

Medicare Integrity Contractor (NBI MEDIC). Developed by Health Integrity, LLC and licensed for one of its contracts—the NBI MEDIC—PLATO™ utilizes a cutting-edge advanced analytics fraud detection process in conjunction with a state-of-the-art web-based user interface tool to present fraud and abuse lead information visually to Medicare Part D plan sponsors. Summary data, based on National Prescription Drug Event Data and actions from all Part D plan sponsors, is shared with law enforcement, CMS, NBI MEDIC, and Part D plan sponsors to review historic actions taken against providers who are enrolled in the Medicare Part D program, which will assist in detecting and preventing fraud, waste, and abuse. *Form Number:* CMS-10517 (OCN: 0938-New); *Frequency:* Monthly; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 1,550; *Total Annual Responses:* 1,550; *Total Annual Hours:* 18,600. (For policy questions regarding this collection contact Delois Newkirk at 410-786-1247).

Dated: April 22, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014-09505 Filed 4-24-14; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-21 and CMS-21B]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any

other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by May 27, 2014.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395-5806 *OR Email:* *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is

publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Quarterly Children's Health Insurance Program (CHIP) Statement of Expenditures for the Title XXI Program (CMS-21) and State Children's Health Insurance Program Budget Report for the Title XXI Program State Plan Expenditures (CMS-21B); *Use:* Form CMS-21 and form CMS-21B provide CMS with the information necessary to issue quarterly grant awards, monitor current year expenditure levels, determine the allowability of state claims for reimbursement, develop Children's Health Insurance Program (CHIP) financial management information, provide for state reporting of waiver expenditures, and ensure that the federally established allotment is not exceeded. Further, these forms are necessary in the redistribution and reallocation of unspent funds over the federally mandated timeframes. *Form Number:* CMS-21 and CMS-21B (OCN: 0938-0731); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 448; *Total Annual Hours:* 7,840. (For policy questions regarding this collection contact Abraham John at 410-786-4519).

Dated: April 22, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014-09507 Filed 4-25-14; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9085-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—January Through March 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 January through March 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	Lori Ashby	(410) 786-6322
X One-time Notices Regarding National Coverage Provisions	Lori Ashby	(410) 786-6322
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	Kate Tillman, RN, MAS	(410) 786-9252
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 information 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>.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance, Program No. 93.774, Medicare—Supplementary Medical Insurance Program, and Program No. 93.714, Medical Assistance Program)

Dated: April 16, 2014.

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: May 3, 2013 (78 FR 26038) July 26, 2013 (78 FR 45233), November 8, 2013 (78 FR 67153) and January 31, 2014 (79 FR 5419). 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 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 Changes to the Laboratory National Coverage Determination (NCD) Edit Software for April 2014 (ICD-10) use CMS-Pub. 100-04, Transmittal No. 2852.

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)	
83	Update to Pub. 100-01, Chapter 7 for Language-Only Changes for ICD-10 Test Case Specification Standard
Medicare Benefit Policy (CMS-Pub. 100-02)	
179	Manual Updates to Clarify Skilled Nursing Facility (SNF), Inpatient Rehabilitation Facility (IRF), Home Health (HH), and Outpatient (OPT) Coverage Pursuant to Jimmo vs. Sebelius
180	Aprepitant for Chemotherapy Induced Emesis Oral Anti-Nausea (Anti-Emetic) Drugs

181	<p>Pub. 100-02 Language-Only Update for ICD-10</p> <p>Admission Requirements</p> <p>Partial Hospitalization Services</p> <p>Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home Coverage of Outpatient Rehabilitation Therapy Services (Physical Therapy, Occupational Therapy, and Speech-Language Pathology Services) Under Medical Insurance</p> <p>Documentation Requirements for Therapy Services</p> <p>Glaucoma Screening</p> <p>Determining Whether or Not the Beneficiary is at High Risk for Developing Colorectal Cancer</p> <p>Screening Pap Smears Limitations for Coverage</p>
182	<p>Implementing the Part B Inpatient Payment Policies from CMS-1599-F</p> <p>Medical and Other Health Services Furnished to Inpatients of Hospitals and Skilled Nursing Facilities</p> <p>Reasonable and Necessary Part A Hospital Inpatient Claim Denials</p> <p>Other Circumstances in Which Payment Cannot Be Made Under Part A</p> <p>Hospital Inpatient Services Paid Only Under Part B</p> <p>Medical and Other Health Services Furnished to SNF Patients</p> <p>Medical and Other Health Services Furnished to Inpatients of Participating Hospitals</p>
Medicare National Coverage Determination (CMS-Pub. 100-03)	
159	<p>Pub 100-03, Chapter 1, language-only update Foreword – Purpose for National Coverage Determinations (NCD) Manual</p> <p>Routine Costs in Clinical Trials (Effective July 9, 2007)</p> <p>Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain</p> <p>Outpatient Hospital Pain Rehabilitation Programs</p> <p>Anesthesia in Cardiac Pacemaker Surgery</p> <p>Percutaneous Transluminal Angioplasty (PTA) (Various Effective Dates Below)</p> <p>Cardiac Pacemakers (Various Effective Dates)</p> <p>Cardiac Pacemaker Evaluation Services</p> <p>Transtelephonic Monitoring of Cardiac Pacemakers</p> <p>Electrocardiographic Services</p> <p>Cardiac Output Monitoring By Thoracic Electrical Bioimpedance (TEB) – Various Effective Dates Below</p> <p>Speech Generating Devices</p> <p>Cochlear Implantation (Effective April 4, 2005)</p> <p>Physician's Office Within an Institution - Coverage of Services and Supplies Incident to a Physician's Services</p> <p>Hospital and Skilled Nursing Facility Admission Diagnostic Procedures</p> <p>Hydrophilic Contact Lens for Corneal Bandage</p> <p>Photodynamic Therapy</p> <p>Ocular Photodynamic Therapy (OPT) - Effective April 3, 2013</p> <p>Photosensitive Drugs</p> <p>Verteporfin - Effective April 3, 2013</p> <p>Hydrophilic Contact Lenses</p> <p>Laparoscopic Cholecystectomy</p>

<p>Certain Drugs Distributed by the National Cancer Institute</p> <p>Stem Cell Transplantation (Various Effective Dates Below)</p> <p>Anticancer Chemotherapy for Colorectal Cancer (Effective January 28, 2005)</p> <p>Abarelix for the Treatment of Prostate Cancer (Effective March 15, 2005)</p> <p>Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions</p> <p>Inpatient Hospital Stays for the Treatment of Alcoholism</p> <p>Chemical Aversion Therapy for Treatment of Alcoholism</p> <p>Use of Visual Tests Prior to and General Anesthesia During Cataract Surgery</p> <p>Withdrawal Treatments for Narcotic Addictions</p> <p>Laser Procedures</p> <p>Diathermy Treatment</p> <p>Lumbar Artificial Disc Replacement (LADR) (Effective August 14, 2007)</p> <p>Induced Lesions of Nerve Tracts</p> <p>Electrical Nerve Stimulators</p> <p>Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Enteral and Parenteral Nutritional Therapy</p> <p>Nesiritide for Treatment of Heart Failure Patients (Effective March 2, 2006)</p> <p>Nebulized Beta Adrenergic Agonist Therapy for Lung Diseases – (Effective September 10, 2007)</p> <p>Screening PAP Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer</p> <p>Computed Tomography (CT)</p> <p>Magnetic Resonance Imaging (MRI) (Various Effective Dates Below)</p> <p>Ultrasound Diagnostic Procedures (Effective May 22, 2007)</p> <p>FDG Positron Emission Tomography (PET) for Dementia and Neurodegenerative Diseases (Effective September 15, 2004)</p> <p>Positron Emission Tomography (PET) (FDG) for Oncologic Conditions - (Various Effective Dates)</p> <p>Digital Subtraction Angiography (DSA Single Photon Emission Computed Tomograph (SPECT)</p> <p>Percutaneous Image-Guided Breast Biopsy Sterilization</p> <p>Water Purification and Softening Systems Used in Conjunction with Home Dialysis</p> <p>Home Use of Oxygen</p> <p>Pulmonary Rehabilitation Services - (Effective September 25, 2007)</p> <p>Treatment of Psoriasis</p> <p>Treatment of Drug Abuse (Chemical Dependency) Wounds – (Effective July 1, 2004)</p> <p>Durable Medical Equipment Reference List (Effective May 5, 2005)</p> <p>Hospital Beds</p> <p>Infusion Pumps</p> <p>Obsolete or Unreliable Diagnostic Tests</p> <p>Intravenous Immune Globulin for the Treatment of Autoimmune Mucocutaneous</p> <p>Blistering Diseases</p>	
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160	Medicare National Coverage Determination (NCD) for Beta Amyloid Positron Emission Tomography (PET) in Dementia and Neurodegenerative Disease Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease
161	National Coverage Determination (NCD) for Single Chamber and Dual Chamber Permanent Cardiac Pacemakers Single and Dual Chamber Permanent Cardiac Pacemakers
162	Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors Positron Emission Tomography (FDG PET) for Oncologic Conditions
163	Aprepitant for Chemotherapy Induced Emesis Oral Agents for Chemotherapy-Induced Emesis
164	Medicare National Coverage Determination (NCD) for Beta Amyloid Positron Emission Tomography (PET) in Dementia and Neurodegenerative Disease Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease
Medicare Claims Processing (CMS-Pub. 100-04)	
2850	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2851	Common Edits and Enhancements Modules (CEM) Code Set Update
2852	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for April 2014 (ICD-10)
2853	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - April 2014
2854	New Waived Tests
2855	Remittance Advice Remark and Claims Adjustment Reason Code and Medicare Remit Easy Print and PC Print Update
2856	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2857	Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits
2858	Claim Status Category and Claim Status Codes Update
2859	Applying the Therapy Caps to Critical Access Hospitals
2860	Part B Claims Submission under the Indirect Payment Procedure (IPP)
2861	2014 Durable Medical Equipment Prosthetics, Orthotics, and Supplies Healthcare Common Procedure Coding System (HCPCS) Code Jurisdiction List
2862	2014 Durable Medical Equipment Prosthetics, Orthotics, and Supplies Healthcare Common Procedure Coding System (HCPCS) Code Jurisdiction List Where to Report Modifiers on the Hospital Part B Claim General Rules for Reporting Outpatient Hospital Services Billing of General Rules for Reporting Outpatient Hospital Services or Autologous Stem Cell Transplants Optional Method for Outpatient Services: Cost-Based Facility Services Plus

	115 percent Fee Schedule Payment for Professional Services Billing and Payment in a Physician Scarcity Area (PSA) Optional Method for Outpatient Services: Cost-Based Facility Services Plus 115 percent Fee Schedule Payment for Professional Services Identifying Primary Care Services Eligible for the PCIP Bill Review for Partial Hospitalization Services Received in Community Mental Health Centers (CMHC) Line Item Date of Service Reporting for Partial Hospitalization
2863	April 2014 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
2864	Additional Data Reporting Requirements for Hospice Claims Data Required on the Institutional Claim to Medicare Contractor
2865	Changes to the Laboratory National Coverage Determination (NCD) Software for ICD-10 Codes
2866	Enforcement of the 5 day Payment Limit for Respite Care Under the Hospice Medicare Benefit
2867	Enforcement of the 5 day Payment Limit for Respite Care Under the Hospice Medicare Benefit
2868	Therapy Modifier Consistency Edits Application of Financial Limitations Discipline Specific Outpatient Rehabilitation Modifiers - All Claims Reporting of Service Units With HCPCS Rebilling Therapy Services for Hospital Inpatients
2869	Issued to a specific, audience not posted to Internet/ Intranet due to Sensitivity of Instruction
2870	Addition of New Fields and Expansion of Existing Model 1 Discount Percentage Field in the Inpatient Hospital Provider Specific File (PSF) and Addition of New Fields and Renaming Payment Fields in the Inpatient Prospective Payment System (IPPS) Pricer Output
2871	Medicare National Coverage Determination (NCD) for Beta Amyloid Positron Emission Tomography (PET) in Dementia and Neurodegenerative Disease Coverage for PET Scans for Dementia and Neurodegenerative Diseases
2872	National Coverage Determination (NCD) for Single Chamber and Dual Chamber Permanent Cardiac Pacemakers Billing Requirements for Cardiac Pacemakers: Single and Dual Chamber Cardiac Pacemakers: Single and Dual Chamber Policy Cardiac Pacemaker Healthcare Common Procedure Coding System (HCPCS) Codes Cardiac Pacemaker Covered ICD-9/ICD-10 Diagnosis Codes Cardiac Pacemaker Claims Require the KX Modifier Cardiac Pacemaker Claims Without the KX modifier Cardiac Pacemaker Non Covered ICD-9/ICD-10 Diagnosis Codes Cardiac Pacemaker Claims Non Covered ICD-9/ICD-10 Diagnosis Codes: Denial Messages

2873	Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors 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 Billing and Coverage Changes for PET Scans
2874	Medicare Claims Processing Pub. 100-04 Chapter 25 Update Form Locators 43-81 Uniform Billing with Form CMS-1450 Disposition of Copies of Completed Forms General Instructions for Completion of Form CMS-1450 for Billing Form Locators 1-15 Form Locators 31-41 Uniform Bill - Form CMS-1450
2875	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2876	Update to Pub 100-04, Claims Processing Manual, Chapter One Section 20.3/CMS No Longer Accepts Provider Requests For A Change of Fiscal Intermediary Solicitation of a Provider to Secure a Change of Fiscal Intermediary Communications CMS No Longer Accepts Provider Requests to Change Their Fiscal Intermediary
2877	Implementing the Part B Inpatient Payment Policies from CMS-1599-F Payment of Part B Services in the Payment Window for Outpatient Services Treated as Inpatient Services when Part A Payment Cannot Be Made Inpatient Part B Hospital Services Editing Of Hospital Part B Inpatient Services: Reasonable and Necessary Part A Hospital Inpatient Denials Editing Of Hospital Part B Inpatient Services: Other Circumstances in Which Payment Cannot Be Made under Part A Implantable Prosthetic Devices Indian Health Service/Tribal Hospital Inpatient Social Admits Payment Window for Outpatient Services Treated as Inpatient Services
2878	Correction CR - Advance Beneficiary Notice of Noncoverage (ABN), Form CMS-R-131 ABN Scope Home Health Agency Use of the ABN General Notice Preparation Requirements
2879	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2880	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2881	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2882	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2883	Aprepitant for Chemotherapy Induced Emesis Aprepitant for Chemotherapy Induced Emesis

	Billing and Payment Instructions for A/B MAC or FIs HCPCS Codes for Oral Anti-Emetic Drugs Claims Processing Jurisdiction for Oral Anti-Emetic Drugs Oral Anti-Emetic Drugs Used as Full Replacement for Intravenous Anti-Emetic Drugs as Part of a Cancer Chemotherapeutic Regimen
2884	Claim Status Category and Claim Status Codes Update
2885	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2886	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2887	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2888	Healthcare Provider Taxonomy Codes (HPTC) Update, April 2014
2889	Common Edits and Enhancements Modules (CEM) Code Set Update
2890	Health Professional Shortage Area (HPSA) Post-payment Review Process
2891	Instructions for Downloading the Medicare ZIP Code File for July 2014
2892	Quarterly Update to the Correct Coding Initiative (CCI) Edits, Version 20.2, Effective July 1, 2014
2893	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2894	April 2014 Update of the Hospital Outpatient Prospective Payment System (OPPS)
2895	Update to Pub. 100-04, Chapter 19 to Provide Language-Only Changes for ICD-10 and ASC X12 FI - Inpatient Acute Care - Medicare Part A - Claims Processing FI Payment Policy and Claims Processing
2896	Indirect Payment Procedure (IPP) - Payment to Entities that Provide Coverage Complementary to Medicare Part B
2897	Indirect Payment Procedure (IPP) - Payment to Entities that Provide Coverage Complementary to Medicare Part B
2898	Update to Pub. 100-04 Chapter 13 to Provide Language-Only Changes for Updating ICD-10 and ASC X12 ICD Coding for Diagnostic Tests Place of Service (POS) Instructions for the Professional Component (PC or Interpretation) and the Technical Component (TC) of Diagnostic Tests Special Billing Instructions for RHCs and FQHCs Payment Requirements Medicare Summary Notices (MSN), Reason Codes, and Remark Codes Billing Instructions Coverage for PET Scans for Dementia and Neurodegenerative Diseases 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 Billing and Coverage Changes for PET Scans Effective for Services on or After April 3, 2009 Billing and Coverage Changes for PET Scans for Cervical Cancer Effective for Services on or After November 10, 2009 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 Payment Methodology and HCPCS Coding FI Payment for Low Osmolar Contrast Material (LOCM) (Radiology)
2899	Pub 100-04, Language Only Update for Chapters Five and Six for Conversion to ICD-10 Other Billing Situations 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 Consolidated Billing Requirement for SNFs 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 Part B Outpatient Rehabilitation and Comprehensive Outpatient Rehabilitation Facility (CORF) Services – General
2900	April 2014 Integrated Outpatient Code Editor (I/OCE) Specifications Version 15.1
2901	April 2014 Update of the Ambulatory Surgical Center (ASC) Payment System
2902	April 2014 Update of the Ambulatory Surgical Center (ASC) Payment System
2903	April 2014 Update of the Hospital Outpatient Prospective Payment System (OPPS) Composite APCs HCPCS Codes Replacements Reporting and Charging Requirements When the Hospital Receives Full Credit for the Replaced Device against the Cost of a More Expensive Replacement Device Prior to January 1, 2014 Reporting Requirements When the Hospital Receives Partial Credit for the Replacement Device Prior to January 1, 2014 Medicare Payment Adjustment Prior to January 1, 2014 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 Medicare Payment Adjustment Beginning January 1, 2014 Billing and Payment for Observation Services Beginning January 1, 2008 Billing and Payment for Direct Referral for Observation Care Furnished

	Beginning January 1, 2008 Drugs, Biologicals, and Radiopharmaceuticals Reporting and Charging Requirements When a Device is Furnished Without Cost to the Hospital Prior to January 1, 2014
2904	Update to Pub. 100-04, Chapter 16 to Provide Language-Only Changes for Updating ICD-10 and ASC X12
2905	Update to Pub. 100-04, Chapters 7 and 8 to Provide Language-Only Changes for Updating ICD-10 and ASC X12 Billing Formats Data Elements Required on Claim for Monthly Capitation Payment Billing Billing for Enteral and Parenteral Nutritional Therapy as a Prosthetic Device Mammography Screening Hospital Services Calculation of the Basic Case-Mix Adjusted Composite Rate and the ESRD Prospective Payment System Rate In-Facility Dialysis Bill Processing Procedures Required Information for In-Facility Claims Paid Under the Composite Rate and the ESRD PPS Payment for Hemodialysis Sessions Ultrafiltration Lab Services Separately Billable ESRD Drugs Physician Billing Requirements to the Carrier Other Information Required on the Form CMS-1500 for Epoetin Alfa (EPO) Other Information Required on the Form CMS-1500 for Darbepoetin Alfa (Aranesp) General Intermediary Bill Processing Procedures for Method I Home Dialysis Services Physician's Services Furnished to a Dialysis Patient Away From Home or Usual Facility Physicians and Supplier (Nonfacility) Billing for ESRD Services/General Billing for Durable Medical Equipment (DME), Orthotic/Prosthetic Devices, and Supplies (including Surgical Dressings)
2906	Pub 100-04, Chapter 28 language-only update for ASC X12 version 5010, implementation of MACs, and MAC coordination with Medigap, Medicaid and Other Complementary Insurers. Medigap/ Definition and Scope Assignment of Claims and Transfer Policy Requirements as of July 2012 Completion of the Claim Form Form CMS-1500/ASC X12 837 Professional COB Form CMS-1450/ASC X12 837 Institutional COB MSN Messages Remittance Notice Messages Returned Medigap Notices Coordination of Medicare With Medigap and Other Complementary Health Insurance Policies Requests for Additional Information Release of Title XVIII Claims Information for Medigap Insurance Purposes by Providers

	Standard Medicare Charges for COB Records General Guidelines for A/B MAC (A, B, or HH) or DME MAC Transfer of Claims Information to Medigap Insurers Consolidation of the Claims Crossover Process Coordination of Benefits Agreement (COBA) Detailed Error Report Notification Process Coordination of Benefits Agreement (COBA) ASC X12 837 5010 Coordination of Benefits (COB) Flat File Errors Coordination of Benefits Agreement (COBA) Full Claim File Repair Process Coordination of Benefits Agreement (COBA) Eligibility File Claims Recovery Process Coordination of Benefits Agreement (COBA) Medigap Claim-Based Crossover Process Coordination of Benefits Agreement (COBA) ASC X12 837 Coordination of Benefits (COB) Mapping National Council for Prescription Drug Programs (NCPDP) Version D.0 Coordination of Benefits (COB) Mapping Requirements Electronic Transmission/ General Requirements Reserved Reserved Beneficiary Insurance Assignment Selection A/B MAC (A) Crossover Claim Requirements B MAC/DME MAC Crossover Claim Requirements Reserved Medigap Insurers Fraud Referral Outline of Complaint Referral Process Medigap Electronic Claims Transfer Agreements
2907	Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens Travel Allowance
2908	Update to Pub. 100-04, Chapter 15 to Provide Language-Only Changes for Updating ICD-10 and ASC X12 Medical Conditions List and Instructions General Billing Guidelines Coding Instructions for Paper and Electronic Claim Forms Fiscal Intermediary Shared System (FISS) Guidelines A/MAC Bill Processing Guidelines Effective April 1, 2002, as a Result of Fee Schedule Implementation Definition
2909	Medicare Claims Processing Pub. 100-04 Chapter 31 Update Health Care Claim Status Category Codes and Health Care Claim Status Codes for Use with the Health Care Claim Status Request and Response ASC X12 Claim Status Request and Response Background Eligibility Connectivity Workflow Claim Status Request/Response Transaction Standard Transmission Requirements Batch Transactions Online Direct Data Entry Interactive/Online (Non-DDE)

	Summary of the ASC X12 276/277 Claim Status Request and Response Process for A/B Medicare Administrative Contractors, DME MACs, CEDI Flat File Translation Requirements Transmission Mode Health Care Eligibility Benefit Inquiry and Response Implementation
2910	Update to Pub. 100-04, Medicare Claims Processing Manual, Chapter 11 to Provide Language-Only Changes for Updating ICD-10 and ASC X12 Completing the Uniform (Institutional Provider) Bill (Form CMS 1450) for Hospice Election Data Required on the Institutional Claim to Medicare Contractor Medicare Summary Notice (MSN) Messages/ASC X12 Remittance Advice Adjustment Reason and Remark Codes
2911	Manual Updates to Clarify Skilled Nursing Facility Advanced Beneficiary Notice (SNF ABN) Requirements Pursuant to Jimmo vs. Sebelius Proper Denial Paragraphs
2912	April Update to the CY 2014 Medicare Physician Fee Schedule Database (MPFSDB)
2913	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2914	Health Professional Shortage Area (HPSA) Post-payment Review Process Post-payment Review
2915	Medicare National Coverage Determination (NCD) for Beta Amyloid Positron Emission Tomography (PET) in Dementia and Neurodegenerative Disease Coverage for PET Scans for Dementia and Neurodegenerative Diseases
2916	Calendar Year (CY) 2014 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment – REVISION
2917	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
Medicare Secondary Payer (CMS-Pub. 100-05)	
99	Apply Front-End Edits to Electronic Correspondence Referral System (ECRS) Files Submitted Via ECRS Web and PDR Assistance Request Action Code BN COBC Electronic Correspondence Referral System (ECRS)
100	The Medicare Contractors and the Shared Systems Shall Send the Correct Cost Avoided Indicator and Special Project Type to the Common Working File (CWF) so the Correct Savings is applied both to the Medicare Secondary Payer (MSP) Savings Report and the Originating Contractor
Medicare Financial Management (CMS-Pub. 100-06)	
230	Notice of New Interest Rate for Medicare Overpayments and Underpayments—2nd qtr Notification for FY 2014
231	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
232	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
Medicare State Operations Manual (CMS-Pub. 100-07)	
99	Revised State Operations Manual (SOM) Appendices A, I, L, and W

100	State Operations Manual (SOM) Appendix AA revisions for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID). Psychiatric Hospitals-Interpretive Guidelines and Survey Procedures/Title AA-Psychiatric Hospitals-Interpretive Guidelines and Survey Procedures/B112/\$482.61(b)(2) Include a Medical History
101	State Operations Manual (SOM) Appendix I revisions for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) II-Survey Procedures and Interpretive Guidelines for Life Safety Code Surveys/Part II-Interpretive Guidelines/II. The Survey Tasks/Task 4- Information Gathering I-Survey Procedures and Interpretive Guidelines for Life Safety Code Surveys/Part II-Interpretive Guidelines/II. The Survey Tasks/Task 2- Entrance Conference/Onsite Preparatory Activities I-Survey Procedures and Interpretive Guidelines for Life Safety Code
102	State Operations Manual (SOM) Appendix Q revisions for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID). Q-Guidelines for Determining Immediate Jeopardy/Attachment C-Overview Recommended Key Components of Systemic Approach to Prevent Abuse and Neglect Q-Guidelines for Determining Immediate Jeopardy/Attachment A Q-Guidelines for Determining Immediate Jeopardy/VIII-Enforcement/ A-Termination for Title XIX-Only NFs, ICFs/IID
103	Revised State Operations Manual (SOM) Hospital Appendix A Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.
104	State Operations Manual (SOM) Appendix M revisions for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)
105	Revised Appendix A, Interpretive Guidelines for Hospitals, Condition of Participation: Quality Assessment and Performance Improvement
Medicare Program Integrity (CMS-Pub. 100-08)	
501	Complex Medical Review
502	Registration of Entities Using the Indirect Payment Procedure (IPP) Registration Letters Indirect Payment Procedure – Background Submission of Registration Applications Processing of Registration Applications Disposition of Registration Applications Revocation of Registration Changes of Information and Other Registration Transactions Indirect Payment Procedure
503	Inter-Jurisdictional Reassignments
504	Revision to Chapter 12 of the Medicare Program Integrity Manual - The Comprehensive Error Rate Testing Program. The Comprehensive Error Rate Testing (CERT) Program MAC Communication with the CERT Program Overview of the CERT Process Providing Sample Information to the CERT Review Contractor Providing Review Information to the CERT Review Contractor MAC Responsibility After Workload Transition Providing Feedback Information to the CERT Review Contractor

	Disputing/Disagreeing With a CERT Decision Voluntary Refunds Handling Appeals Resulting From CERT Initiated Denials CERT Appeal Results Disseminating CERT Information Error Rate Reduction Plans (ERRPs) Contacting Non-Responders & Documentation Requests Late Documentation Received by the CERT Review Contractor Handling Overpayments and Underpayments Resulting From the CERT
505	Removing Prohibition Requesting Additional Documentation During Prepayment and Postpayment Review
506	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
507	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
508	Supplemental Medical Review Contractor Overview of Program Integrity and Provider Compliance Medicare Improper Payment Reduction Efforts - Provider Compliance Types of Contractors Improper Payment Prevention Goals Applicable Program Integrity Manual Sections Performance Metrics Types of Claims for Which Contractors Are Responsible Quality of Care Issues and Potential Fraud Issues The MAC and SMRC Medical Review Program Goal of MAC and SMRC MR Program Provider Self Audits Coordination Among Contractors Maintaining the Confidentiality of MR Medical Records and Documents Medical Review Manager Contractor Medical Director (CMD)
509	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
00	None
Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)	
00	None
Medicare Managed Care (CMS-Pub. 100-16)	
116	Conversion from ICD-9 to ICD-10 and from ASC X12 Version 4010 to 5010 Expanded Alternative Verification Methodology Calibration of the CMS-HCC Risk Adjustment Models Model Similarities Operations Sources of Data Format Diagnosis Cluster Valid Diagnosis Codes Health Insurance Portability and Accountability Act (HIPAA) Glossary of Terms Rules for Payment of “Significant Cost” NCDs and LCBs

	Special Rules for the September 2000 NCD on Clinical Trials Category B Investigational Device Exemption (IDE) Trials Adjustment to MA Payments Under the CMS-HCC Risk Adjustment Models Role and Responsibilities of Plan Sponsors
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
00	None
Demonstrations (CMS-Pub. 100-19)	
94	Affordable Care Act Bundled Payments for Care Improvement Initiative - Recurring File Updates Models 2 and 4 April 2014 Update
95	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
96	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
97	MAPCP Demonstration - Update for ICD-10
One Time Notification (CMS-Pub. 100-20)	
1332	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
1333	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
1334	Occurrence Span Code 72; Identification of Outpatient Time Associated with an Inpatient Hospital Admission and Inpatient Claim for Payment
1335	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1336	Modifying the Daily Common Working File (CWF) to Medicare Beneficiary Database (MBD) File to Include Diagnosis Codes on the Health Insurance Portability and Accountability Act Eligibility Transaction System (HETS) 270/271 Transactions
1337	Encounter Data System Payer ID: Payer ID Creation for the Financial Alignment Demonstration for Medicare Medicaid Plans (MMPs)
1338	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
1339	CWF Editing for Vaccines Furnished at Hospice – Correction
1340	Health Insurance Portability and Accountability Act (HIPAA) EDI Front End Updates for July 2014
1341	Changing Fiscal Intermediary Shared System (FISS) Action on Informational Unsolicited Responses (IURs) From Canceled Claims to Adjustments
1342	Reporting principal and interest amounts when refunding previously recouped money on the Remittance Advice (RA)
1343	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
1344	Fee for Service Beneficiary Data Streamlining (FFS BDS)
1345	Implementing Operating Rule (OR)-Phase III ERA Or Dual Delivery of ERA and Paper Remittance
1346	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
1347	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1348	Handling Bankrupt Suppliers within VMS

1349	Implementation of NACHA Operating Rules for Health Care Electronic Funds Transfers (EFT)
1350	Clarification of Remittance Advice Code Combination Reports Generated by Shared Systems
1351	Implementation of HIPAA Standards and Operating Rules for Health Care Electronic Funds Transfers
1352	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1353	International Classification of Diseases, 10th Revision (ICD-10) Testing with Providers through the Common Edits and Enhancements Module (CEM) and Common Electronic Data Interchange (CEDI).
1354	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1355	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1356	Modifying the Daily Common Working File (CWF) to Medicare Beneficiary Database (MBD) File to Include Diagnosis Codes on the Health Insurance Portability and Accountability Act Eligibility Transaction System (HETS) 270/271 Transaction
1357	International Classification of Diseases, 10th Revision (ICD-10) Testing with Providers through the Common Edits and Enhancements Module (CEM) and Common Electronic Data Interchange (CEDI)
1358	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-Oct. 1, 2013 version 3.0.3
1359	The Coordination of Benefits Contractor (COBC) to Remove and No Longer Apply Federal Tax Information (FTI) Received through the Internal Revenue Service (IRS), Social Security Administration (SSA), Centers for Medicare and Medicaid Services (CMS) Medicare Secondary Payer (MSP) Data Match Program on the Common Working File (CWF).
1360	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-Oct. 1, 2013 version 3.0.3
1361	Implementation of NACHA Operating Rules for Health Care Electronic Funds Transfers (EFT)
1362	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
1363	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-Feb. 1, 2014 version 3.0.4
1364	Pioneer Accountable Care Organization (ACO) Payment Adjustment
Medicare Quality Reporting Incentive (CMS-Pub. 100-22)	
19	Electronic Prescribing (eRx) Incentive Supplemental Payment
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
2	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction

**Addendum II: Regulation Documents Published
in the Federal Register (January through March 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-1Q14QPU.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 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
PET (FDG) for Solid Tumors	NCD220.6.17	TR162	02/06/2014	06/11/2013
Beta Amyloid PET in Dementia/ Neurodegenerative Disease	NCD 220.6.18	TN160	02/06/2014	09/27/2013
Single-Chamber/Dual-Chamber Permanent Cardiac Pacemakers	NCD20.8	TN 161	02/06/2014	08/13/2013
Aprepitant for Chemotherapy-Induced Emesis	NCD110.18	TN163	02/21/2014	05/29/2013

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (January through March 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
G130288	Medtronic Activa PC+S System Cook Custom Aortic Endograft and Zenith t-Branch Endovascular Graft	01/03/2014
G130292	EXOGEN Ultrasound Bone Healing System	01/08/2014
G130300	Focused Ultrasound Stimulator For Aesthetic Use	01/22/2014
G130132	Therapy Cool Flex Ablation Catheter	01/22/2014
G130237	Embosphere Microspheres	01/24/2014
G130303	Concert Implant	01/30/2014
G140003	Essure System for Permanent Birth Control	01/31/2014
G130248	SIR-Spore Microspheres	01/31/2014
G130228	SIR-Spheres Microspheres Brachytherapy Device Plus Delivery	01/31/2014
G130127	VIDI ICV Filter System	02/04/2014
G140006	Medtronic Tined Leads (Models 3889 and 3093) and the Medtronic Restoreprime Neurostimulatory (Model 37701)	02/04/2014
G130244	LUTONIX 035 Drug Coated Balloon PTA Catheter	02/06/2014
G140001	Nucleus 24 Auditory Brainstem Implant (ABI)	02/07/2014
G130245	Micra Transcatheter Pacemaker System Model MC1VR01	02/10/2014
G130278	Embozene Microspheres	02/11/2014
G130290	BrainSonix BX Pulsar 1001 Focused Ultrasonic	02/12/2014
G130276	Sentinel Cerebral Protection System	02/14/2014
G130205	Embosphere	02/14/2014
G130172	Tigerpaw System II	02/21/2014
G140014	RMY Contact Lens	02/21/2014
G140013	FAME 3	02/21/2014
G130190	Vascular Embolization Device	02/26/2014
BB15909	Emergency Use - Treatment of using Haploidentical Parental Adenovirus Specific T-Cells using the CliniMACS System (Cytokine Capture Reagent, Interferon-gamma)	02/27/2014
G130213	Vascular Sealing System	02/28/2014
G140019	Implany, Cochlear	03/05/2014
G140020	Dako PD-L1 IHC pharmDx kit	03/06/2014
G140021	Toronto EVLP System	03/06/2014
G140025	COSTATUS SYSTEM	03/12/2014
G130223	Concentric Medical, Inc	03/20/2014
G130287	Microtransponder, Inc	03/20/2014
G130034	BIOFREEDOM Drug Coated Coronary Stent System	03/25/2014
G140028	Teosyal RHA Global Action (TP30L), Teosyal RHA Deep Lines (TP27L)	03/26/2014
G140030	Best-CLI	03/27/2014
G140032	MolecularMD MRDX BCR-ABL TEST	03/27/2014

Addendum VI: Approval Numbers for Collections of Information (January through March 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, (January through March 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 facility is a new listing for this quarter.			
Capital Regional Medical Center 2626 Capital Medical Boulevard Tallahassee, FL 32308	100254	02/27/2014	FL
Berwick Hospital Center 701 E. 16th Street Berwick, PA 18603	1316919699	02/27/2014	PA
Texas Heart Health and Vascular Hospital Arlington 811 Wright Street Arlington, TX 76012	670071	02/27/2014	TX
Doctors Hospital 3651 Wheeler Road Augusta, GA 30909	110177	03/05/2014	GA
Baylor Medical Center at McKinney 5252 W. University Drive. Hwy 380 At Lake Forest Drive McKinney, TX 75071	670082	03/24/2014	TX

Facility	Provider Number	Effective Date	State
Editorial changes (shown in bold) were made to the facilities listed below.			
FROM: Southwest Washington Medical Center TO: PeaceHealth Southwest Medical Center 400 N.E. Mother Joseph Place Vancouver, WA 98668 P.O. Box 1600	500050	05/26/2005	WA
Covenant Healthcare 900 Cooper Avenue Saginaw, MI 48602	230070	06/22/2006	MI

Addendum VIII:

American College of Cardiology's National Cardiovascular Data Registry Sites (January through March 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.		
Carolina Pines Regional Medical Center	Hartsville	SC
Charlotte Regional Medical Center	Punta Gorda	FL
Town & Country Hospital	Tampa	FL
Crossgates River Oaks Hospital	Brandon	MS
St. Cloud Regional Medical Center	Saint Cloud	FL
Summit Medical Center	Van Buren	AR
Saint Mary's Mercy Medical Center	Grand Rapids	MI
Fisher-Titus Medical Center	Norwalk	OH
University Medical Center	Lebanon	TN
Geisinger Community Medical Center	Scranton	PA
Tulare District Hospital	Tulare	CA
Lake Norman Regional Medical Center	Mooreville	NC
Methodist Mansfield Medical Center	Mansfield	TX
University of Texas Health Science Center at Tyler	Tyler	TX
Mercy Hospital Ada	Ada	OK
Hospital totalCor	Sao Paulo	Brazil
St. Luke's Warren Campus	Phillipsburg	NJ
Castle Rock Adventist	Castle Rock	CO
New York Presbyterian - Weill Cornell Medical Center	New York	NY
Santa Rosa Medical Center	Milton	FL
Shands Lake Shore Regional Medical Center	Lake City	FL
Bayfront Health Spring Hill	Spring Hill	FL
Williamson Memorial Hospital	Williamson	WV
Pine Creek Medical Center	Dallas	TX
New York Presbyterian Hospital-Columbia	New York	NY
Central Carolina (TENET)	Sanford	NC
Saint Vincent Medical Center North	Little Rock	AR
Children's Hospital of Los Angeles	Los Angeles	CA
Northbank Surgical Center	Salem	OR
Children's Hospital of Philadelphia	Philadelphia	PA
Mary Lanning Healthcare	Hastings	NE
Mercy Tiffin Hospital	Tiffin	OH
Wilson Medical Center	Wilson	NC
Signature Healthcare Brockton Hospital	Brockton	MA
Norton Brownsboro Hospital	Louisville	KY

Facility	City	State
The following facilities are new listings for this quarter.		
Walnut Hill Medical Center	Dallas	TX
Coronado Surgery Center	Henderson	NV
Eastern New Mexico Medical Center	Roswell	NM
Valley View Hospital	Glenwood Springs	CO
The Heart Hospital Baylor Denton	Denton	TX
Baylor Medical Center Carrollton	Carrollton	TX
Temecula Valley Hospital	Temecula	CA
St Mary's Medical Center	Blue Springs	MO
The following facilities are terminated as of this quarter.		
Oconee Regional Medical Center	Milledgeville	GA
Charlotte Regional Medical Center	Punta Gorda	FL
Crossgates River Oaks Hospital	Brandon	MS
Shands Lake Shore Regional Medical Center	Lake City	FL

Addendum IX: Active CMS Coverage-Related Guidance Documents (January through March 2014)

There were no CMS coverage-related guidance documents published in the January through March 2014 quarter. To obtain the document, visit the CMS coverage website at <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=23>. For questions or additional information, contact Lori Ashby (410-786-6322).

Addendum X: List of Special One-Time Notices Regarding National Coverage Provisions (January through March 2014)

There were no special one-time notices regarding national coverage provisions published in the January through March 2014 quarter. This information is available at www.cms.hhs.gov/coverage. For questions or additional information, contact Lori Ashby (410-786-6322).

Addendum XI: National Oncologic PET Registry (NOPR) (January through March 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 January through March 2014 quarter. This information is available at

<http://www.cms.gov/MedicareApprovedFacilities/NOPR/list.asp#TopOfPage>. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (January through March 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/MedicareApprovedFacilities/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.			
Moses H. Cone Memorial Hospital 1200 North Elm Street Greensboro NC 27401-1020	340091	01/08/2014	NC
Mercy General Hospital 4001 J Street Sacramento, CA 95819	050071	02/12/2014	CA

Geisinger Wyoming Valley Medical Center 1000 East Mountain Drive Wilkes Barre, PA 18711	39-0270	02/26/2014	PA
Tulane University Hospital and Clinic 1415 Tulane Avenue New Orleans, LA 70112	190176	03/15/2013	LA
Editorial changes (shown in bold) were made to the facilities listed below.			
FROM: Clarian Health Partners, Inc. (Methodist Hospital) TO: Indiana University Health, Inc. 1701 N. Senate Boulevard Indianapolis, IN 46206	150056	11/25/2003	IN

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (January through March 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 January through March 2014 quarter. This information is available at www.cms.gov/MedicareApprovedFacilities/LVRS/list.asp#TopOfPage. For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (January through March 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 January through March 2014 period. This information is available at www.cms.gov/MedicareApprovedFacilities/BSF/list.asp#TopOfPage. For questions or additional information, contact Kate Tillman, RN, MAS (410-786-9252).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (January through March 2014)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the January through March 2014 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. 2014-09288 Filed 4-24-14; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services**

[CMS-1466-N]

Medicare Program: Notice of Two Membership Appointments to the Advisory Panel on Hospital Outpatient Payment

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces two new membership appointments to the Advisory Panel on Hospital Outpatient Payment (the Panel). The two new appointments to the Panel will each serve a 4-year period. The new members will have terms that begin on February 16, 2014 and continue through February 15, 2018. The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services concerning the clinical integrity of the Ambulatory Payment Classification groups and their relative payment weights. The Panel also addresses and makes recommendations regarding supervision of hospital outpatient services. The advice provided by the Panel will be considered as we prepare the annual updates for the hospital outpatient prospective payment system.

FOR FURTHER INFORMATION CONTACT: For additional information on the Panel meeting dates, agenda topics, copy of the charter, as well as updates to the Panel's activities, search our Internet Web site: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>. For other information regarding the Panel, contact Carol Schwartz, the Designated Federal Officer (DFO) at CMS, Center for Medicare, Hospital and Ambulatory Policy Group, Division of Outpatient Care, 7500 Security Boulevard, Mail Stop C4-05-17, Baltimore, MD 21244-1850, phone (410) 786-3985.

SUPPLEMENTARY INFORMATION:**I. Background**

The Department of Health and Human Services (the Secretary) is required by section 1833(t)(9)(A) of the Social Security Act (the Act) (42 U.S.C. 1395l(t)(9)(A)) and section 222 of the

Public Health Service Act (PHS Act) (42 U.S.C. 217a) to consult with an expert outside advisory panel on the clinical integrity of the Ambulatory Payment Classification groups and relative payment weights, which are major elements of the Medicare Hospital Outpatient Prospective Payment System (OPPS), and the appropriate supervision level for hospital outpatient services. The Panel is governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92-463), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory panels. The Panel Charter provides that the Panel shall meet up to 3 times annually. We consider the technical advice provided by the Panel as we prepare the proposed and final rules to update the OPPS for the following calendar year.

The Panel shall consist of a chair and up to 19 members who are full-time employees of hospitals, hospital systems, or other Medicare providers. The Secretary or a designee selects the Panel membership based upon either self-nominations or nominations submitted by Medicare providers and other interested organizations. New appointments are made in a manner that ensures a balanced membership under the FACA guidelines.

The Panel presently consists of the following members and a Chair.

- Edith Hambrick, M.D., J.D., Chair, CMS Medical Officer.
- Karen Borman, M.D., FACS.
- Kari S. Cornicelli, C.P.A., FHFMA.
- Brian D. Kavanagh, M.D., MPH.
- Scott Manaker, M.D., Ph.D.
- John Marshall, CRA, RCC, CIRCC, RT(R), FAHRA.
- Jim Nelson, M.B.A., C.P.A., FHFMA.
- Leah Osbahr, M.A., MPH.
- Jacqueline Phillips.
- Traci Rabine.
- Michael Rabovsky, M.D.
- Marianna V. Spanaki-Varela, MD, Ph.D., M.B.A.
- Gale Walker.
- Kris Zimmer.

II. Provisions of the Notice

We published a notice in the **Federal Register** on November 1, 2013, entitled "Medicare Program; Solicitation of Five Nominations to the Advisory Panel on Hospital Outpatient Payment (HOP, the Panel)" (78 FR 65660). The notice solicited nominations for five new members to fill the vacancies on the Panel beginning September 30, 2013. As a result of that notice, we are announcing two new members to the Panel. The Panel currently consists of 15 members. The two new Panel

members appointments are for 4-year terms beginning on February 16, 2014.

New Appointments to the Panel

The two new members of the Panel with terms beginning on February 16, 2014 and continuing through February 15, 2018 are as follows:

- Wendy Resnick, FHFMA.
- Johnathan Pregler, M.D.

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Dated: April 17, 2014.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014-09289 Filed 4-24-14; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2010-N-0555]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Device Tracking

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for the tracking of medical devices.

DATES: Submit either electronic or written comments on the collection of information by June 24, 2014.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of