

By direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 2015-01856 Filed 1-27-15; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meeting of the Community Preventive Services Task Force

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: The Centers for Disease Control and Prevention (CDC) announces the next meeting of the Community Preventive Services Task Force (Task Force). The Task Force is an independent, nonpartisan, nonfederal, and unpaid panel. Its members represent a broad range of research, practice, and policy expertise in prevention, wellness, health promotion, and public health, and are appointed by the CDC Director. The Task Force was convened in 1996 by the Department of Health and Human Services (HHS) to identify community preventive programs, services, and policies that increase healthy longevity, save lives and dollars and improve Americans' quality of life. CDC is mandated to provide ongoing administrative, research, and technical support for the operations of the Task Force. During its meetings, the Task Force considers the findings of systematic reviews on existing research and issues recommendations. Task Force recommendations provide information about evidence-based options that decision makers and stakeholders can consider when determining what best meets the specific needs, preferences, available resources, and constraints of their jurisdictions and constituents. The Task Force's recommendations, along with the systematic reviews of the scientific evidence on which they are based, are compiled in *The Guide to Community Preventive Services (Community Guide)*.

DATES: The meeting will be held on Wednesday, February 25, 2015 from 8:30 a.m. to 6:00 p.m. EST and Thursday, February 26, 2015 from 8:30 a.m. to 1:00 p.m. EST.

ADDRESSES: The Task Force Meeting will be held at CDC Edward R. Roybal Campus, Tom Harkin Global Communications Center (Building 19),

1600 Clifton Road NE., Atlanta, GA 30333. You should be aware that the meeting location is in a Federal government building; therefore, Federal security measures are applicable. For additional information, please see Roybal Campus Security Guidelines under **SUPPLEMENTARY INFORMATION**. Information regarding meeting logistics will be available on the Community Guide Web site (www.thecommunityguide.org).

Meeting Accessibility: This meeting is open to the public, limited only by space availability in the meeting location. All meeting attendees must RSVP to ensure the required security procedures are completed to gain access to the CDC's Global Communications Center.

U.S. citizens must RSVP by 2/15/2015.

Non U.S. citizens must RSVP by 2/9/2015 due to additional security steps that must be completed.

In addition to in-person participation, individuals may view presentations via live video stream on the Internet. Those interested in accessing the live stream must also RSVP, and additional information will be sent to registrants requesting connectivity via the Internet in advance of the meeting. Failure to RSVP by the dates identified could result in an inability to attend the Task Force meeting due to the strict security regulations on federal facilities.

For Further Information and to RSVP Contact: Terica Scott, The Community Guide Branch; Division of Epidemiology, and Library Services; Center for Surveillance, Epidemiology and Laboratory Services; Office of Public Health Scientific Services; Centers for Disease Control and Prevention, 1600 Clifton Road, MS-E-69, Atlanta, GA 30333, phone: (404) 498-6360, email: CPSTF@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose: The purpose of the meeting is for the Task Force to consider the findings of systematic reviews and issue findings and recommendations. Task Force recommendations provide information about evidence-based options that decision makers and stakeholders can consider when determining what best meets the specific needs, preferences, available resources, and constraints of their jurisdictions and constituents.

Matters To Be Discussed: Vaccinations, Obesity, Cardiovascular Disease, and Health Equity. Topics are subject to change.

Roybal Campus Security Guidelines: The Edward R. Roybal Campus is the headquarters of the U.S. Centers for

Disease Control and Prevention and is located at 1600 Clifton Road NE., Atlanta, Georgia. The meeting is being held in a Federal government building; therefore, Federal security measures are applicable.

All meeting attendees must RSVP by the dates outlined under *Meeting Accessibility*. In planning your arrival time, please take into account the need to park and clear security. All visitors must enter the Roybal Campus through the entrance on Clifton Road. Your car may be searched, and the guard force will then direct visitors to the designated parking area. Upon arrival at the facility, visitors must present government issued photo identification (e.g., a valid federal identification badge, state driver's license, state non-driver's identification card, or passport). Non-United States citizens must complete the required security paperwork prior to the meeting date and must present a valid passport, visa, Permanent Resident Card, or other type of work authorization document upon arrival at the facility. All persons entering the building must pass through a metal detector. Visitors will be issued a visitor's ID badge at the entrance to Building 19 and may be escorted to the meeting room. All items brought to HHS/CDC are subject to inspection.

Dated: January 27, 2015.

Ron A. Otten,

Acting Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2015-01875 Filed 1-30-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9088-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—October Through December 2014

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 2014, 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

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: January 23, 2015.

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: January 31, 2014 (79 FR 5419), April 25, 2014 (79 FR 22976), July 25, 2014 (79 FR 43475) and November 14, 2014 (79 FR 68253). For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (October through December 2014)

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 Coverage of Ultrasound Screening for Abdominal Aortic Aneurysms (AAA) and Screening Fecal-Occult Blood Tests (FOBT) Coverage Criteria use CMS-Pub. 100-02, Transmittal No. 196.

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)	
	None
Medicare Benefit Policy (CMS-Pub. 100-02)	
195	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
196	Medicare Coverage of Ultrasound Screening for Abdominal Aortic Aneurysms (AAA) and Screening Fecal-Occult Blood Tests (FOBT) Coverage Criteria
197	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
198	Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption (IDE) Studies Coverage of Medical Devices Food and Drug Administration (FDA)-Approved Investigational Device Exemption (IDE) Studies

	<p>Medicare Requirements for Coverage of Items and Services in FDA-Approved Category A and B IDE Studies</p> <p>Payment for Items and Services in Category A and B IDE Studies</p> <p>FDA Withdrawal of IDE Approval or Change in Categorization</p> <p>16/10/General Exclusions from Coverage</p> <p>Re-evaluation of FDA-approved IDE Device Categorization Decision</p> <p>Hospital Institutional Review Board (IRB) Approved Non-significant Risk Devices</p> <p>14/30.1/Payment for Hospital IRB Approved Non-significant Risk Devices</p> <p>Services Related to and Required as a Result of Services Which are Not Covered Under Medicare Confidentiality of IDE Information</p>
199	<p>Implementation of Changes in the End-Stage Renal Disease Prospective Payment System (ESRD PPS) for Calendar Year (CY) 2015</p> <p>ESRD PPS Case-Mix Adjustments</p> <p>Renal Dialysis Items and Services</p> <p>Laboratory Services</p> <p>Drugs and Biologicals</p> <p>Definitions Relating to ESRD</p> <p>Home Dialysis Items and Services</p> <p>Equipment and Supplies</p> <p>Other Services</p> <p>ESRD Prospective Payment System (PPS) Base Rate</p> <p>Home Dialysis Training</p>
200	<p>Implementation of Changes in the End-Stage Renal Disease Prospective Payment System (ESRD PPS) for Calendar Year (CY) 2015</p> <p>Definitions Relating to ESRD</p> <p>Renal Dialysis Items and Services</p> <p>Laboratory Services</p> <p>ESRD PPS Case-Mix Adjustments</p> <p>Equipment and Supplies</p> <p>Home Dialysis Items and Services</p> <p>Home Dialysis Training</p> <p>Other Services</p> <p>ESRD Prospective Payment System (PPS) Base Rate</p> <p>Drugs and Biologicals</p>
201	<p>Medicare Benefit Policy Manual - RHC and FQHC Update - Chapter 13</p> <p>RHC General Information</p> <p>Copayment for FQHC Preventive Health Services</p> <p>Requirements</p> <p>FQHC Staffing</p> <p>RHC and FQHC Visits</p> <p>Location</p> <p>Hours of Operation</p> <p>Multiple Visits on Same Day and Exceptions</p> <p>Global Billing</p> <p>RHC Services</p> <p>FQHC Services</p> <p>Non RHC/FQHC Services</p> <p>Description of Non RHC/FQHC Services</p> <p>RHC and FQHC Payment Rates, Exceptions, and Adjustments</p>

	<p>RHCs and FQHCs Billing Under the AIR</p> <p>RHC Per-Visit Payment Limit and Exceptions</p> <p>FQHC Per-Visit Payment Limit</p> <p>FQHCs Billing Under the PPS Payment Rate and Adjustments</p> <p>Payment Codes for FQHCs Billing Under the PPS</p> <p>Cost Reports</p> <p>Productivity Standards</p> <p>RIIC and FQHC Patient Charges, Coinsurance, Deductible and Waivers</p> <p>Charges and Waivers</p> <p>Graduate Medical Education</p> <p>Transitional Care Management (TCM) Services</p> <p>Services and Supplies Furnished Incident to Physician's Services</p> <p>Provision of Incident to Services and Supplies</p> <p>Payment for Incident to Services and Supplies</p> <p>Nurse Practitioner, Physician Assistant, and Certified Nurse Midwife Services</p> <p>Outpatient Mental Health Treatment Limitation</p> <p>Physical and Occupational Therapy</p> <p>Description of Visiting Nursing Services</p> <p>Requirements of Visiting Nursing Services</p> <p>Home Health Agency Shortage Area</p> <p>Telehealth Services</p> <p>Preventive Health Services</p> <p>Preventive Health Services in RHCs</p> <p>Copayment and Deductible for RIIC Preventive Health Services</p> <p>Preventive Health Services in FQHCs</p> <p>FQHC General Information</p>
202	<p>Modifications to Medicare Part B Coverage of Pneumococcal Vaccinations</p> <p>Immunizations</p>
Medicare National Coverage Determination (CMS-Pub. 100-03)	
175	<p>Intensive Cardiac Rehabilitation Program - Benson-Henry Institute Cardiac Wellness Program</p>
176	<p>Medicare Coverage of Ultrasound Screening for Abdominal Aortic Aneurysms (AAA) and Screening Fecal-Occult Blood Tests (FOBT)</p> <p>Colorectal Cancer Screening Tests</p>
177	<p>Screening for Hepatitis C Virus (HCV) in Adults</p>
178	<p>Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction</p>
Medicare Claims Processing (CMS-Pub. 100-04)	
3083	<p>Form CMS-1500 Instructions: Revised for Form Version 02/12</p> <p>Items 14-33 Provider of Service or Supplier Information</p> <p>Items 1-11 Patient and Insured Information</p> <p>Items 11a-13 Patient and Insured Information</p> <p>Health Insurance Claim Form CMS-1500</p>
3084	<p>Intensive Cardiac Rehabilitation Program - Benson-Henry Institute Cardiac Wellness Program</p> <p>Requirements for CR and ICR Services on Institutional Claims</p>
3085	<p>Update to Pub. 100-04, Chapter 17 to Provide Language-Only Changes for Updating ICD-10 and ASC X12</p> <p>Claims Processing Requirements - General</p> <p>Billing Drugs Electronically - NCPDP</p>

	<p>MSN/Claim Adjustment Message Codes for Oral Cancer Drug Denials HPCPD Codes for Oral Anti-Emetic Drugs Submitting the Prescription Order Numbers and No Pay Modifiers Billing and Payment Instructions for A/B MACs (A) Requirements for Billing A/B MAC (A) for Immunosuppressive Drugs MSN/Remittance Messages for Immunosuppressive Drugs Intravenous Immune Globulin Claims Processing Rules for ESAs Administered to Cancer Patients for Anti-Anemia Therapy Hospital Outpatient Payment Under OPPS for New, Unclassified Drugs and Biologicals After FDA Approval But Before Assignment of a Product-Specific Drug or Biological HCPCS Code Hospital Billing For Take-Home Drugs The Competitive Acquisition Program (CAP) for Drugs and Biologicals Not Paid on a Cost or Prospective Payment Basis Denial/Claim Adjustment and Remark Messages for Anti-Emetic Drugs</p>
3086	<p>Update to Pub. 100-04, Chapter 1 to Provide Language-Only Changes for Updating ICD-10 and ASC X12 Foreword Formats for Submitting Claims to Medicare Electronic Submission Requirements Paper Formats for Institutional Claims Paper Formats for Professional and Supplier Claims Remittance Advices Payment Jurisdiction Among Local A/B MACs for Services Paid Under the Physician Fee Schedule Claims Processing Instructions for Payment Jurisdiction Payment to Physician or Other Supplier for Diagnostic Tests Subject to the Anti-01/Markup Payment Limitation/ Claims Submitted to A/B MACs (B) Billing Procedures for Entities Qualified to Receive Payment on Basis of Reassignment/ for A/B MACs(B) Processed Claims Billing for Diagnostic Tests (Other Than Clinical Diagnostic Laboratory Tests) Subject to the Anti-Markup Payment Limitation/ Claims Submitted to AB/MACs(B) Billing Form as Request for Payment Beneficiary Request for Payment on Provider Record – Institutional Claims ASC X12 837 Institutional Claim Format and Form CMS 1450 Definition of a Claim for Payment Policy and Billing Instructions for Condition Code 44 General Information on Non-covered Charges on Institutional Claims Determining Start Date of Timely Filing Period -- Date of Service Form Prescribed by CMS In Accordance with CMS Instructions Handling Incomplete or Invalid Submissions Claims Forms CMS 1490S and CMS-1450 Conditional Data Element Requirements for A/B MACs (B) and DME MACs B MAC(B) Specific Requirements for Certain Specialties/ Services Payer Only Codes Utilized by Medicare Inpatient Part A Hospital Adjustment Bills</p>

	Consistency Edits for Institutional Claims
3087	2015 Annual Update for the Health Professional Shortage Area (HPSA) Bonus Payments
3088	2015 Annual Update of Healthcare Common Procedure Coding System (HCPCS) Codes for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Update
3089	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3090	Ambulance Inflation Factor for CY 2015 and Productivity Adjustment Ambulance Inflation Factor (AIF)
3091	<p>Update to Pub. 100-04 Chapter 13 to Provide Language-Only Changes for Updating ICD-10 and ASC X12 ICD Coding for Diagnostic Tests A/B MAC (A) Payment for Low Osmolar Contrast Material (LOCM) (Radiology) Special Billing Instructions for RHCs Payment Requirements Medicare Summary Notices (MSN), Reason Codes, and Remark Codes Billing Instructions Coverage for PET Scans for Dementia and Neurodegenerative Diseases Payment Methodology and HCPCS Coding Billing and Coverage Changes for PET Scans Billing and Coverage Changes for PET Scans for Cervical Cancer Effective for Services on or After November 10, 2009 Billing and Coverage Changes for PET (NaF-18) Scans to Identify Bone Metastasis of Cancer Effective for Claims With Dates of Services on or After February 26, 2010 EMC Formats Billing Requirements for CMS - Approved Clinical Trials and Coverage With Evidence Development Claims for PET Scans for Neurodegenerative Diseases, Previously Specified Cancer Indications, and All Other Cancer Indications Not Previously Specified</p>
3092	Annual Medicare Physician Fee Schedule (MPFS) Files Delivery and Implementation
3093	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3094	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3095	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3096	<p>Medicare Coverage of Ultrasound Screening for Abdominal Aortic Aneurysms (AAA) and Screening Fecal-Occult Blood Tests (FOBT) Coverage Initial Preventive Physical Examination (IPPE) and Annual Wellness Visit (AWV) Initial Preventive Physical Examination (IPPE) Ultrasound Screening for Abdominal Aortic Aneurysm (AAA) Definitions HCPCS Codes, Frequency Requirements, and Age Requirements (If Applicable)</p>
3097	October Update to the CY 2014 Medicare Physician Fee Schedule Database

	(MPFSDB)
3098	Reporting the Service Location National Provider Identifier (NPI) on Anti-Markup and Reference Laboratory Claims 3099 Payment Jurisdiction for Services Subject to the Anti-Markup Payment Limitation Diagnostic Tests Subject to the Anti-Markup Payment Limitation Billing for Diagnostic Tests (Other Than Clinical Diagnostic Laboratory Tests) Subject to the Anti-Markup Payment Limitation/Claims Submitted to A/B MACs (B) Conditional Data Element Requirements for A/B MACs (B) and DMEMACs Carrier Specific Requirements for Certain Specialties/Services Paper Claim Submission To Carriers/B MACs (B) Electronic Claim Submission to Carriers/B MACs (B) Items 14-33 - Provider of Service or Supplier Information Payment to Physician or Other Supplier for Diagnostic Tests Subject to the Anti-Markup Payment Limitation - Claims Submitted to A/B MACs (B)
3099	Instructions for Retrieving the 2015 Pricing and HCPCS Data Files through CMS' Mainframe Telecommunications Systems
3100	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3101	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3102	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3103	Reporting the Service Location National Provider Identifier (NPI) on Anti-Markup and Reference Laboratory Claims Payment Jurisdiction for Services Subject to the Anti-Markup Payment Limitation Diagnostic Tests Subject to the Anti-Markup Payment Limitation Billing for Diagnostic Tests (Other Than Clinical Diagnostic Laboratory Tests) Subject to the Anti-Markup Payment Limitation/Claims Submitted to A/B MACs (B) Conditional Data Element Requirements for A/B MACs (B) and DMEMACs Carrier Specific Requirements for Certain Specialties/Services Paper Claim Submission To Carriers/B MACs (B) Electronic Claim Submission to Carriers/B MACs (B) Items 14-33 - Provider of Service or Supplier Information Payment to Physician or Other Supplier for Diagnostic Tests Subject to the Anti-Markup Payment Limitation - Claims Submitted to A/B MACs (B)
3104	Correction to Remittance Information When HIPPS Codes are Re-coded by Medicare Systems Decision Logic Used by the Pricer on Claims HH PPS Claims Adjustments of Episode Payment - Confirming OASIS Assessment Items
3105	Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption (IDE) Studies Billing Requirements for Providers Billing for Category B IDE Devices and Routine Care Items and Services in Category B IDE Studies

	Billing Requirements for Providers Billing for Routine Care Items and Services in Category A IDE Studies Investigational Device Exemption (IDE) Studies
3106	Implementing the Payment Policies related to Patient Status from CMS-1599-F Inpatient Part B Hospital Services
3107	Medicare Shared Systems Modifications Necessary to Capture various HIPAA compliant fields Payments on the MPFS for Providers With Multiple Service Locations
3108	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3109	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3110	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3111	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3112	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3113	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3114	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3115	Modifications to the National Coordination of Benefits Agreement (COBA) Crossover Process Claims Crossover Disposition and Coordination of Benefits Agreement Bypass Indicators
3116	Elimination of the 50/50 Payment Rule for Laboratory Services on End Stage Renal Disease (ESRD) Claims Lab Services Automated Multi-Channel Chemistry (AMCC) Tests for ESRD Beneficiaries
3117	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3118	Correction to Remittance Messages When Hospice Claims are Reduced Due to Late Filing of the Notice of Election. Data Required on the Institutional Claim to Medicare Contractor Notice of Election (NOE) - Form CMS 1450
3119	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3120	Therapy Cap Values for Calendar Year (CY) 2015
3121	2015 Annual Update to the Therapy Code List
3122	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3123	October Quarterly Update for 2014 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule
3124	2015 Healthcare Common Procedure Coding System (HCPCS) Annual Update Reminder
3125	Implementation of Changes in the End-Stage Renal Disease Prospective Payment System (ESRD PPS) for Calendar Year (CY) 2015

	Required Information for In-Facility Claims Paid Under the Composite Rate and the ESRD PPS
3126	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3127	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)
3128	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3129	CY 2015 Update for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
3130	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3131	Common Edits and Enhancements Modules (CEM) Code Set Update
3132	Quarterly Update to the Correct Coding Initiative (CCI) Edits, Version 21.1, Effective April 1, 2015
3133	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
3134	Instructions for Downloading the Medicare ZIP Code File for April 2015
3135	Implement Operating Rules - Phase III ERA EFT: CORE 360 Uniform Use of Claim Adjustment Reason Codes (CARC) and Remittance Advice Remark Codes (RARC) Rule - Update from CAQH CORE
3136	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - April 2015
3137	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
3138	Fiscal Year (FY) 2015 Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) PPS Changes
3139	Implementation of Changes in the End-Stage Renal Disease Prospective Payment System (ESRD PPS) for Calendar Year (CY) 2015 Required Information for In-Facility Claims Paid Under the Composite Rate and the ESRD PPS
3140	Home Health Prospective Payment System (HH PPS) Rate Update for Calendar Year (CY) 2015
3141	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
3142	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
3143	Claim Status Category and Claim Status Codes Update
3144	Medicare Physician Fee Schedule Database (MPFSDB) 2015 File Layout Manual Addendum
3145	Home Health Prospective Payment System (HH PPS) Rate Update for Calendar Year (CY) 2015
3146	Preventive and Screening Services — Update - Intensive Behavioral Therapy

	for Obesity, Screening Digital Tomosynthesis Mammography, and Anesthesia Associated with Screening Colonoscopy
3147	Calendar Year (CY) 2015 Rural Health Clinic (RHC) and Federally Qualified Health Centers (FQHC) Updates: Payment Rate Increases for RHCs and FQHCs Billing Under the All-Inclusive Rate System (AIR) and Urban and Rural Designations for FQHCs Billing Under the AIR
3148	2015 Durable Medical Equipment Prosthetics, Orthotics, and Supplies Healthcare Common Procedure Coding System (HCPCS) Code Jurisdiction List
3149	New Waived Tests
3150	January 2015 Update of the Hospital Outpatient Prospective Payment System (OPPS) Billing for “Sometimes Therapy” Services that May be Paid as Non-Therapy Services for Hospital Outpatients Packaging Billing for Linear Accelerator (Robotic Image-Guided and Non-Robotic Image-Guided) SRS Planning and Delivery Comprehensive APCs
3151	Correction to Remittance Information When HIPPS Codes are Re-coded by Medicare Systems Adjustments of Episode Payment - Confirming OASIS Assessment Items HH PPS Claims Decision Logic Used by the Pricer on Claims
3152	Calendar Year (CY) 2015 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
3153	January 2015 Integrated Outpatient Code Editor (I/OCE) Specifications Version 16.0
3154	Automation of the Request for Reopening Claims Process Application to Special Claim Types
3155	Issued to a specific audience not posted to Internet/ Intranet due to Confidentiality of Instruction
3156	January 2015 Update of the Hospital Outpatient Prospective Payment System (OPPS) Billing for “Sometimes Therapy” Services that May be Paid as Non-Therapy Services for Hospital Outpatients Packaging Billing for Linear Accelerator (Robotic Image-Guided and Non-Robotic Image-Guided) SRS Planning and Delivery Comprehensive APCs
3157	Summary of Policies in the CY 2015 Medicare Physician Fee Schedule (MPFS) Final Rule and Telehealth Originating Site Facility Fee Payment Amount
3158	January 2015 Update of the Ambulatory Surgical Center (ASC) Payment System
3159	Modifications to Medicare Part B Coverage of Pneumococcal Vaccinations Roster Claims Submitted to Carriers/AB MACs for Mass Immunization Pneumococcal Vaccine
Medicare Secondary Payer (CMS-Pub. 100-05)	
105	Electronic Correspondence Referral System (ECRS) notification regarding Defense of Marriage Act (DOMA) and ICD-10 changes COBC Electronic Correspondence Referral System (ECRS)
106	Medicare Secondary Payer (MSP) Group Health Plan (GHP) Working Aged Policy -- Definition of “Spouse”; Same-Sex Marriages Definitions Working Aged

107	Update to Pub. 100-05, Chapters 05 and 06 to Provide Language-Only Changes for Updating ICD-10 and ASC X12 Medicare Secondary Payment Part A Claims Determination for Services Received on ASC X12 837 Institutional Electronic or Hard Copy Claim Formats Identification of Liability and No-Fault Situations Conditional Medicare Payment Medicare Secondary Payment Part B Claims Determination for Services Received on ASC X12 837 Professional Electronic Claims Sources That May Identify Other Insurance Coverage
108	Inpatient Hospital Claims and Medicare Secondary Payer (MSP) Claims with Medicare Coinsurance Days and/or Medicare Lifetime Reserve Days Occurring in the Seventh to Fifteenth Years Return Codes Payment Calculation for Inpatient Bills (MSPPAYAI Module)
109	Electronic Correspondence Referral System (ECRS) notification regarding Defense of Marriage Act (DOMA) and ICD-10 changes
Medicare Financial Management (CMS-Pub. 100-06)	
242	Medicare Financial Management Manual, Chapter 7, Internal Controls Certification Package for Internal Controls (CPIC) Requirements List of CMS Contractor Control Objectives Certification Statement CPIC - Report of Internal Control Deficiencies Statement on Standards for Attestation Engagements (SSAE) Number 16, Reporting on Controls at Service Providers Submission, Review, and Approval of Corrective Action Plans Corrective Action Plan (CAP) Reports CMS Finding Numbers Quarterly CAP Report OMB Circular A-123, Appendix A: Internal Controls Over Financial Reporting (ICOFR)
243	Notice of New Interest Rate for Medicare Overpayments and Underpayments - 1st Qtr Notification for FY 2015
244	Treasury Report on Receivables (TROR) Reporting Debts RTA, Pending Final Disposition
245	Required Changes to the Company Entry Description Value in the Batch Header Record for Backup Withholding Files
246	Recovery Auditor Appeal Adjustments with "RI" Indicator Tracking Appeals and Reopenings
247	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
248	Revision of Pub. 100-06 - Medicare Financial Management Manual, Chapter 6 - Intermediary and Carrier Financial Reports, and Pub. 100-09 - Medicare Contractor Beneficiary and Provider Communications, Chapter 6 - Provider Customer Service Program Part B - Inquiries Body of Report
Medicare State Operations Manual (CMS-Pub. 100-07)	
123	Notice of New Interest Rate for Medicare Overpayments and Underpayments - 1st Qtr Notification for FY 2015
124	Revisions to State Operations Manual (SOM), Appendix W, Interpretive Guidelines for Critical Access Hospitals

125	Revisions to State Operations Manual (SOM) Chapter 2
126	Revisions to State Operations Manual (SOM), Chapter 4 - "Program Administration and Fiscal Management"
127	Revisions to State Operations Manual (SOM), Chapter 4 - "Program Administration and Fiscal Management"
128	Revisions to State Operations Manual (SOM) Table of Contents Appendix J and Appendix Table of Contents Letter J Description
129	State Operations Manual (SOM) Appendix Y- Organ Procurement Organization (OPO) Interpretive Guidance Revisions to §486.318 Condition: Outcome Measures
130	Revisions to State Operations Manual (SOM), Appendix PP - "Guidance to Surveyors for Long Term Care Facilities"
Medicare Program Integrity (CMS-Pub. 100-08)	
546	Documentation for Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) Repair Claims. This CR rescinds and fully replaces CR 8843. Suppliers Documentation for DMEPOS Repair Claims
547	Review Timeliness Requirements for Complex Review Complex Medical Review Requesting Additional Documentation During Prepayment and Postpayment Review
548	Deletion of Program Integrity Manual Exhibit 34
549	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
550	One on One Education
551	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
552	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
553	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
554	New Timeframe for Response to Additional Documentation Requests Time-Frames for Submission
555	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
556	Revisions to Pub. 100-08, Program Integrity Manual (PIM), Chapter 15 Background Owning and Managing Organizations End-Stage Renal Disease Facilities (ESRDs)
557	Update to CMS Publication 100-08, Chapter 3, Section 3.2.3.4 (Additional Documentation Request Required and Optional Elements) Additional Documentation Request Required and Optional Elements
558	Update to the Program Integrity Manual (Pub. 100-08) Exhibit 36 - Overview of the Comprehensive Error Rate Testing (CERT) Process CERT Formats for A/B MACs (B) and DME MACs and Shared Systems CERT Formats for A/B MAC (A) MACs and Shared Systems Overview of the CERT Process
559	Issued to a specific audience not, to Internet/Intranet due to Confidentiality of Instruction
560	Program Integrity Manual Chapter 12 Revision

	<p>Contacting Non-Responders and Documentation Requests</p> <p>MAC Communication with the CERT Program</p> <p>Overview of the CERT Process</p> <p>Providing Sample Information to the CERT Review Contractor</p> <p>MAC Responsibility After Workload Transition</p> <p>Providing Feedback Information to the CERT Review Contractor</p> <p>Disputing/Disagreeing with a CERT Decision</p> <p>Handling Overpayments and Underpayments Resulting From the CERT Findings</p> <p>Disseminating CERT Information</p> <p>MAC Error Rate Reduction Plan (ERRPs)</p> <p>The Comprehensive Error Rate Testing (CERT) Program</p>
561	<p>Incorporation of Certain Provider Enrollment Policies in CMS-4159-F into Pub. 100-08, Program Integrity Manual (PIM), Chapter 15</p> <p>Indian Health Services (IHS) Facilities</p> <p>Skilled Nursing Facilities (SNFs)</p> <p>Ambulatory Surgical Centers (ASCs)</p> <p>CLIA Labs</p> <p>Mammography Screening Centers</p> <p>Pharmacies</p> <p>2/Revocations</p> <p>Radiation Therapy Centers</p> <p>Suppliers of Ambulance Services</p> <p>Intensive Cardiac Rehabilitation (ICR)</p> <p>Diabetes Self-Management Training (DSMT)</p> <p>Mass Immunizers Who Roster Bill</p> <p>Inter-Jurisdictional Reassignments</p> <p>Receiving Missing/Clarifying Data/Documentation</p> <p>Documentation</p> <p>Denials</p> <p>Non-Certified Suppliers and Individual Practitioners</p> <p>Certified Providers and Certified Suppliers</p> <p>Establishing an Effective Date of Medicare Billing Privileges</p> <p>Application Fees</p> <p>Claims against Surety Bonds</p> <p>Release of Information</p> <p>Deactivations</p> <p>Reactivations</p> <p>Reactivations - Deactivation for Reasons Other Than Non-Submission of a Claim/Reactivations - Deactivation for Non-Submission of a Claim Portable X-Ray Suppliers (PXRSS)</p>
562	Issued to a specific audience not, to Internet/Intranet due to Confidentiality of Instruction
563	Issued to a specific audience not, to Internet/Intranet due to Confidentiality of Instruction
564	Issued to a specific audience not, to Internet/Intranet due to Confidentiality of Instruction
565	Update to CMS Publication 100-08, Chapter 3, Section 3.2.3.2 (Time Frames for Submission)

Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
30	None Revision of Pub. 100-06 - Medicare Financial Management Manual, Chapter 6 – Intermediary and Carrier Financial Reports, and Pub. 100-09 - Medicare Contractor Beneficiary and Provider Communications, Chapter 6 - Provider Customer Service Program
	Reporting Provider and Beneficiary Inquiry Workload Data in the Contractor Reporting of Operational Workload Data (CROWD)
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)	
119	Chapter 16b: Special Needs Plans The majority of sections of the chapter were revised and rearranged. Additionally there are several sections with new content.
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
	None
Demonstrations (CMS-Pub. 100-19)	
109	Updates to the Model 4 Bundled Payment of Care Initiative (BPCI) Payment Calculation to Include Uncompensated Care Payment (UCP) and Reduction in Payment Due to Sequestration
110	Termination of Multi-Payer Advance Primary Care Practice (MAPCP) Demonstration in Minnesota and Pennsylvania
111	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
112	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
113	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
114	Affordable Care Act Bundled Payments for Care Improvement Initiative – Recurring File Updates Models 2 and 4 April 2015 Updates
One Time Notification (CMS-Pub. 100-20)	
1429	Fee for Service Beneficiary Data Streamlining (FFS BDS) Updates to Operational Issues
1430	Issued to a specific audience not posted to Internet/ Intranet due to Sensitivity of Instruction
1431	Issued to a specific audience not posted to Internet/ Intranet due to Sensitivity of Instruction
1432	Issued to a specific audience not posted to Internet/ Intranet due to Sensitivity of Instruction
1433	Additional Instruction on the Use of Claims Adjustment Reason Codes (CARCs) and Remittance Advice Remark Codes (RARCs) with Regard to Operating Rule: 360 Compliance
1434	Issued to a specific audience not posted to Internet/ Intranet due to Sensitivity of Instruction
1435	New Informational Unsolicited Response (IUR) Process for Durable Medical Equipment (DME) Items Furnished during a Part A Hospital Inpatient Stay

1436	Fee for Service Beneficiary Data Streamlining (FFS BDS) Phase II Analysis
1437	Data Quality Between the Multi Carrier System (MCS) and ViPS Medicare System (VMS) and the Common Working File (CWF)
1438	Data Quality between the Fiscal Intermediary Shared System (FISS) and the Common Working File (CWF)
1439	Issued to a specific audience not posted to Internet/ Intranet due to Sensitivity of Instruction
1440	Health Insurance Portability and Accountability Act (HIPAA) EDI Front End Updates for April 2015
1441	Implementation Instructions for the A/B and DME Medicare Administrative Contractors (MACs) and their Designated Shared Systems to Send the Correct Cost Avoided Indicator and Special Project Type to the Common Working File (CWF) To Ensure Correct Savings is Applied Both to the Medicare Secondary Payer (MSP) Savings Report and the Originating Contractor
1442	Issued to a specific audience not posted to Internet/ Intranet due to Sensitivity of Instruction
1443	Issued to a specific audience not posted to Internet/ Intranet due to Sensitivity of Instruction
1444	Analysis and Design to Automate Adjustments That Are Completed In The Common Working File (CWF) When Inpatient (INP) Or Skilled Nursing Facility (SNF) Claims Are Processed Out Of Sequence
1445	Rescind and Replace of CR 8409: Reclassification of Certain Durable Medical Equipment from the Inexpensive and Routinely Purchased Payment Category to the Capped Rental Payment Category
1446	IDR Shared Systems Daily Claims Feeds Expansion to Accommodate Medical Review Data Elements
1447	Rescind and Replace of CR 8409: Reclassification of Certain Durable Medical Equipment from the Inexpensive and Routinely Purchased Payment Category to the Capped Rental Payment Category
1448	Fee for Service Beneficiary Data Streamlining (FFS BDS) Updates to Operational Issues
1449	2015 Electronic Health Record System Payment Adjustment Letter
Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)	
35	Issued to a specific audience not posted to Internet/ Intranet due to Confidentiality of Instructions
36	Issued to a specific audience not posted to Internet/ Intranet due to Confidentiality of Instructions
37	Issued to a specific audience not posted to Internet/ Intranet due to Confidentiality of Instructions
38	Issued to a specific audience not posted to Internet/ Intranet due to Confidentiality of Instructions

Addendum II: Regulation Documents Published in the Federal Register (October through December 2014)

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-4Q14QPU.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 (October through December 2014)

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
Medicare Coverage of Ultrasound Screening for Abdominal Aortic Aneurysms (AAA) and Screening Fecal-Occult Blood Tests (FOBT)	NCD210.3	R176	10/17/2014	01/24/2014
Screening Hepatitis C Virus in Adults	NCD210.13	R177	11/19/2014	06/02/2014
Transcatheter Mitral Valve Repair (TMVR)-National Coverage Determination (NCD)	NCD20.33	R178	12/05/2014	08/07/2014

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (October through December 2014)

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
G140170	Syncardia Temporary Total Artificial Heart (TAH-T) System	10/03/2014
G140120	Revanesse Ultra	10/08/2014
G140171	Juvederm Voluma XC Gel Implant	10/08/2014
G140174	Spiration Valve System Model PIV-C26N	10/08/2014
G140175	IlluminOss Bone Stabilization System	10/08/2014
G140177	Tiara Valve; Tiara Delivery System	10/08/2014
G140172	AMICUS Separator System	10/09/2014
G130249	Rodo Abutment System	10/15/2014
G140055	Oncozene Microspheres	10/16/2014
G140104	Celotres	10/17/2014
G140173	A Randomize Trial Comparing Use of Continuous Glucose Monitoring with and without Routine Blood Glucose Monitoring in Adults with Type 1 Diabetes	10/20/2014
G140181	Medtronic Activa PC+S	10/29/2014
G140074	TriGuard HDH Embolic Deflection Device	10/29/2014
G140184	NovoTF-100A System	10/30/2014
G140185	CompuFlo Epidural Computer Controlled Anesthesia System EPI 6000	10/31/2014
G140187	Medtronic Activa PC+S	10/31/2014
G140189	ThermoCool SmartTouch SF Catheter D-1347-XX-SI And D-1348-XX-SI	10/31/2014
G140188	Ventana PD-L1 (SP263) Rabbit Monoclonal Primary Antibody	10/31/2014
G140158	aura6000 Targeted Hypoglossal Neurostimulation (THN) System	11/06/2014
G140194	Lumifi With Crux Vena Cava Filter System Model 7070	11/07/2014
G140198	Vysis Egrf CDx Fish Kit (LISZT NO. 08N75)	11/07/2014
G140199	Brainsway Deep TMS Device For The Treatment of Post-Traumatic Stress Disorder (PTSD)	11/07/2014
G140200	Activa PC+S Neurostimulation System	11/13/2014
G140203	Activa PC+S Neurostimulation System and Neurostimulation Systems for DBS	11/14/2014
G140201	Pediatric Cystoscope For Use in Fetal Neural Tube Defect Repair	11/14/2014
G140207	TAAA Debranching Stent Graft System	11/20/2014
G140107	Bionir Ridaforolimus Eluting Coronary Stent System	11/21/2014
G140190	EXALENZ BREATHID LF System 13C-Methacetin Breath Test	11/24/2014
G140212	Self Expanding Mitral Transcatheter Heart Valve System, Model 9800	11/25/2014
G130285	Magnap (Magnetic Apnea Prevention) Device	11/28/2014
G140214	XprESS Device for Eustachian Tube Dilation	12/03/2014
G140215	Ventana PD-L1 (SP263) Rabbit Monoclonal Primary Antibody	12/03/2014
G140219	Cervical Pessary	12/04/2014
G140226	Med-El Maestro Cochlear Implant System	12/10/2014
G140223	Accell Matristem SurgicalMatrix PSMX-6 Layers-10cm x 15cm (Accell, Inc.); Boston Scientific Wallflex Fully Covered Esophageal Stent	12/11/2014
G140126	Alfapump	12/12/2014
G140225	Early Feasibility Study of The Networked Neuroprosthesis for Grasp and Trunk Function in Spinal Cord Injury	12/12/2014

IDE	Device	Start Date
G140230	Gore Tag Thoracic Branch Endoprosthesis	12/17/2014
G140235	Exalenz BreathID For Use With C-Laeled Palmitate	12/18/2014
G140229	Juvederm Voluma (Allergan)	12/19/2014
G140233	2008K@home Nocturnal Hemodialysis Indication	12/19/2014
G140234	1.5T And 3.0T MRI Scanners	12/19/2014
G140240	Bioprosthetic Mitral Valve System	12/19/2014
G140193	Starflo Glaucoma Implant Model 92101	12/19/2014
G140239	Doctormate Renqiao Remote Ischemic Conditioning Device Type: IPC-906X	12/21/2014

Addendum VI: Approval Numbers for Collections of Information (October through December 2014)

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, (October through December 2014)

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.			
Los Alamitos Medical Center 3751 Katella Avenue Los Alamitos, CA 90720	050551	10/10/2014	CA
Walnut Hill Medical Center 7502 Greenville Avenue Dallas, TX 75231	670092	10/30/2014	TX
Einstein Medical Center Montgomery 559 West Germantown Pike East Norriton, PA 19403	390329	12/15/2014	PA
Editorial changes (in bold) for this quarter.			
Physicians Regional Healthcare System, Collier Boulevard 8300 Collier Boulevard Naples, FL 34114	100286	04/12/2012	FL
Physicians Regional Healthcare System, Pine Ridge 6101 Pine Ridge Road Naples, FL 34119	100286	11/16/2006	FL
FROM: Heart Hospital of New Mexico TO: Heart Hospital of New Mexico at Lovelace Medical Center 504 Elm Street N.E. Albuquerque, NM 87102	32009	06/20/2005	NM
FROM: Swedish Medical Center-Providence Campus TO: Swedish Medical Center- Cherry Hill 500 17th Avenue Seattle WA 98122	500025	05/23/2005	WA
FROM: The Indiana Heart Hospital, LLC TO: Community Heart and Vascular Hospital 1500 N. Ritter Indianapolis, IN 46219	15-0074	08/04/2005	IN

Addendum VIII: American College of Cardiology's National Cardiovascular Data Registry Sites (October through December 2014)

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.		
University of Arkansas Medical Sciences Physician	Little Rock	AR
Verdugo Hills Hospital	Glendale	CA
Morris Hospital	Morris	IL
Truman Medical Centers	Kansas City	MO
Great Plains Health	North Platte	NE
St. Vincent Blount	Oneonta	AL
Citizens Medical Center	Victoria	TX
Iiilo Medical Center	Iiilo	HI
Seton Medical Center Hays	Kyle	TX
The following facilities are terminations for this quarter.		
Watsonville Community Hospital	Watsonville	CA
Owensboro Health Regional Hospital	Owensboro	KY
Bartow Regional Medical Center	Bartow	FL
Camden Clark Medical Center-St Joseph Campus	Parkersburg	WV
Carlsbad Medical Center	Carlsbad	NM
Bayfront Health Spring Hill	Spring Hill	FL

Addendum IX: Active CMS Coverage-Related Guidance Documents (October through December 2014)

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>. For questions or additional information, contact JoAnna Baldwin (410-786-7205).

Addendum X:

List of Special One-Time Notices Regarding National Coverage Provisions (October through December 2014)

There were no special one-time notices regarding national coverage provisions published in the October through December 2014 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) (October through December 2014)

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 October through December 2014 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 (October through December 2014)

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 facility was de-certified this quarter.			
Rush University Medical Center 1653 West Congress Parkway Chicago, IL 60612	140119	12/18/2014	IL

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (October through December 2014)

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 October through December 2014 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 (October through December 2014)

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 October through December 2014 period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/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 (October through December 2014)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the October through December 2014 quarter.

This information is available on our website at

www.cms.gov/MedicareApprovedFacilities/PETDT/ist.asp#TopOfPage.

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-6059-N2]

Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of the Extended Temporary Moratoria on Enrollment of Ambulance Suppliers and Home Health Agencies in Designated Geographic Locations

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

ACTION: Extension of temporary moratoria.

SUMMARY: This document announces the extension of temporary moratoria on the enrollment of new ambulance suppliers and home health agencies (HHAs) in specific locations within designated metropolitan areas in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey to prevent and combat fraud, waste, and abuse.

DATES: *Effective Dates:* January 29, 2015.

FOR FURTHER INFORMATION CONTACT:

Belinda Gravel, (410) 786-8934.

News media representatives must contact CMS' Public Affairs Office at (202) 690-6145 or email them at press@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. CMS' Imposition of Temporary Enrollment Moratoria

Section 6401(a) of the Affordable Care Act added a new section 1866(j)(7) to the Social Security Act (the Act) to provide the Secretary with authority to impose a temporary moratorium on the enrollment of new Medicare, Medicaid or CHIP providers and suppliers, including categories of providers and suppliers, if the Secretary determines a moratorium is necessary to prevent or combat fraud, waste, or abuse under these programs. For a more detailed explanation of these authorities, please see the July 31, 2013 notice (78 FR 46339) or February 4, 2014 extension and establishment of a temporary moratoria document (hereinafter referred to as the February 4, 2014 moratoria document or notice) (79 FR 6475).

Based on this authority and our regulations at § 424.570, we have implemented three phases of the moratoria to date. In the notice issued on July 31, 2013 (78 FR 46339), we imposed moratoria on the enrollment of home health agencies in Miami-Dade County, Florida and Cook County, Illinois and surrounding counties and on the enrollment of ground ambulance suppliers in the Harris County, Texas area and surrounding counties. Then, in the notice published on February 4, 2014 (79 FR 6475), we extended the initial moratoria and imposed moratoria on the enrollment of home health agencies in Broward County, Florida, Dallas County, Texas, Harris County, Texas and Wayne County, Michigan and surrounding counties and on the enrollment of ground ambulance suppliers in Philadelphia, PA and surrounding counties. In the notice published on August 1, 2014 (79 FR 44702), CMS extended all of the above-mentioned moratoria.

B. Determination of the Need for Extending a Moratorium

In extending these enrollment moratoria, CMS considered both qualitative and quantitative factors suggesting a high risk of fraud, waste, or abuse. CMS relied on law enforcement's longstanding experience with ongoing and emerging fraud trends and activities through civil, criminal, and

administrative investigations and prosecutions. CMS' determination of a high risk of fraud, waste, or abuse in these provider and supplier types within these geographic locations was then confirmed by CMS' data analysis, which relied on factors the agency identified as strong indicators of risk. (For a more detailed explanation of this determination process and of these authorities, see the July 31, 2013 notice (78 FR 46339) or February 4, 2014 moratoria document (79 FR 6475)).

1. Consultation With Law Enforcement

In consultation with the HHS-Office of Inspector General (OIG) and the Department of Justice (DOJ), CMS identified two provider and supplier types in nine geographic locations that warrant a temporary enrollment moratorium. For a more detailed discussion of this consultation process, see the July 31, 2013 notice (78 FR 46339) or February 4, 2014 moratoria document (79 FR 6475).

2. Beneficiary Access to Care

Beneficiary access to care in Medicare, Medicaid, and CHIP is of critical importance to CMS and its state partners, and CMS carefully evaluated access for the target moratorium locations. Prior to imposing and extending these moratoria, CMS consulted with the appropriate State Medicaid Agencies and with the appropriate State Department of Emergency Medical Services to determine if the moratoria would create an access to care issue for Medicaid and CHIP beneficiaries in the targeted locations and surrounding counties. All of CMS' state partners were supportive of CMS analysis and proposals, and together with CMS, determined that these moratoria will not create access to care issues for Medicaid or CHIP beneficiaries. CMS also reviewed Medicare data for these areas and found there are no current problems with access to HHAs or ground ambulance suppliers.

3. Lifting a Temporary Moratorium

In accordance with § 424.570(b), a temporary enrollment moratorium imposed by CMS will remain in effect for 6 months. (For a more detailed explanation of how CMS can lift a temporary moratorium, see the July 31, 2013 notice (78 FR 46339) or February 4, 2014 moratoria document (79 FR 6475)). If CMS deems it necessary, the moratorium may be extended in 6-month increments. CMS will evaluate whether to extend or lift the moratorium before any subsequent moratorium periods. If one or more of the moratoria