IDEs | John Manlove | (410) 786-6877 |
| VI Collections of Information | Mitch Bryman | (410) 786-5258 |
| VII Medicare -Approved Carotid Stent Facilities | Lori Ashby | (410) 786-6322 |
| VIII American College of Cardiology-National Cardiovascular Data Registry Sites | Marie Casey, BSN, MPH. | (410) 786-7861 |
| 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 | Marie Casey, BSN, MPH. | (410) 786-7861 |
| XIII Medicare-Approved Lung Volume Reduction Surgery Facilities | Marie Casey, BSN, MPH. | (410) 786-7861 |
| XIV Medicare-Approved Bariatric Surgery Facilities | Jamie Hermansen | (410) 786-2064 |
| XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials | Stuart Caplan, RN, MAS. | (410) 786-8564 |
| All Other Information | Annette Brewer | (410) 786-6580 |

SUPPLEMENTARY INFORMATION:

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 20, 2015.

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 25, 2014 (79 FR 22976), July 25, 2014 (79 FR 43475) and November 14, 2014 (79 FR 68253), and February 2, 2015 (80 FR 5537). For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (January through March 2015)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: <http://cms.gov/manuals>.

How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400

designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at <http://www.gpo.gov/libraries/>

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the Medicare National Coverage Determination (CMS-Pub. 100-03) Transmittal No. 180.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual. For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

| Transmittal Number | Manual/Subject/Publication Number |
|---|---|
| Medicare General Information (CMS-Pub. 100-01) | |
| 90 | Rescinds/Replaces CR 7468 - Updated Instructions for the Change Request Implementation Report (CRIR) and Technical Direction Letter (TDL) Sample Cover Letter/Attestation Statement CR Implementation Report (CRIR) Template TDL Compliance Report (TCR) Template Contractor Implementation of Change Requests and Compliance with Technical Direction Letters Compliance Report (TCR) |
| Medicare Benefit Policy (CMS-Pub. 100-02) | |
| 203 | Payment Repairs to Capped Rental Equipment Prior to the End of the 13-Month Cap Repairs, Maintenance, Replacement, and Delivery |
| 204 | Updates to the Medicare Internet-Only Manual Chapters for Skilled Nursing Facility (SNF) Providers Readmission to a SNF Three-Day Prior Hospitalization |
| Medicare National Coverage Determination (CMS-Pub. 100-03) | |
| 179 | National Coverage Determination (NCD) for Single Chamber and Dual |

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| | Chamber Permanent Cardiac Pacemakers - This CR rescinds and fully replaces CR 8525 Single Chamber and Dual Chamber Permanent Cardiac Pacemakers |
| 180 | Removal of Multiple National Coverage Determinations Using Expedited Process |
| Medicare Claims Processing (CMS-Pub. 100-04) | |
| 3160 | Preventive and Screening Services — Update - Intensive Behavioral Therapy for Obesity, Screening Digital Tomosynthesis Mammography, and Anesthesia Associated with Screening Colonoscopy Table of Preventive and Screening Services HCPCS and Diagnosis for Mammography Services Screening Digital Tomosynthesis Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Payment Deductible and Coinsurance Policy Common Working File (CWF) Edits Professional Billing Requirements Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Institutional Billing Requirements |
| 3161 | Remittance Advice Remark and Claims Adjustment Reason Code and Medicare Remit Easy Print and PC Print Update |
| 3162 | Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors (This CR rescinds and fully replaces CR8468/TR2873 dated February 6, 2014) Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors (This CR rescinds and fully replaces CR8468/TR2873 dated February 6, 2014) Billing and Coverage Changes for PET Scans Billing Requirements for CMS-Approved Clinical Trials and Coverage with Evidence Claims for PET Scans for Neurodegenerative Diseases, Previously Specified Cancer Indications, and All Other Cancer Indications Not Previously Specified |
| 3163 | January 2015 Update of the Ambulatory Surgical Center (ASC) Payment System |
| 3164 | Medicare Shared Systems Modifications Necessary to Capture Various HIPAA Compliant Payments on the MPFS for Providers With Multiple Service Locations |
| 3165 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3166 | Emergency Update to the CY 2015 Medicare Physician Fee Schedule Database (MPFSDB) |
| 3167 | Modifications to the National Coordination of Benefits Agreement (COBA) Crossover Process |
| 3168 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3169 | Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens |

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| 3170 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3171 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3172 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3173 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3174 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3175 | Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)-Blinded Clinical Trial – Follow-Up CR to Implement a Second Claims Processing Procedure Code |
| 3176 | Preventing Inappropriate Payments on Home Health Low Utilization Payment Adjustment (LUPA) Claims HH PPS Claims Request for Anticipated Payment (RAP) Adjustments of Episode Payment - Low Utilization Payment Adjustments (LUPAs) |
| 3177 | Updating CMS IOM 100-04, Chapter 26 with Specialty Code B1 Nonphysician Practitioner, Supplier, and Provider Specialty Codes |
| 3178 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3179 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3180 | April 2015 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files |
| 3181 | Implementation of New NUBC Condition Code “53” “Initial placement of a medical device provided as part of a clinical trial or a free sample” Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category B IDE Billing No Cost Items Due to Recall, Replacement, or Free Sample Reporting and Charging Requirements When a Device is Furnished Without Cost to the Hospital or When the Hospital Receives a Full or Partial Credit for the Replacement Device Beginning January 1, 2014 |
| 3182 | Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits |
| 3183 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3184 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3185 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3186 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3187 | Language Only Update to Pub 100-04, Chapter 30 for ASC X12 and Claim References Processing Initial Denials |

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| | Bill Processing Applicability of the Limitation on Liability Provision to Claims for Ancillary, Outpatient Provider and Rural Health Clinic Services Payable Under Part B Preparation of Denial Notices |
| 3188 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3189 | Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens |
| 3190 | CY 2015 Update for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule |
| 3191 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3192 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3193 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3194 | Update to the Federally Qualified Health Centers (FQHC) Prospective Payment System (PPS) - Recurring File Updates |
| 3195 | Final MSN Redesign-Related Update to Chapter 21 of the Medicare Claims Processing Manual Basic Concepts and Approaches Format Conventions for the MSN Specifications for Section 1: Summary (Page 1) Specifications for Section 2: Making the Most of Your Medicare (Page 2) Specifications for Section 3: Claims Claims Calculations Specifications for Section 4 (Last Page): Denials and Appeals Specifications for Pay MSN Cover Sheet and Check Specifications for Envelopes Specifications for RRB Part B MSNs Specifications for SSA Part B MSNs Character Measurements for Fonts Specifications for Spanish MSN Specifications for Content Variations of Spanish MSNs Exhibits of the Extended Family of MSNs in Black & White General Information, Explanatory, and Denial Messages Exhibits of MSNs in Spanish Exhibits of the Extended Family of MSNs in Color Exhibits of Alternate Scenarios |
| 3196 | Payment Repairs to Capped Rental Equipment Prior to the End of the 13-Month Cap Maintenance and Service of Capped Rental Items General Payment for Maintenance and Service of Equipment |
| 3197 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3198 | Instructions for Downloading the Medicare ZIP Code File for July 2015 |
| 3199 | Revisions to Medicare Claims Processing Manual for Foreign, Emergency and Shipboard Claims Emergency and Foreign Hospital Services |

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| | Services Rendered By Nonparticipating Providers Establishing an Emergency Qualifications of an Emergency Services Hospital Coverage Requirements for Emergency Hospital Services in Foreign Countries Services Furnished in a Foreign Hospital Nearest to Beneficiary's U.S. Residence Coverage of Physician and Ambulance Services Furnished Outside U.S. Claims for Services Furnished in Canada to Qualified Railroad Retirement Beneficiaries Claims from Hospital-Leased Laboratories Not Meeting Conditions of Participation Nonemergency Part B Medical and Other Health Services Elections to Bill for Services Rendered By Nonparticipating Hospitals Processing Claims Contractors Designated to Process Foreign Claims Contractor Processing Guidelines Medicare Approved Charges for Services Rendered in Canada or Mexico Accessibility Criteria Medical Necessity Time Limitation on Emergency and Foreign Claims Payment Denial for Medicare Services Furnished to Alien Beneficiaries Who Are Not Lawfully Present in the United States Appeals on Claims for Emergency and Foreign Services Payment for Services Received By Nonparticipating Providers Payment for Services from Foreign Hospitals Attending Physician's Statement and Documentation of Medicare Emergency Designated Contractors Model Letters, Nonparticipating Hospital and Emergency Claims Model Letter to Nonparticipating Hospital That Elected to Bill For Current Year Model Letter to Nonparticipating Hospital That Did Not Elect to Bill for Current Year Full Denial - Foreign Claim - Beneficiary Filed Full Denial - Hospital-Filed or Beneficiary-Filed Emergency Claim Partial Denial - Hospital-Filed or Beneficiary-Filed Emergency Claim Denial - Military Personnel/Eligible Dependents Full Denial - Shipboard Claim - Beneficiary filed Model Letter to Nonparticipating Hospital That Requests to Bill the Program |
| 3200 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3201 | Healthcare Provider Taxonomy Codes (HPTCs) April 2015 Code Set Update |
| 3202 | Common Edits and Enhancements Modules (CEM) Code Set Update |
| 3203 | Automation of the Request for Reopening Claims Process Application to Special Claim Types |
| 3204 | National Coverage Determination (NCD) for Single Chamber and Dual Chamber Permanent Cardiac Pacemakers - This CR rescinds and fully replaces CR 8525 TOC Cardiac Pacemakers: Single Chamber and Dual Chamber |

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| | Cardiac Pacemakers:Single Chamber and Dual Chamber Policy Cardiac Pacemaker Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) Codes Cardiac Pacemaker Covered ICD-9/ICD-10 Diagnosis Codes Cardiac Pacemaker Claims Non-Covered ICD-9/ICD-10 Diagnosis Codes: Denial Messages Cardiac Pacemaker Claims Without the KX modifier Cardiac Pacemaker Non -Covered ICD-10 Diagnosis Codes Cardiac Pacemaker Claims Require the KX Modifier |
| 3205 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3206 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3207 | New Waived Tests |
| 3208 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3209 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3210 | Final MSN Redesign-Related Update to Chapter 21 of the Medicare Claims Processing Manual Format Conventions for the MSN Basic Concepts and Approaches |
| 3211 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3212 | April 2015 Update of the Ambulatory Surgical Center (ASC) Payment System |
| 3213 | Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction |
| 3214 | April 2015 Update of the Ambulatory Surgical Center (ASC) Payment System |
| 3215 | Screening for Hepatitis C Virus (HCV) in Adults Common Working File (CWF) Edits Institutional Billing Requirements Professional Billing Requirements Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Screening for Hepatitis C Virus (HCV) |
| 3216 | Updates to the Medicare Internet-Only Manual Chapters for Skilled Nursing Facility (SNF) Providers Hospital's "Facility Charge" in Connection with Clinic Services of a Physician Transportation of Equipment Billed by a SNF to a MAC Screening and Preventive Services SNF CB Annual Update Process for Part A MACs Health Insurance Prospective Payment System (HIPPS) Rate Code Coding PPS Bills for Ancillary Services Adjustment Requests SNF PPS Pricer Software Input/Output Record Layout SNF PPS Rate Components |

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| | Decision Logic Used by the Pricer on Claims Annual Updates to the SNF Pricer Leave of Absence Other Excluded Services Beyond the Scope of a SNF Part A Benefit |
| 3217 | April 2015 Update of the Hospital Outpatient Prospective Payment Inpatient-only Services Use of HCPCS Modifier - PO Payment Window for Outpatient Services Treated as Inpatient Services System (OPPS) |
| 3218 | April 2015 Integrated Outpatient Code Editor (I/OCE) Specifications Version 16.1 |
| 3219 | Automation of the Request for Reopening Claims Process Application to Special Claim Types |
| 3220 | Update to Pub. 100-04, Chapters 5 and 6 to Provide Language-Only Changes for Updating ICD-10, ASC X12, and Medicare Administrative Contractor (MAC) Implementation Part B Outpatient Rehabilitation and Comprehensive Outpatient Rehabilitation Facility (CORF) Services – General Application of Financial Limitations Multiple Procedure Payment Reductions for Outpatient Rehabilitation Services Reporting of Service Units With HCPCS Coding Guidance for Certain CPT Codes - All Claims General Off-Site CORF Services Notifying Patient of Service Denial Billing for DME, Prosthetic and Orthotic Devices, and Surgical Dressings Addendum A - Chapter 5, Section 20.4 - Coding Guidance for Certain CPT Codes - All Claims Other Billing Situations Billing SNF PPS Services Billing Procedures for Periodic Interim Payment (PIP) Method of Payment Total and Noncovered Charges Services in Excess of Covered Services Reporting Accommodations on Claims Bills with Covered and Noncovered Days Billing in Benefits Exhaust and No-Payment Situations Consolidated Billing Requirement for SNFs |
| 3221 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3222 | Quarterly Update to the Correct Coding Initiative (CCI) Edits, Version 21.2, Effective July 1, 2015 |
| 3223 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| 3224 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction |
| Medicare Secondary Payer (CMS-Pub. 100-05) | |
| 110 | None |
| Medicare Financial Management (CMS-Pub. 100-06) | |
| 249 | Notice of New Interest Rate for Medicare Overpayments and Underpayments |

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| | - 2nd Qtr Notification for FY 2015 |
| Medicare State Operations Manual (CMS-Pub. 100-07) | |
| 131 | New to State Operations Manual (SOM), Appendix N- Psychiatric Residential Treatment Facilities (PRTF) Interpretive Guidance |
| 132 | New Additions to State Operating Manual (SOM), Psychiatric Residential Treatment Facilities (PRTF) Chapter 2 |
| 133 | Revisions to the State Operations Manual (SOM) - Appendix PP – Guidance to Surveyors for Long-Term Care Facilities |
| 134 | Revisions to State Operations Manual (SOM) Exhibit 138 EMTALA Physician Review Worksheet Revisions |
| 135 | Revisions to State Operations Manual (SOM) Appendix J, Part II – Interpretive Guidelines – Responsibilities of Intermediate Care Facilities for Individuals with Intellectual Disabilities Revisions. An addition of a New Exhibit to the State Operations Manual (SOM) for Intermediate Care Facilities for Individuals with - Intellectual Disabilities (ICF/IID), Probes and Procedures for Appendix J, Part II Interpretive Guidelines- Responsibilities of Intermediate Care Facilities for Individuals with Intellectual Disabilities |
| 136 | Revisions to State Operations Manual (SOM) Appendices A, G, L and T related to Hospitals, Rural Health Clinics, Ambulatory Surgical Centers and Swing Beds |
| Medicare Program Integrity (CMS-Pub. 100-08) | |
| 566 | New Timeframe for Response to Additional Documentation Requests Time-Frames for Submission |
| 567 | New Timeframe for Response to Additional Documentation Requests |
| 568 | Review Timeliness Requirements for Prepay Review |
| 569 | Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction |
| 570 | Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction |
| 571 | Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction |
| 572 | Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction |
| 573 | Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction |
| 574 | Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction |
| 575 | Incorporation of Revalidation Policies into Pub. 100-08, Program Integrity Manual (PIM), Chapter 15 |
| 576 | Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction |
| 577 | Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction |
| 578 | Incorporation of Revalidation Policies into Pub. 100-08, Program Integrity NPI Punctuation Licenses and Certifications Section 2 of the Form CMS-8551 Practice Location Information Voluntary Terminations |

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| | Model Acknowledgement Letter Acknowledgement Letter Example Model Revalidation Letter Model Revalidation Letter – CHOW Scenario Only Model Large Group Revalidation Notification Letter Model Revalidation Pend Letter Deactivation Actions Approval Letter Guidance Denial Example #6 – Existing or Delinquent Overpayments Revocation Letter Guidance Provider and Supplier Revalidations Revalidation Lists Mailing Revalidation Letters Non-Response to Revalidation Actions Phone Calls Pend Status Model Revalidation Deactivation Letter Manual (PIM), Chapter 15 |
| 579 | Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction |
| 580 | Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction |
| 581 | Incorporation of Certain Provider Enrollment Policies in CMS-6045-F into Pub. 100-08, Program Integrity Manual (PIM), Chapter 15 Deceased Practitioners Denials Establishing an Effective Date of Medicare Billing Privileges Model Revocation Letter for Part B Suppliers and Certified Providers and Suppliers Corrective Action Plans (CAPs) Corrective Action Plans (CAPs) Revocations Definitions |
| 582 | Incorporation of Certain Provider Enrollment Policies in CMS-6045-F into Pub. 100-08, Program Integrity Manual (PIM), Chapter 15 Definitions Denials Deceased Practitioners Model Revocation Letter for Part B Suppliers and Certified Providers and Suppliers Corrective Action Plans (CAPs) Corrective Action Plans (CAPs) Revocations Establishing an Effective Date of Medicare Billing Privileges |
| 583 | Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction |
| 584 | Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction |

| Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09) | |
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| 31 | Update of IOM Pub. 100-09, Chapter 6, section 30.2.11 to include the requirements for implementing Quality Assurance Monitoring at the Medicare Administrative Contractors. Contingency Plans Direct Monitoring Quality Assurance Monitoring (QAM) Remote Monitoring Monitoring CSR Calls |
| Medicare Quality Improvement Organization (CMS- Pub. 100-10) | |
| | None |
| Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14) | |
| 00 | None |
| Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15) | |
| | None |
| Medicare Managed Care (CMS-Pub. 100-16) | |
| 120 | Chapter 4, Quality Improvement Program |
| Medicare Business Partners Systems Security (CMS-Pub. 100-17) | |
| | None |
| Demonstrations (CMS-Pub. 100-19) | |
| 115 | Implementation of the Intravenous Immune Globulin (IVIG) demonstration - Processing for home health service overlap editing |
| 116 | Implementing Home Health Travel Reimbursement Payment Changes for FCIIP (Frontier Community Health Integration Project) Mandated by section 123 of MIPPA 2008 and as amended by section 3126 of the ACA 2010 |
| One Time Notification (CMS-Pub. 100-20) | |
| 1450 | Moratorium on Classification of Long-Term Care Hospitals (LTCH) or Satellites/Increase in Certified LTCH Beds |
| 1451 | International Classification of Diseases, Tenth Revision (ICD-10) Limited End-to-end testing with Submitters for 2015 |
| 1452 | Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction |
| 1453 | Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction |
| 1454 | Issued to a specific, audience not to Internet/ Intranet due to a Confidentiality of Instruction |
| 1455 | Corrections to Processing Service Facility Information on Hospice Claims |
| 1456 | Phase Two: Changing Fiscal Intermediary Shared System (FISS) Action on Informational Unsolicited Responses (IURs) From Canceled Claims to Adjustments |
| 1457 | Renaming PPS-FLX6- PAYMENT Field in the Inpatient Prospective Payment System (IPPS) Pricer Output |
| 1458 | Fee for Service Beneficiary Data Streamlining (FFS BDS) Phase II Beneficiary Address Analysis and Design |
| 1459 | Continuation of Systematic Validation of Payment Group Codes for Prospective Payment Systems (PPS) Based on Patient Assessments |
| 1460 | Health Insurance Portability and Accountability Act (HIPAA) EDI Front End Updates for July 2015 |

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| 1461 | Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction |
| 1462 | Identifying "No Documentation" Medical Necessity Denials for Claims Flagged for Recovery Auditor Review |
| 1463 | Identification of Obsolete Shared System Maintainer (SSM) On-Request Jobs |
| 1464 | Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction |
| 1465 | Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction |
| 1466 | Use of Modifiers KK, KG, KU, and KW under the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program |
| 1467 | Reporting Force Balance Claim Payment on the Electronic Remittance Advice (ERA) 835 and Cross Over Beneficiary (COB) 837 Claim Transactions |
| 1468 | Identification of Obsolete Shared System Maintainer (SSM) Reports |
| 1469 | Develop Rough Order of Magnitude (ROM) for Appeals Workload in Preparation for Implementation of International Classification of Diseases-10th Revision (ICD-10) |
| 1470 | Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP): Additional Instructions for Grandfathered Items Subject to CBP |
| 1471 | Renaming PPS-FLX6- PAYMENT Field in the Inpatient Prospective Payment System (IPPS) Pricer Output |
| 1472 | International Classification of Diseases, 10th Revision (ICD-10) Testing - Acknowledgement Testing with Providers |
| 1473 | Correction of the Maintenance of the Medicare Status Code |
| 1474 | Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction |
| 1475 | Health Insurance Portability and Accountability Act (HIPAA) EDI Front End Updates for April 2015 |
| 1476 | Health Insurance Portability and Accountability Act (HIPAA) EDI Front End Updates for April 2015 |
| 1477 | Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction |
| 1478 | 10 Conversion/Coding Infrastructure Revisions/ICD-9 Updates to National Coverage Determinations (NCDs)--2nd Maintenance CR |
| 1479 | Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction |
| 1480 | Health Insurance Portability and Accountability Act (HIPAA) EDI Front End Updates for July 2015 |
| 1481 | Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction |
| 1482 | Use of Modifiers KK, KG, KU, and KW under the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program |
| 1483 | Identifying "No Documentation" Medical Necessity Denials for Claims Flagged for Recovery Auditor Review |

| Medicare Quality Reporting Incentive Programs (CMS-Pub. 100-22) | |
|---|---|
| 39 | Payments to Hospice Agencies That Do Not Submit Required Quality Data |
| Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25) | |
| | None |

Addendum II: Regulation Documents Published in the Federal Register (January through March 2015)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register**, contact GPO at www.gpo.gov/fdsys. 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-1Q15QPU.pdf>

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

Addendum III: CMS Rulings

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

The rulings can be accessed at <http://www.cms.gov/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 2015)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. For the purposes of this quarterly notice, we list only the specific updates that have occurred in the 3-month period. This information is available at: www.cms.gov/medicare-coverage-database/. For questions or additional information, contact Wanda Belle (410-786-7491).

| Title | NCDM Section | Transmittal Number | Issue Date | Effective Date |
|--|---|--------------------|------------|----------------|
| Removal of Multiple National Coverage Determinations Using Expedited Process | NCD50.6, NCD160.4, NCD160.6, NCD160.9, NCD190.4, NCD220.7, NCD220.8 | R80 | 03/06/2015 | 12/18/2014 |
| National Coverage Determination (NCD) for Single Chamber and Dual Chamber Permanent Cardiac Pacemakers | NCD20.8.3 | R179 | 02/20/2015 | 08/13/2013 |

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (January through March 2015)

Addendum V includes listings of the FDA-approved investigational device exemption (IDE) numbers that the FDA assigns. The listings are organized according to the categories to which the devices are assigned (that is, Category A or Category B), and identified by the IDE

number. For the purposes of this quarterly notice, we list only the specific updates to the Category B IDEs as of the ending date of the period covered by this notice and a contact person for questions or additional information. For questions or additional information, contact John Manlove (410-786-6877).

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c) devices fall into one of three classes. To assist CMS under this categorization process, the FDA assigns one of two categories to each FDA-approved investigational device exemption (IDE). Category A refers to experimental IDEs, and Category B refers to non-experimental IDEs. To obtain more information about the classes or categories, please refer to the notice published in the April 21, 1997 **Federal Register** (62 FR 19328).

| IDE | Device | Start Date |
|---------|---|------------|
| G140237 | Neruostar TMS Therapy | 01/02/2015 |
| G140244 | Cochlear Implant | 01/07/2015 |
| G140218 | Automated Remote Ischemic Conditioning (autoRIC) Device | 01/08/2015 |
| G140209 | Inspire Upper Airway Stimulation (UAS) | 01/09/2015 |
| G140246 | SENZA Spinal Cord Stimulation (SCS) System | 01/09/2015 |
| G140041 | Penumbra, TREVO, and Solitaire | 01/14/2015 |
| G140178 | Resolute Onyx Zotarolimus Coronary Stent System | 01/15/2015 |
| G130195 | LUM 2.6 Imaging System | 01/16/2015 |
| G140253 | EmboTrap Revascularization Device | 01/27/2015 |
| G140254 | BreathID MCS | 01/28/2015 |
| G140252 | Myeloma Prognostic Risk Signaure, MYPRS | 01/28/2015 |
| G140251 | Physio-Stim Model 3315OA | 01/29/2015 |
| G140255 | SmartPatch PNS System For The Treatment of Pain Following Total Knee Arthroplasty (TKA) Utilizing Preoperative Lead Placement | 01/29/2015 |
| G140078 | Osiro Sirolimus Eluting Coronary Stent System | 01/30/2015 |
| G150004 | Diode Laser | 02/05/2015 |
| G140213 | Embosphere Microspheres | 02/06/2015 |
| G150006 | Neuroform Atlas Stent System | 02/06/2015 |
| G150012 | Ocelusin 500 Artificial | 02/12/2015 |
| G140071 | Juvederm | 02/13/2015 |
| G140211 | Substernal Pacing Acute Clinical Evaluation (Space) Study | 02/13/2015 |
| G140118 | COMBO Bio-engineered Sirolimus Eluting Stent | 02/19/2015 |
| G150020 | Injectible Calcium Hydroxylapatite With And Without Triamcinolone Acetate For The Treatment of Volume Loss To Dorsum Areas of the Hands | 02/20/2015 |
| G150019 | CorMatrix ECM Tricuspod Valve | 02/25/2015 |
| G150024 | Endurant Evo AAA Stent Graft System | 02/27/2015 |
| G150026 | High-Resolution Microendoscopy (HRME) | 02/27/2015 |
| G150028 | Trevo Retriever; Solitaire FR Revascularization Device; Penumbra system thrombectomy system | 03/04/2015 |

| IDE | Device | Start Date |
|---------|---|------------|
| G140134 | Lenstec SBL-3 Multifocal Posterior Chamber Intraocular Lens (MIOL) | 03/04/2015 |
| G140130 | Embosphere Microspheres | 03/06/2015 |
| G150030 | BK Medical/Analogic 8666-RF laparoscopic transducer and bedside flex Focus 1202 imaging system (Intrathoracic use during video-assisted thoracoscopy) | 03/06/2015 |
| G150031 | Hyalrheuma Injectable Viscosupplement | 03/10/2015 |
| G140154 | Simplify Disc | 03/11/2015 |
| G150007 | Asahi Gudewires & Corsair Microcatheter | 03/20/2015 |
| G120054 | GAMMAPOD | 03/20/2015 |
| G140245 | Syncardia Temporary Total Artificial Heart (TAH-4) System | 03/20/2015 |
| G150037 | HEMOBLAST Bellows Hemostatic Agent | 03/20/2015 |
| G150036 | Simplicity Spyral Multi-Electrode Renal Denervation Catheter and Simplicity G3 Renal Denervation RF Generator | 03/25/2015 |
| G130021 | NANOKNIFE System | 03/25/2015 |

Addendum VI: Approval Numbers for Collections of Information (January through March 2015)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact Mitch Bryman (410-786-5258).

Addendum VII: Medicare-Approved Carotid Stent Facilities, (January through March 2015)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: <http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage>

For questions or additional information, contact Lori Ashby (410-786-6322).

| Facility | Provider Number | Effective Date | State |
|---|-----------------|----------------|-------|
| The following facilities are new listings for this quarter. | | | |
| The Rochester General Hospital 1425 Portland Avenue Rochester, NY 14621 | 70005A | 01/15/2015 | NY |
| Methodist Richardson Medical Center 2831 E. President George Bush Highway Richardson TX 75082-3561 | 430537 | 02/26/2015 | TX |
| Editorial changes (in bold) for this quarter: | | | |
| Rhode Island Hospital 593 Eddy Street Providence, RI 02903 | 410007 | 07/07/2005 | RI |
| FROM: Franciscan Health System d/b/a St. Joseph Medical Center TO: CIII Franciscan Health – St. Joseph Medical Center 1717 South J Street Tacoma, WA 98401-2197 | 500108 | 07/31/2006 | WA |
| FROM: St. Joseph Medical Center Heart Institute TO: University Of Maryland St. Joseph Medical Center 7601 Osler Drive Towson, MD 21204-7582 | 210063 | 05/17/2005 | MD |
| FROM: The Baldwin County Eastern Shore Health Care Authority d/b/a Thomas Hospital TO: Gulf Health Hospitals, Inc. d/b/a Thomas Hospital 750 Morphy Avenue Fairhope, AL 36532 | 010100 | 04/07/2005 | AL |
| FROM: St John's Mercy Medical Center TO: Mercy Hospital St Louis 615 South New Ballas Road St. Louis, MO 63141 | 260020 | 08/24/2005 | MO |
| FROM: Town and Country Hospital TO: Tampa Community Hospital 6001 Webb Road Tampa, FL 33615-3241 | 100255 | 05/05/2005 | FL |
| FROM: Bon Secours Cottage Health Services TO: Beaumont Grosse Pointe 468 Cadieux Road Grosse Pointe, MI 48230 | 230089 | 09/15/2005 | MI |
| FROM: Carolinas Medical Center Mercy TO: Carolinas HealthCare System – Pineville 10628 Park Road Charlotte, NC 28210 | 340098 | 11/08/2007 | NC |
| Kaiser Sunnyside Medical Center 10180 SE Sunnyside Road Clackamas, OR 97015 | 380091 | 06/30/2010 | OR |
| Good Samaritan Regional Health Center 1 Good Samaritan Way Mt. Vernon, IL 62864 | 140046 | 04/25/2013 | IL |
| Porter Regional Hospital 85 East US Highway 6 Valparaiso, IN 46383 | 150035 | 05/02/2006 | IN |

| Facility | Provider Number | Effective Date | State |
|---|-----------------|----------------|-------|
| FROM: Regional Medical Center of Hopkins County TO: Baptist Health Madisonville 900 Hospital Drive Madisonville, KY 42431 | 180093 | 07/15/2005 | KY |

**Addendum VIII:
American College of Cardiology's National Cardiovascular Data
Registry Sites (January through March 2015)**

Addendum VIII includes a list of the American College of Cardiology's National Cardiovascular Data Registry Sites. We cover implantable cardioverter defibrillators (ICDs) for certain clinical indications, as long as information about the procedures is reported to a central registry. Detailed descriptions of the covered indications are available in the NCD. In January 2005, CMS established the ICD Abstraction Tool through the Quality Network Exchange (QNet) as a temporary data collection mechanism. On October 27, 2005, CMS announced that the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) ICD Registry satisfies the data reporting requirements in the NCD. Hospitals needed to transition to the ACC-NCDR ICD Registry by April 2006.

Effective January 27, 2005, to obtain reimbursement, Medicare NCD policy requires that providers implanting ICDs for primary prevention clinical indications (that is, patients without a history of cardiac arrest or spontaneous arrhythmia) report data on each primary prevention ICD procedure. Details of the clinical indications that are covered by Medicare and their respective data reporting requirements are available in the Medicare NCD Manual, which is on the CMS website at <http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961>

A provider can use either of two mechanisms to satisfy the data reporting requirement. Patients may be enrolled either in an Investigational Device Exemption trial studying ICDs as identified by the FDA or in the ACC-NCDR ICD registry. Therefore, for a beneficiary to receive a Medicare-covered ICD implantation for primary prevention, the beneficiary must receive the scan in a facility that participates in the ACC-NCDR ICD registry. The entire list of facilities that participate in the ACC-NCDR ICD registry can be found at www.ncdr.com/webncdr/common

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information

is available by accessing our website and clicking on the link for the American College of Cardiology’s National Cardiovascular Data Registry at: www.ncdr.com/webncdr/common. For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

| Facility | City | State |
|--|------------------|-------|
| The following facilities are new listings for this quarter. | | |
| Owensboro Health Regional Hospital | Owensboro | KY |
| Yakima Valley Memorial Hospital | Yakima | WA |
| University Hospitals Bedford Medical Center | Bedford | OH |
| University Hospitals Richmond Medical Center | Richmond Heights | OH |
| Doctors Hospital-Tidwell | Houston | TX |
| Resolute Health Hospital | New Braunfels | TX |
| Baylor Jack and Jane Hamilton At Fort Worth | Dallas | TX |
| Children's Hospital of The King's Daughters, Inc. | Norfolk | VA |
| Ranchos Los Amigos National Rehabilitation Center | Downey | CA |
| Unity Medical and Surgical Hospital | Mishawaka | IN |
| Presbyterian Hospital-Huntersville | Huntersville | NC |
| McLaren Lapeer Region | Lapeer | MI |
| Vail Valley Medical Center | Vail | CO |
| St. Joseph's Hospital - South | Riverview | FL |
| Bayonne Medical Center | Bayonne | NJ |
| Phelps Memorial Hospital Center | Sleepy Hollow | NY |
| Beth Israel Deaconess Hospital-Plymouth, Inc. | Plymouth | MA |
| Mercy St. Anne Hospital | Toledo | OH |
| Apogee Surgery Center | Redding | CA |
| Physicians of Winter Haven D/b/A/ Day Surgery Center | Winter Haven | FL |
| Mercy Hospital | Moose Lake | MI |
| Southern California Hospital At Culver City | Culver City | CA |
| Harrison Memorial Hospital | Cynthiana | KY |
| Florida Hospital - Altamonte Springs | Orlando | FL |
| Memorial Hermann Katy Hospital | Katy | TX |
| The following facilities are terminations for this quarter. | | |
| Avera St. Luke’s | Aberdeen | SD |
| Holy Cross Hospital | Taos | NM |
| Waco Surgery Center | Waco | TX |
| Trios Health | Kennewick | WA |
| Fleming County Hospital | Flemingsburg | KY |
| MaryVale Hospital | Phoenix | AZ |

Addendum IX: Active CMS Coverage-Related Guidance Documents (January through March 2015)

CMS issued a guidance document on November 20, 2014 titled “Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document”. Although CMS has several policy

vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS’s implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27>. There are no additional Active CMS Coverage-Related Guidance Documents for the January through March 2015 quarter. 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 2015)

There were no special one-time notices regarding national coverage provisions published in the January through March 2015 quarter. This information is available at 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 2015)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the January through March 2015 quarter. This information is available at <http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage>. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (January through March 2015)

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

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred to the list of Medicare-approved facilities that meet our standards in the 3-month period. This information is available at <http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage>. For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

| Facility | Provider Number | Date Approved | State |
|--|-----------------|---------------|-------|
| The following facilities are new listings for this quarter. | | | |
| Mercy Medical Center 1111 6th Avenue Des Moines, IA 50314 | 16-0083 | 01/07/2015 | IA |
| CHI Health Nebraska Heart 7500 South 91st Street Lincoln, NE 68526 | 28-0128 | 11/19/2014 | NE |
| Memorial Regional Hospital 1111 6th Avenue Des Moines, IA 50314 | 10-0038 | 08/20/2014 | IA |
| Mercy Hospital Springfield 1235 East Cherokee Springfield, MO 65804 | 260065 | 02/11/2015 | MO |
| St. Luke's Hospital 801 Ostrum Street Bethlehem, PA 18015 | 390049 | 12/18/2014 | PA |
| The following facility was de-certified this quarter. | | | |
| The Indiana Heart Hospital, LLC 8075 N Shadeland Avenue Indianapolis, IN 46250 | 150154 | 10/01/2014 | IN |

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (January through March 2015)

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

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

Only the first two types are in the list. There were no updates to the listing of facilities for lung volume reduction surgery published in the January through March 2015 quarter. This information is available at www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage. For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (January through March 2015)

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

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS's minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the January through March 2015 period. This information is available at www.cms.gov/MedicareApprovedFacilities/BSE/list.asp#TopOfPage. For questions or additional information, contact Jamie Hermansen (410-786-2064).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (January through March 2015)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the January through March 2015 quarter.

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

[FR Doc. 2015-09539 Filed 4-23-15; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

**Administration for Native Americans;
Notice of Meeting**

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice of tribal consultation.

SUMMARY: The Department of Health and Human Services, Administration for Children and Families, Administration for Native Americans (ANA) will host a Tribal Consultation to consult on the Community Native Language Coordination Initiative, an expansion of funding for ANA proposed in the President's fiscal year 2016 budget.

DATES: May 20, 2015.

ADDRESSES: 200 Independence Ave. SW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Lillian A. Sparks Robinson,