

have to provide a short statement about why they are electing to implement an unreasonable rate increase. This statement would be entered into a data entry text box in the Rate Review Data Collection System and would not need to be more than a paragraph or two in length. There is no form or instructions associated with this statement apart from the requirements provided in the regulation.

The Final Justification Statement will be posted on an HHS Web site in the same location as the Preliminary Justification and Rate Review Final Determination. Additionally, health insurance issuers implementing rate increases that were determined to be unreasonable, must post all of this information—the Preliminary Justification, the Rate Review Final Determination, and the Final Justification Statement on their Web sites for a period of 3 years.

In addition to the aforementioned requirements, we revised the information collection request as a result of an amendment to the regulation discussed in the final rule that published September 6, 2011 (76 FR 54969). The amendment to the rate review final rule updated the applicability of the rate review requirements to include products that would be considered part of the individual or small group market had they not been sold through associations, including those that are considered to be large group products under State law or have been otherwise excluded from State's existing definitions for individual and small group products. This change resulted in an increase in the total number of rate increases that are subject to the rate review reporting requirements. The amendment did not propose any changes to the information that issuers must submit for each rate increase. Thus, burden associated with each rate increase submission remains unchanged from the final rate review rule. The revised association product reporting requirements took effect on November 1, 2011. CMS received a 6 month Emergency PRA approval for the revised association reporting requirements on October 31, 2011 (OMB-0938-1141). CMS is now requesting a 3-year OMB approval of these collection requirements. *Form Number:* CMS-10379 (OCN: 0938-1141); *Frequency:* Annually; *Affected Public:* Private Sector and States; *Number of Respondents:* 452; *Number of Responses:* 3,571; *Total Annual Hours:* 14,630. (For policy questions regarding this collection, contact Sally McCarty at (301) 492-4489. For all other issues call (410) 786-1326.)

4. *Type of Information Collection Request:* New information collection; *Title of Information Collection:* Medical Loss Ratio Annual Reporting and Rebate Calculation; *Use:* Under Section 2718 of the Affordable Care Act and implementing regulations at 45 CFR Part 158 (75 FR 74864, December 1, 2010 (Interim Final Rule); 75 FR 82277, December 30, 2010 (Technical Correction); and 76 FR 76574, December 7, 2011 (Final Rule with comment period)), a health insurance issuer (issuer) offering group or individual health insurance coverage must submit a report to the Secretary concerning the amount the issuer spends each year on claims, quality improvement expenses, non-claims costs, Federal and State taxes and licensing and regulatory fees, and the amount of earned premium. An issuer must provide an annual rebate to enrollees if the amount it spends on certain costs compared to its premium revenue (excluding Federal and States taxes and licensing and regulatory fees) does not meet a certain ratio, referred to as the medical loss ratio (MLR). An interim final rule (IFR) implementing the MLR was published on December 1, 2010 (75 FR 74865) and modified by technical corrections on December 30, 2010 (75 FR 82277), which added Part 158 to Title 45 of the Code of Federal Regulations. The IFR is effective January 1, 2011. A final rule regarding selected provisions of the interim final rule was published on December 7, 2011 (76 FR 76574) and an interim final rule regarding an issue not included in issuers' reporting requirements (distribution of rebates by non-federal governmental plans) was also published on December 7, 2011 (76 FR 76596). Each issuer is required to submit MLR data annually, including information about any rebates it must provide, on a form prescribed by CMS for each large group market, small group market, and individual market within each State in which the issuer conducts business. Data is to be submitted electronically through CMS' Health Insurance Oversight System (HIOS). Additionally, each issuer is required to maintain for a period of seven years all documents, records and other evidence that support the data included in each issuer's annual report to the Secretary. *Form Number:* CMS-10418; *Frequency:* Annually; *Affected Public:* Private Sector; Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 527; *Number of Responses:* 5,530; *Total Annual Hours:* 352,563. (For policy questions regarding this collection, contact Carol Jimenez at

(301) 492-4457. For all other issues, call (410) 786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by February 14, 2012:

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: December 13, 2011.

Martique Jones,

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

[FR Doc. 2011-32290 Filed 12-15-11; 8:45 a.m.]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9068-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July Through September 2011

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 July through September 2011, 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	Sarah J. McClain	(410) 786-2294
VIII American College of Cardiology-National Cardiovascular Data Registry Sites.	JoAnna Baldwin, MS	(410) 786-7205
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.	JoAnna Baldwin, MS	(410) 786-7205
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	JoAnna Baldwin, MS	(410) 786-7205
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

Among other things, 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. Summary of the Solicitation for Comments and Response to Comments

As explained in the notice with comment period that published in the August 8, 2011 **Federal Register** (76 FR 48564), technology has advanced since we published our first notice on June 9, 1988, and the information provided in this notice is now available in more efficient, economical, and accessible ways to meet the requirement for publication set forth in the statute. Each quarter, we publish the most current and relevant information; however, many of the quarterly notices simply duplicate the information that was previously published, since there often are no new relevant updates in some categories for the quarter. In addition, there is a 3-month lapse between the information available on the Web site and information covered by this quarterly notice.

In the August 8, 2011 notice (76 FR 48564), we solicited comments on alternative formats to provide this information to the public. For example, we explained that we could publish a notice that provided only Web links to the addenda, or provide this information on a newly-created CMS Quarterly Issuance Web page. We solicited comments and any additional information as to whether these alternative processes would improve accessibility to information. We also inquired whether a new format would pose a problem to those who access the information contained in this notice or pose an unintended burden to beneficiaries, providers, and suppliers.

We did not receive any comments in response to our solicitation.

III. Revised Format for the Quarterly Issuance Notices

While we are publishing the quarterly notice required by section 1871(c) of the Act, we will no longer republish duplicative information that is available to the public elsewhere. We believe this approach is in alignment with CMS' commitment to the general principles of the President's Executive Order 13563 released January 2011 entitled "Improving Regulation and Regulatory Review," which promotes modifying and streamlining an agency's regulatory program to be more effective in achieving regulatory objectives. Section 6 of Executive Order 13563 requires agencies to identify regulations that may be "outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand or repeal them in accordance with what has been learned." This approach is also in alignment with the President's Open Government and Transparency Initiative that establishes a system of transparency, public participation, and collaboration.

Therefore, beginning with this quarterly notice, we will provide 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.

IV. 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: December 8, 2011 .

Jacquelyn Y. White,
Director, Office of Strategic Operations and Regulatory Affairs.

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Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the Medicare National Coverage Determination publication titled Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer Autologous Cellular Immunotherapy Treatment –use CMS-Pub. 100-03, Transmittal No. 133.

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

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: December 17, 2010 (75 FR 79174), March 31, 2011 (76 FR 17873), August 8, 2011 (76 FR 48564) and November 4, 2011 (76 FR 68467). For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the Web site to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (July through September 2011)

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

Transmittal Number	Manual/Subject/Publication Number
70	Medicare General Information (CMS-Pub. 100-01) October 2011 Update to the CMS Standard File for Reason Codes for the Fiscal Intermediary Shared System (FISS)
00	Medicare Benefit Policy (CMS-Pub. 100-02) None
133	Medicare National Coverage Determination (CMS-Pub. 100-03) Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer Autologous Cellular Immunotherapy Treatment
134	Magnetic Resonance Imaging (MRI) in Medicare Beneficiaries with FDA-Approved Implanted Permanent Pacemakers (PMs) for use in an MRI Environment
135	Magnetic Resonance Imaging (MRI) in Medicare Beneficiaries with FDA-Approved Implanted Permanent Pacemakers (PMs) for use in an MRI Environment
2249	Medicare Claims Processing (CMS-Pub. 100-04) Issued to a specific audience, not posted to Internet/Intranet/ due to Sensitivity of Instruction
2250	Non-systems Internet Only Manual (IOM) Changes Form Locators 1-15 Form Locators 43-81
2251	Pharmacy Billing for Drugs Provided "Incident to" a Physician Service (This CR rescinds and fully replaces CR 7109.) Payment Rules for Drugs and Biologicals Exceptions to Average Sales Price (ASP) Payment Methodology
2252	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality
2253	Influenza Virus Vaccine
2254	Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer Autologous Cellular Immunotherapy treatment of Metastatic Prostate Cancer Policy Healthcare Common Procedure coding System (HCPCS) Codes Types of Bills (TOB) and Revenue Codes Payment Method Medicare Summary Notices(MSNs), Remittance Advice Remark Codes (RARCs),Claims Adjustment Reason Codes (CARCs),and Group Codes
2255	Quarterly Update to the End-Stage Renal Disease Prospective Payment System
2256	
2257	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for October 2011
2258	Correction to Processing of Hospice Discharge Claims Table of Contents Hospice Pre-Election Evaluation and Counseling Services

Transmittal Number	Manual/Subject/Publication Number
2259	Data Required on the Institutional Claim to Medicare Contractor Claims From Medicare Advantage Organizations Independent Attending Physician Services Processing Professional Claims for Hospice Beneficiaries Claims After the End of Hospice Election Period Billing and Payment for Services Unrelated to Terminal Illness Frequency of Billing and Same Day Billing Contractor Responsibilities for Publishing Hospice Information Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2260	Update to Hospice Payment Rates, Hospice Cap, Hospice Wage Index and the Hospice Pricer for FY 2012
2261	Affordable Care Act - Section 3113 - Laboratory Demonstration for Certain Complex Diagnostic Tests (This CR fully Rescinds and Replaces CR 7413) Items 14-33 - Provider of Service or Supplier Information
2262	Implementation of the MIPPA 153c End Stage Renal Disease (ESRD) Quality Incentive Program (QIP) and Other Requirements for ESRD Claims Outpatient Provider Specific File Calculation of the Basic Case-Mix Adjusted Composite Rate and the ESRD Prospective Payment System Rate Required Information for In-Facility Claims Paid Under the Composite Rate and the ESRD PPS Coding for Adequacy of Dialysis, Vascular Access and Infection Requirement for Providing Route of Administration Codes for Erythropoiesis Stimulating Agents (ESAs) Epoetin Alfa (EPO) Darbepoetin Alfa (Aranesp) for ESRD Patients Claim Adjustment Reason Code (CARC), Remittance Advice Remark Code (RARC), and Medicare Remit Easy Print (MREP) and PC Print Update
2263	October 2011 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
2264	Quarterly Update to the Correct Coding Initiative (CCI) Edits, Version 17.3, Effective October 1, 2011
2265	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2266	Anesthesiologist Services in a Method II Critical Access Hospital (CAH) Physician Rendering Anesthesia in a Hospital Outpatient Setting
2267	Clarification of Payment for ESRD-Related Services Under the Monthly Capitation Payment (Center Based Patients) Payment for Managing Patients on Home Dialysis
2268	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
2269	Pharmacy Billing for Drugs Provided "Incident To" a Physician Service (This CR rescinds and fully replaces CR 7109). Payment Rules for Drugs and Biologicals Exceptions to Average Sales Price (ASP) Payment Methodology
2270	Healthcare Provider Taxonomy Codes (HPTC) Update October 2011
2271	Issued to a specific audience not posted to Internet/ Intranet due to Sensitivity of Instruction List of Medicare Telehealth Services
2272	Inpatient or Emergency Department Telehealth Consultation Services versus Inpatient
2273	
2274	Evaluation and Management (E/M) Visits Initial Inpatient or Emergency Department Telehealth Consultations Defined Follow-Up Inpatient or Emergency Department Telehealth Consultations Defined Originating Site Facility Fee Payment Methodology
2275	Annual Update for the Health Professional Shortage Area (HPSA) Bonus Payments Inpatient Rehabilitation Facility (IRF) Annual Update: Prospective Payment System (PPS) Pricer Changes for FY 2012 Payment Provisions Under IRF PPS
2276	October Update to the CY 2011 Medicare Physician Fee Schedule Database (MPFSDB)
2277	October 2011 Integrated Outpatient Code Editor (IOCE) Specifications Version 12.3
2278	2012 Healthcare Common Procedure Coding System (HCPCS) Annual Update Reminder
2279	Annual Clotting Factor Furnishing Fee Update 2012 Clotting Factor Furnishing Fee
2280	Instructions for Downloading the Medicare ZIP Code File for January 2012
2281	Issued to a specific audience not posted to Internet/Intranet due to Sensitivity of Instruction
2282	Clarification of Evaluation and Management Payment Policy Table of Contents Payment for Hospital Observation Services and Observation or Inpatient Care Services (Including Admission and Discharge Services) Payment for Inpatient Hospital Visits – General Payment for Initial Hospital Care Services and Observation or Inpatient Care Services (Including Admission and Discharge Services) Consultation Services Nursing Facility Services Prolonged Services With Direct Face-to-Face Patient Contact Service (ZZZ codes)
2283	Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens
2284	Clarification to Chapter 26, Section 10.4 - Items 14-33 - Provider of Service or Supplier Information
2285	Items 14-33/Provider of Service or Supplier Information
2286	Attending Physician Identifiers on Religious Nonmedical Health Care Institution Claims
2287	2012 Annual Update of Healthcare Common Procedure Coding System (HCPCS) Codes for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Update Medicare Physician Fee Schedule Database (MPFSDB) 2012 File Layout Manual Addendum
2288	Establishing a Quarterly Recurring Update Notification Process for Temporary "K" and "Q" Codes Description of Healthcare Common Procedure Coding System (HCPCS)
2289	Fiscal Year (FY) 2012 Inpatient Psychiatric Facility (IPF) PPS Changes
2290	October 2011 Update of the Ambulatory Surgery Center (ASC) Payment System
2291	Fiscal Year (FY) 2012 Inpatient Prospective Payment System (IPPS), Long-Term Care Hospital (LTCH) PPS, and Critical Access Hospital (CAH) Changes Submitting Bills In Sequence for a Continuous Inpatient Stay or Course of Treatment Medicare Payment for Ambulance Services Furnished by Certain CAHs
2292	Medicare Part A Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Pricer Update FY 2012
2293	Magnetic Resonance Imaging (MRI) in Medicare Beneficiaries with FDA-Approved Implanted Permanent Pacemakers (PMs) for use in an MRI Environment Magnetic Resonance Imaging (MRI) Procedures Payment Requirements Medicare Summary Notices (MSN), Reason Codes, and Remark Codes
2294	Issued to a specific audience not posted to Internet/Intranet due to Confidentiality of Instruction

Transmittal Number	Manual/Subject/Publication Number	Manual/Subject/Publication Number
2295	Issued to a specific audience not posted to Internet/Intranet due to Confidentiality of Instruction	Medicare and Medicaid Extenders Act of 2010 (MMEA) Provisions Components of the Ambulance Fee Schedule
2296	October 2011 Update of the Hospital Outpatient Prospective Payment System (OPPS)	Claim Status Category and Claim Status Codes Update
2297	Issued to a specific audience not posted to Internet/Intranet due to Sensitivity of Instruction	Medicare Secondary Payer (CMS-Pub. 100-05)
2298	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for October 2011	Requesting the Common Working File (CWF) to Cease Submitting First Claim Development (FCD) and Trauma Code Development (TCD) Alerts to the Coordination of Benefits Contractor (COBC)
2299	Enhance the Multi-Carrier System (MCS) and ViPS Medicare System (VMS) to maintain five full years of pricing data and to automatically price Claims/adjustments at the rates in effect at the dates of service. Update Factor for Fee Schedule Services Online Pricing Files for DMEPOS	Updates to the Electronic Correspondence Referral System (ECRS) Web User Guide v2.0 and Chapter 5
2300	October Quarterly Update to 2011 Annual Update of HCPCS Codes Used for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Enforcement	Coordination With the Coordination of Benefits Contractor (COBC)
2301	Inpatient Rehabilitation Facility (IRF) Annual Update: Prospective Payment System (PPS) Pricer Changes for FY 2012 Payment Provisions Under IRF PPS	COBC Electronic Correspondence Referral System (ECRS) CRS Functional Description
2302	Issued to a specific audience not posted to Internet/Intranet due to Confidentiality of Instruction	Technical Overview - Impact on Contractor Data Centers
2303	Teaching Physician Services Evaluation and Management (E/M) Services Surgical Procedures Physician Billing in the Teaching Setting	Medicare Financial Management (CMS-Pub. 100-06)
2304	Claim Adjustment Reason Code (CARC), Remittance Advice Remark Code (RARCC), and Medicare Remit Easy Print (MIREP) and PC Print Update	Notice of New Interest Rate for Medicare Overpayments and Underpayments - 4th Notification for FY 2011
2305	October 2011 Update of the Ambulatory Surgery Center (ASC) Payment System	Add Physician Specialty Codes for Cardiac Electrophysiology (21) and Sports Medicine (23) to CROWD Forms "F" (ParDoc) and "8" (OptOut).
2306	Clinical Laboratory Fee Schedule - Medicare Travel Allowance Fees for Collection of Specimens	Table of Contents
2307	Magnetic Resonance Imaging (MRI) in Medicare Beneficiaries with FDA-Approved Implanted Permanent Pacemakers (PMs) for use in an MRI Environment Magnetic Resonance Imaging (MRI) Procedures Payment Requirements Medicare Summary Notices (MSN), Reason Codes, and Remark Codes	Part D(1) - Claims Processing Timeliness - All Claims
2308	Issued to a specific audience not posted to Internet/Intranet due to Sensitivity of Instruction	Part E - Interest Payment Data
2309	Maintenance and Update of the Temporary Hook Created to Hold OPPS Claims that Include Certain Drug HCPCS Codes	Classification of Claims for Counting
2310	Ambulance Inflation Factor for CY 2012 Ambulance Inflation Factor (AIF)	Participating Physician/Supplier Report Purpose and Scope
2311	Implementation of the MIPPA 153c End Stage Renal Disease (ESRD) Quality Incentive Program (QIP) and Other Requirements for ESRD Claims Outpatient Provider Specific File Calculation of the Basic Case-Mix Adjusted Composite Rate and the ESRD Prospective Payment System Rate Required Information for In-Facility Claims Paid Under the Composite Rate and the ESRD PPS	Due Date
2312	Coding for Adequacy of Dialysis, Vascular Access and Infection Requirement for Providing Route of Administration Codes for Erythropoiesis Stimulating Agents (ESAs) Epoetin Alfa (EPO) Darbepoetin Alfa (Aranesp) for ESRD Patients Pharmacy Billing for Drugs Provided "Incident To" a Physician Service This CR rescinds and fully replaces CR 7109. Payment Rules for Drugs and Biologicals Exceptions to Average Sales Price (ASP) Payment Methodology	Specialty Codes Physician/Limited License Physician Specialty Codes Non-Physician Practitioner/Supplier Specialty Codes Checking Reports Exhibit
2313	Updates to the Internet Only Manual, Pub. 100-04, Chapter 15-Ambulance, to include the	Definitions of Provider Specialty Codes for Opt Out Reporting Exhibit
192	Recovery Audit Program MAC-issued Demand Letters Adjusting the Claim	Recovery Audit Program MAC-issued Demand Letters Adjusting the Claim
193	Recovery Audit Program Tracking Appeals and Reopenings	Recovery Audit Program Tracking Appeals and Reopenings
194	Medicare Financial Management Manual, Chapter 7, Internal Control Requirements	Medicare Financial Management Manual, Chapter 7, Internal Control Requirements
195	To Create Form 9 Within the Contractor Reporting of Operational and Workload Data (CROWD) System for the Reporting of Primary Care Incentive Payments (PCIP) and HPSA Surgical Incentive Payments (HSIP).	To Create Form 9 Within the Contractor Reporting of Operational and Workload Data (CROWD) System for the Reporting of Primary Care Incentive Payments (PCIP) and HPSA Surgical Incentive Payments (HSIP).
00	None	Medicare State Operations Manual (CMS-Pub. 100-07)
378	Prospective Billing for Refills of DMEPOS Items Provided on a Recurring Basis Billing for Refills of DMEPOS Items Provided on a Recurring Basis Refills of DMEPOS Items Provided on a Recurring Basis	Medicare Program Integrity (CMS-Pub. 100-08)
379	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction	Prospective Billing for Refills of DMEPOS Items Provided on a Recurring Basis Billing for Refills of DMEPOS Items Provided on a Recurring Basis Refills of DMEPOS Items Provided on a Recurring Basis
380	Advanced Diagnostic Imaging Accreditation Enrollment Procedures Advanced Diagnostic Imaging	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
381	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality	Advanced Diagnostic Imaging Accreditation Enrollment Procedures Advanced Diagnostic Imaging

Transmittal Number	Manual/Subject/Publication Number
382	Preferred Provider Organizations (PPOs)
383	QI Program Requirements for Private Fee-For-Service (PFFS) and Medicare Medical Savings Account (MSA) Plans
384	QI Program Requirements for Special Needs Plans (SNPs)
385	Additional SNP QI Program Requirements
386	Additional SNP QI Program Requirements
8551	SNP Quality Data Reporting Requirements
387	General
388	SNP Reporting Measures Requirements
389	SNP Structure and Process Measures
00	SNP-Specific Medicare HOS Requirements
00	SNP-Specific Medicare CAHPS® Requirements
00	Medicare and Medicaid Quality Reporting Requirements for D-SNPs
00	Quality Improvement Organizations (QIOs)
00	Medicare Advantage (MA) Deeming Program
00	Deeming Requirements
00	Obligations of Deemed MAOs
100	General
100	Deemed Status and CMS Surveys
100	Removal of an MAOs Deemed Status
100	Removal of an MAOs Deemed Status
100	CMS' Role in Deeming
100	Oversight of AOs
100	Equivalency Review
100	Validation Review
100	Onsite Observation of an AO
100	Enforcement Authority
100	Notice of Intent to Withdraw Approval
100	Obligations of AOs with Deeming Authority
100	Application Requirements
100	Application Notices
100	Withdrawing an Application
100	Reporting Requirements
100	Reconsideration of Application Denials, Removal of Approval of Deeming Authority and Non-Renewals of Deeming Authority
100	Informal Hearing Procedures
100	Informal Hearing Findings
100	Final Reconsideration Determinations
100	Standard Reporting Requirements for MAOs for HEDIS®, HOS and CAHPS®
100	General
100	HEDIS® Reporting Requirements
100	Additional Information Regarding HEDIS®
100	HEDIS® Submission Requirements
100	Summary and Patient-Level Data
100	HEDIS® Compliance Audit Requirements
100	Final Audit Reports, Use and Release
100	Medicare HOS Requirements
100	HOS Survey Process Requirements
100	HOS Modified
100	HOS Data Feedback
100	Medicare CAHPS® Requirements
100	Information Regarding the CAHPS® Satisfaction Survey

Transmittal Number	Manual/Subject/Publication Number
382	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality
383	Update to Pub. 100-08, Medicare Program Integrity Manual - Chapter 3
384	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality
385	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality
386	Ordering/Referring Providers Who Are not Enrolled in Medicare Section 2 of the Form CMS 8551
387	Model Approval Letter for Providers who Order and Refer Only
388	Ordering/Referring Providers Who are not enrolled in Medicare
389	Eligible Physicians and Practitioners who need to Enroll in the Medicare Program for the Sole Purpose of Ordering and Referring Services for Medicare Beneficiaries
389	Ordering/Referring Providers Who Are Not Enrolled in Medicare
389	Additional Review Activities for Home Health Agencies (HHAs)
389	Proof of Delivery and Delivery Methods
00	Medicare Contractor and Provider Communications (CMS-Pub. 100-09)
00	None
00	Medicare End-Stage Renal Disease Network Organizations (CMS Pub 100-14)
00	None
100	Medicare Managed Care (CMS-Pub. 100-16)
100	Chapter 5, "Quality Improvement Program"
100	Overview of Quality Improvement (QI) Program Requirements
100	Definitions
100	Quality Data Reporting Requirements
100	Quality Improvement (QI) Program
100	QI Program Requirements
100	Chronic Care Improvement Program (CCIP)
100	Types of CCIPs
100	Evaluation of CCIPs and Scoring Criteria
100	CCIP Compliance Indicator 1-Target Population and Method of Identifying Eligible Enrollees
100	CCIP Compliance Indicator 2- Method for Enrolling Participants and Participation Rates
100	CCIP Compliance Indicator 3- Whether the CCIP is Designed to Improve Health Outcomes
100	CCIP Compliance Indicator 4- Data Sources Used to Identify the Need for a CCIP
100	CCIP Compliance Indicator 5- Intervention
100	CCIP Compliance Indicator 6- Program Monitoring and Delegation Oversight
100	CCIP Compliance Indicator 7- Outcome Measures
100	Quality Improvement Projects (QIPs)
100	Characteristics of QIPs
100	Evaluation of QIPs and Scoring Criteria
100	QIP Compliance Indicator 1- Target Population
100	QIP Compliance Indicator 2- Topic Focus and Relevance to the Medicare Population
100	QIP Compliance Indicator 3- QI Indicators, Data Sources and Collection Methodology
100	QIP Compliance Indicator 4- Participation
100	QIP Compliance Indicator 5- Results
100	QIP Compliance Indicator 6- Intervention
100	CMS and Department of Health and Human Services (DHHS) QI Initiatives
100	General
100	CMS Directed Special Projects
100	QI Program Health Information Systems
100	QI Program Remedial Action
100	QI Program Requirements for MAOs Using Physician Incentive Plans (PIPs)
100	QI Program Requirements for Medicare Advantage Regional and Local

Transmittal Number	Manual/Subject/Publication Number	Transmittal Number	Manual/Subject/Publication Number
	MAOs with Special Circumstances		Instruction
	Medicare Business Partners Systems Security (CMS-Pub. 100-17)	926	Medicare Remit Easy Print (MREP) and PC Print User Guide Update for Implementation of version 5010A1
11	CMS Business Partners Systems Security Manual	927	Populating REF Segment - Other Claim Related Adjustment - for Healthcare Claim Payment/Advice or Transaction 835 Version 5010A1
74	Demonstrations (CMS-Pub. 100-19)	928	Systems Analysis of New Medicare Summary Notice (MSN) Design
75	Affordable Care Act - Section 3113 - Laboratory Demonstration for Certain Complex Diagnostic Tests (This CR Fully Rescinds and Replaces CR 7278)	929	Discontinuation of FISS Data Feed to Legacy Provider Statistical and Reimbursement (PSandR) System
76	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality	930	Issued to specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
77	None	931	Health Insurance Portability and Accountability Act (HIPAA) 5010 837 Institutional (837I) Edits and 5010 837 Professional (837P) Edits - January 2012 Version
78	Method of Cost Settlement for Inpatient Services for Rural Hospitals Participating Under Demonstrations Authorized by Section 410A of the Medicare Modernization Act. Sections 1123 and 10313 of the Affordable Care Act authorized an expansion of the demonstration and an extension for additional 5-year period. This CR gives instructions for this additional 5-year period. This CR s an extension of CR 5020 for additional 5-year period.	932	Issued to specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
79	Affordable Care Act - Section 3113 - Laboratory Demonstration for Certain Complex Diagnostic Tests (This CR fully Rescinds and Replaces CR 7413)	933	Health Insurance Portability and Accountability (HIPAA) 5010/D.0 Fixes - January 2012
80	Implementation Support and Payment Processing for the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration	934	Issued to specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
	Implementation Support and Payment Processing for the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration	935	Analysis CR - The Inclusion of Veterans Administration (VA) Skilled Nursing Facility (SNF) claims to the VA Medicare Remittance Advice (eMRA) Process
	One Time Notification (CMS-Pub. 100-20)	936	Expand the Expert Claims Processing System (ECPSS) for the Fiscal Intermediary Shared System (FISS) to accommodate ICD-10
910	VMS Utility Run for DME MAC's identification of edits for ICD-10	937	Issued to specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
911	Implementing the Recompetition Award for the Jurisdiction D DME Medicare Administrative Contractor (MAC) Workload	938	Issued to specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
912	Durable Medical Equipment National Competitive Bidding: Correction to Permit Payment for Certain Grandfathered Accessories and Supplies	939	Independent Laboratory Billing of Automated Multi-Channel Chemistry (AMCC) Organ Disease Panel Laboratory Tests for Beneficiaries who are not Receiving Dialysis for Treatment of End Stage Renal Disease (ESRD)
913	Issued to specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction	940	Reporting of Recoupment for Overpayment on the Remittance Advice (RA) with Patient Control Number
914	Issued to specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction	941	Common Working File (CWF) Editing Update for Pulmonary Rehabilitation Services (PR) and Cardiac and Intensive Cardiac Rehabilitation Services
915	Additional Healthcare Common Procedure Coding System (HCPCS) Codes Subject to Clinical Laboratory Improvement Amendments (CLIA) Edits	942	Instructions to Accept and Process All Ambulance Transportation Healthcare Common Procedure Coding System (HCPCS) Codes
916	Issued to specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction	943	Issued to specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
917	October Common Edits and Enhancements Module (CEM) and Receipt, Control and Balancing Updates	944	Conference Calls and Research Hours to Identify an Automated Solution for Tracking and Reporting Recovery Auditor Reopening and Appeals throughout the Medicare Appeals Process
918	HIPAA 5010 National Testing Day and Week	945	Informational Message on the 835
919	Add Patient Status Codes to Bypass DA02 Edit in Common Working File (CWF)	946	Implementation of the HIPAA Version 5010 276/277 Claim Status Edits January 2012 Release
920	Expand the Fiscal Intermediary Shared System (FISS) End Stage Renal Disease (ESRD) Parameter Files, Hook Selection Files, and Medical Policy Parameter Files to Accommodate the Requirements for ICD-10.	947	Revisions to Change Request 7362: "Integrated Data Repository (IDR) Claims Sourcing from Shared Systems - Implementation" to Require Transmission of CMN History Data
921	Common Edits and Enhancements Modules (CEM) Code Set Update	948	Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program: Allowing Contract or Non-contract Suppliers to Maintain and Service the Enteral Nutrition Equipment that they Provided in the 15th Continuous Month of Rental
922	Addition of Medical Severity Diagnosis Related Group (MS-DRG) 265 to the list subject to Inpatient Prospective Payment System (IPPS) Replaced Devices Offered Without Cost or With a Credit Policy	949	Medicare Fee-For-Service Claims Processing Guidance for Implementing International Classification of Diseases, 10th Edition (ICD-10)
923	Issued to specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction	950	Medicare Fee-For-Service Claims Processing Guidance for Implementing International Classification of Diseases, 10th Edition (ICD-10)
924	Implementing the Recompetition Award for the Jurisdiction A Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Workload	951	HITECH - Annual 1099 Address File - Requirements for Submitting Updated Address, TIN
925	Issued to specific audience, not posted to Internet/ Intranet due to Confidentiality of		

Transmittal Number	Manual/Subject/Publication Number
	and Full Legal Name for all HITECH Payees Receiving EHR Incentive Payments During the Calendar Year
952	Fee For Service Common Eligibility Services Conference Calls and Research
953	Issued to specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
954	Revise MCS System to Accommodate ICD-10
955	Analysis and Design for Documentation Status Data Feed from Shared Systems for (CR 7455)
956	Issued to specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
957	Request for Common Working File (CWF) System to Support the Automated Edit Project Field Test
958	Additional Fields for Additional Documentation Request (ADR), Automated Development System (ADS) Letters
959	Populating REF Segment - Other Claim Related Adjustment - for Healthcare Claim Payment/Advice or Transaction 835 version 5010A1
960	Update the existing VIPS Medicare System (VMS) Utilization Parameter files for ICD-10.
961	Issued to specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
962	HITECH - Annual 1099 Address File - Requirements for Submitting Updated Address, TIN and Full Legal Name for all HITECH Payees Receiving EHR Incentive Payments During the Calendar Year

Addendum II: Regulation Documents Published in the Federal Register (July through September 2011)

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 Web site <http://www.archives.gov/federal-register/> provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our Web site at:

<http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-3Q11QPU.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/Rulings/CMSR/hist.asp#TopOfPage>. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

Addendum IV: Medicare National Coverage Determinations (July through September 2011)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS Web site. For the purposes of this quarterly notice, we list only the specific updates that have occurred in the 3-month period. This information is available on our Web site 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
Magnetic Resonance Imaging (MRI) in Medicare Beneficiaries with Implanted (PMs) or ICDs	220.1	R134NCD	07/07/2011	08/26/2011
Autologous Cellular Immunotherapy for Prostate Cancer	110.22	R133NCD	07/08/2011	06/30/2011
Magnetic Resonance Imaging (MRI) in Medicare Beneficiaries with Implanted (PMs) or ICDs	220.1	R135NCD	08/26/2011	08/26/2011
October Clinical Lab Edits	190	R2298	09/02/2011	10/03/2011

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDES) (July through September 2011)

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
G110107	DexCom G4 Continuous Glucose Monitoring System	07/06/11
G110008	Sonalleve MR-HIFU Fibroid Therapy System	07/06/11
G110064	Flexion Atrial Flutter Study with the Therapy Coolflex ablation Catheter	07/08/11
G110061	CELT ACD Vascular Closure Device	07/19/11
BB14755	Magnetic-Activated Cell Sorter (ClimiMACS, Miltenyi)	07/19/11
G110091	NeuroStar TMS Therapy System	07/22/11
G100337	Absolute Pro and Absolute Pro LL Self-Expanding Peripheral Stent Systems	07/27/11
G100089	Essure Permanent Birth Control System	07/28/11
G110092	OMEGA Monorail Coronary Stent System	08/03/11
G110009	Blomet Stimulator System	08/04/11
G090229	Glaukos Suprachoroidal Stent Model G3	08/05/11
G110053	Venous Window Needle Guide (VWNG)	08/10/11
G080199	Coscal Adhesion Prevention Device	08/10/11
G100326	Glaukos Trabecular Micro-bypass Stent Injector System, Model G2-M-IS (with GTS400 stent)	08/11/11
G110031	XIENCE PRIME AND XIENCE PRIME LL Everolimus Eluting Coronary Stent System, XIENCE V Everolimus Eluting Coronary Stent System for EXCEL Clinical Trial	08/12/11
G110130	iFuse Implant System	08/18/11
G110022	AirXpander Tissue Expander System	08/23/11
G110138	VIKY UP - Uterine Positioner	08/24/11
G110132	Ex-vivo Perfusion and Ventilation of Lungs Recovered from Non-Heart-Beating Donors to Assess Transplant Suitability	08/25/11
G110067	Endologix Fenestrated Stent Graft System	08/25/11
G110133	Iowa Cochlear Implant Clinical Research Center Hybrid L24 and Standard Cochlear Implants in Profoundly Deaf Infants	08/26/11
BB14795	Miltenyi CliniMACS cell selection device	08/31/11
G110035	Viper System Fenestrated Polyaxial Screw Fixation Augmented with the Confidence Spinal Cement System	09/01/11
BB14796	ACP Double Syringe System	09/01/11
G110103	EXPERT CTO Clinical Trial - Evaluation of the Xience Coronary Stent, Performance and Technique in Chronic Total Occlusions Clinical Trial	09/02/11
G110157	Exaleanz Breath System	09/07/11
G110150	TECNIS Toric I-Piece Intraocular Lens (IOL) Model ZCT100	09/08/11
G110153	Sirtex Technology Pty Ltd/Radioactive Yttrium Microspheres	09/09/11
G110080	Endovet Pulmonary Catheter Kit	09/15/11
G110012	Blomet Stimulator System	09/15/11
G110158	Lifecell Tissue Matrix	09/15/11
G110101	Zenith p-Branch Endovascular Graft	06/29/11

G110105	Intrauterine Septrafilin Slurry	06/30/11
G100196	GORE TIGRIS Vascular Stent	09/21/11
G100125	Cool-tip Radiofrequency Ablation System	09/26/11
BB14771	Magnetic-Activated Cell Sorter (ClimiMACS, Miltenyi)	09/27/11
G110118	Perfane-L with 0.3% Lidocaine	09/29/11
G100283	PREVAIL Single Port Access Paragastric Implant System	09/30/11
BB14602	Magnetic-Activated Sorter (ClimiMACS, Miltenyi)	09/30/11
G110051	Artisan Aphakia Lens for Correction of Aphakia in Children	09/30/11
G100014	Freedom Solo Heart Valve	09/30/11
G100093	AquoSys Microfistula Implant System	09/30/11

Addendum VI: Approval Numbers for Collections of Information (July through September 2011)

All approval numbers are available to the public at [Reginfo.gov](http://www.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, (July through September 2011)

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 on our Web site at:

<http://www.cms.gov/MedicareApprovedFacilities/CASE/list.asp#TopOfPage>. For questions or additional information, contact Sarah J. McClain (410-786-2294).

Facility	Provider Number	Effective Date	State	Other Information
The following facilities are new listings for this quarter.				
West Chester Hospital	360354	07/05/2011	OH	
7700 University Drive West Chester, OH 45069				
Memorial Hospital of Tampa	1023098258	07/15/2011	FL	
2901 Swann Avenue Tampa FL 33609-4057				
Palms of Pasadena Hospital	100126	07/15/2011	FL	
1501 Pasadena Avenue South				

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

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

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

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred to the list of Medicare-approved ICD facilities in the 3-month period. This information is available by accessing our Web site and clicking on the link for the American College of Cardiology's National Cardiovascular Data Registry at: www.ncdr.com/webncdr/common. For questions or additional information, contact Joanna Baldwin, MS (410-786-7205).

Facility	Provider Number	Effective Date	State	Other Information
St. Petersburg, FL 33707 EHCA – Emory Johns Creek Hospital 6325 Hospital Parkway Johns Creek, GA 30097	1679632137	08/04/2011	GA	
UW Medicine – Northwest Hospital 1550 North 115th Street Seattle, WA 98133	1700861580	08/04/2011	WA	
Aurora Sheboygan Memorial Medical Center 2629 N. 7th Street Sheboygan, WI 53083-4998	520035	08/26/2011	WI	
Baylor Medical Center at Irving 1901 N. MacArthur Boulevard Irving, TX 75061	450079	08/26/2011	TX	
Portland Adventist Medical Center 10123 SE Market St Portland, OR 97216-2941	380060	09/15/2011	OR	
Lake Pointe Medical Center 6800 Scenic Drive Rowlett, TX 75088	450742	09/23/2011	TX	
Southeast Alabama Medical Center 1108 Ross Clark Circle Dothan, AL 36301-3088	1164403861	10/06/2011	AL	
The following facilities have been deleted for this quarter.				
Conroe Regional Medical Center 504 Medical Center Boulevard Conroe, TX 77304	450222		TX	
Columbia Hospital 2201 45th Street West Palm Beach, FL 33407	100234		FL	
University Hospital and Medical Center 7201 North University Drive Tamarac, FL 33321	100224		FL	
Editorial changes (shown in bold) were made to the facilities listed below.				
University of Colorado Hospital 12605 E. 16th Avenue Aurora, CO 80045	060024	07/15/2005	CO	
From: Clarian Health Partners, Inc To: Indiana University Health, Inc. 340 West 10th Street Indianapolis, IN 46202	150056	05/23/2005	IN	
From: Capital Health System - Mercer Campus Hopewell One Capital Way Pennington, NJ 08534	1073516183	09/28/2009	NJ	

Facility Name	Address 1	City	State	Zip Code
The following facilities are new listings for this quarter.				
Advocate Trinity Hospital	2320 E. 93 Street	Chicago	IL	60617
Beth Israel Medical Center	First Avenue @ East 16th Street	New York	NY	10003
Central Michigan Community Hospital	1221 South Drive	Mount Pleasant	MI	48858
Children's Hospital and Medical Center	8200 Dodge Street	Omaha	NE	68114
Franciscan Healthcare	700 West Avenue S.	La Crosse	WI	54601
Horizon Medical Center	111 Highway 70E	Dickson	TN	37055
Indian River Surgery Center	1200 37 th Street	Vero Beach	FL	32960
Indiana University Health West Hospital	1111 North Ronald Reagan Parkway	Avon	IN	46123
Kalispell Regional Medical Center	310 Sunnyview Lane	Kalispell	MT	59901

Addendum VIII: American College of Cardiology's National Cardiovascular Data Registry Sites (July through September 2011)

Addendum VIII includes a list of the American College of Cardiology's National Cardiovascular Data Registry Sites. We cover implantable cardioverter defibrillators

Facility Name	Address 1	City	State	Zip Code
Loma Linda University Medical Center - Murrieta	28062 Baxter Road	Murrieta	CA	92563
Matagorda Regional Medical Center	104 7th Street	Bay City	TX	77414
Methodist West Houston Hospital	18500 Katy Freeway	Houston	TX	77094
Nationwide Children's Hospital	700 Children's Drive	Columbus	OH	43205
Oakwood Southshore Medical Center	5450 Fort Street	Trenton	MI	48183
Outpatient Surgical and Laser Center	501 Glades Road	Boca Raton	FL	33432
Placentia Linda Hospital (TENET)	1301 Rose Drive	Placentia	CA	92870

Facility Name **Address 1** **City** **State** **Zip Code**
The following facilities are no longer participants in the ACC-NCDR-ICD Registry as of this notice.

Hualapai Mountain Medical Ctr.	3801 Santa Rosa Drive	Kingman	AZ	86401
Columbia Hospital	2025 E Newport Avenue	Milwaukee	WI	53211

Addendum IX: Active CMS Coverage-Related Guidance Documents (July through September 2011)

There were no CMS coverage-related guidance documents published in the July through September 2011 quarter. To obtain full-text copies of these documents, visit the CMS Coverage Web site at http://www.cms.gov/mcd/index_list.asp?list_type=med_1 and click on the archives link. For questions or additional information, contact Lori Ashby (410-786-6322).

Addendum X: List of Special One-Time Notices Regarding National Coverage Provisions (July through September 2011)

There were no special one-time notices regarding national coverage provisions published in the July through September 2011 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) (July through September 2011)

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.

Facility Name	Address 1	City	State	Zip Code
Southern Maryland Hospital	7503 Surrattis Road	Clinton	MD	20735
St. Luke's Patients Medical Center	4600 East Sam Houston Beltway	Pasadena	TX	77505
Trumbull Memorial Hospital	1350 E. Market Street	Warren	OH	44482
Waco Surgery Center	7003 Woodway Drive Suite 307	Waco	TX	76712
Wadley Regional Medical Center	1000 Pine Street	Texarkana	TX	75501
West Calcasieu Cameron Hospital	701 Cypress Street	Sulphur	LA	70663
Wuesthoff Medical Center Melbourne	250 N. Wickham Road	Melbourne	FL	32935

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 new facilities that meet CMS's requirements for performing PET scans under National Coverage Determination CAG-00181N published in the July through September 2011 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 (July through September 2011)

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 on our Web site at <http://www.cms.gov/MedicareApprovedFacilities/VAD/list.asp#TopOfPage>. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

Facility	Provider number	Date Approved	State
The following are new listings for this quarter.			
Piedmont Hospital 1968 Peachtree Road, NW Atlanta, GA 30309	110083	06/09/2011	GA
Albert Einstein Medical center 501 Old York road Philadelphia, PA 19141	390142	10/07/2011	PA
Editorial changes (shown in bold) were made to the facility listed below.			
From: University of Colorado Hospital To: University of Colorado Authority 12605 E. 16th avenue Aurora, CO 80045	060024	07/23/2008	CO

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (July through September 2011)

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 additions to the listing of facilities for lung volume reduction surgery published in the July through

September 2011 quarter. This information is available on our Web site at www.cms.gov/MedicareApprovedFacilities/LVRS/list.asp#TopOfPage. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (July through September 2011)

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).

For the purposes of this quarterly notice, we list only the specific updates to Medicare-approved facilities that meet CMS's minimum facility standards for bariatric surgery and have been certified by ACS and/or ASMBS in the 3-month period. This information is available on our Web site at www.cms.gov/MedicareApprovedFacilities/BSF/list.asp#TopOfPage. For questions or additional information, contact Kate Tillman, RN, MAS (410-786-9252).

Facility Name	Provider Number	Date Approved	State	Other Information
The following facilities are new listings for this quarter.				
Bon Secours St. Francis Health System 135 Commonwealth Drive Suite 210 Greenville, SC 29615	420023	08/03/11	SC	ASMBS
Preston Memorial Hospital 300 South Price Street Kingwood, WV 26537	511312	08/03/11	WV	ASMBS

Facility Name	Provider Number	Date Approved	State	Other Information
Vista Medical Center East 1324 N. Sheridan Road Waukegan, IL 60087	1639120694	08/03/11	IL	ASMBS
The Hospital of Central Connecticut at New Britain General 100 Grand Street New Britain, CT 06050	1053477075	07/22/11	CT	ACS
Mount Sinai School of Medicine 5 East 98th Street, 15th Floor New York, NY 10029		07/15/11	NY	ACS
Bailey Medical Center, LLC 10502 N. 110th East Avenue Owasso, OK 74055	1205846037	06/06/11	OK	ACS
Lake Norman Regional Medical Center 171 Fairview Road Mooresville, NC	340129	08/03/11	NC	ASMBS
Bon Secours Mary Immaculate Hospital 12720 McManus Boulevard Newport News, VA 23602	49-0041	08/30/11	VA	ASMBS
Baylor Medical Center at Trophy Club 2850 East Highway 114 Trophy Club, TX 76262	450-883	08/30/11	TX	ASMBS
Memorial Hospital of Tampa 2901 Swann Avenue Tampa, FL 33609	10-0206	08/30/11	FL	ASMBS
Nassau University Medical Center 2201 Hempstead Turnpike East Meadow, NY 11554	33-0027	08/30/11	NY	ASMBS
Berkshire Medical Center 725 North Street Pittsfield, MA 01201	1295765261	08/11/11	MA	ACS
Mission Hospital 2 Medical Park Drive Asheville, NC 28803	340002	08/20/11	NC	ASMBS
Medical Center Hospital 500 West 4th Street Odessa, TX 79761	450132	09/27/11	TX	ASMBS
Editorial changes (shown in bold) were made to the facilities listed below.				
Barnes Jewish Hospital 216 South Kingshighway Boulevard St. Louis, MO 63110	260032	08/29/06	MO	ASMBS
East Texas Medical Center 1000 South Beckham Street Tyler, TX 75701	450083	02/24/06	TX	ASMBS
Maine Medical Center 22 Bramhall Street Portland, Maine 04102	200009	09/28/09	ME	ACS
Morristown Medical Center 100 Madison Avenue Morristown, NJ 07962	1053384776	01/25/07	NJ	ACS
Charleston Area Medical Center 800 Pennsylvania Avenue Charleston, WV 25302	510022	04/04/07	WV	ASMBS
Temple University Hospital 3401 North Broad Street Philadelphia, PA 19140	390027	09/17/07	PA	ASMBS
Flagler Hospital 400 Health Park Boulevard St. Augustine, FL 32086	100090	07/21/08	FL	ASMBS
From: Bridges Center at Tempe St. Luke's To: Tempe St. Luke's Hospital - Bridges Center for Surgical Weight Loss 1500 South Mill Avenue Tempe, AZ 85281	030037	09/17/10	AZ	ASMBS
From: St. Luke's Medical Center To: St. Luke's Medical Center - Bridges Center for Surgical Weight Loss 1800 E. Van Buren Street, Suite 307B Phoenix, AZ 85006	030037	03/10/06	AZ	ASMBS
From: West Hills Hospital To: West Hills Hospital and Medical Center 7300 Medical Center Drive West Hills, CA 91307	050481	06/18/07	CA	ASMBS
Orange Regional Medical Center 707 East Main Street Middletown, NY 10940	33-0126	03/25/11	NY	ASMBS
St. Anthony's Hospital 2807 Little York Road Houston, TX 75224	450795	03/18/09	TX	ASMBS

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (July through September 2011)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the July through September 2011 quarter.

This information is available on our Web site at www.cms.gov/Medicare/ApprovedFacilities/PETDT/hist.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-1586-N]****Medicare Program; First Semi-Annual Meeting of the Advisory Panel on Hospital Outpatient Payment (HOP—Formerly Known as the Advisory Panel on Ambulatory Payment Classification Groups—APC Panel)—February 27, 28, and 29, 2012****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Notice.

SUMMARY: This notice announces the first semi-annual meeting of the Advisory Panel on Hospital Outpatient Payment (HOP), formerly known as the Advisory Panel on Ambulatory Payment Classification Groups (the APC Panel) for 2012. The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services (DHHS) (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) (the Administrator) on the clinical integrity of the APC groups and their associated weights, and hospital outpatient supervision issues.

DATES: *Meeting Date:* The first semi-annual meeting in 2012 is scheduled for the following dates and times:

- Monday, February 27, 2012, 1 p.m. to 5 p.m. eastern standard time (e.s.t.)¹
- Tuesday, February 28, 2012, 9 a.m. to 5 p.m. (e.s.t.)¹
- Wednesday, February 29, 2012, 9 a.m. to 5 p.m. (e.s.t.)¹

Note: ¹ The times listed in this notice are approximate times; consequently, the meetings may last longer than listed in this notice, but will not begin before the posted times.

Deadlines

Deadline for Presentations and Comments (which includes both hardcopy and email submissions)—5 p.m. (e.s.t.), Friday, December 30, 2011. (See below for submission instructions.)

Deadline for Meeting Registration (**Note:** Those who do not pre register may not be able to attend the meeting since seating space is limited)—5 p.m. (e.s.t.), Friday, January 27, 2012.

Deadline for Requests for Special Accommodations—5 p.m. (e.s.t.), Friday, January 27, 2012.

Submission Instructions for Presentations and Comments

Because of staffing and resource limitations, we cannot accept written comments and or presentations by FAX, nor can we print written comments and presentations received by email for dissemination at the meeting.

Presentations:

Presentations must be based on the scope of the Panel designated in the Charter. Any presentations outside of the scope of this Panel will be returned and or amendments requested. Unrelated topics include, but are not limited to, the conversion factor, charge compression, revisions to the cost report, pass-through payments, correct coding, new technology applications (including supporting information/documentation), provider payment adjustments, and which types of practitioners are permitted to supervise hospital outpatient services.

All presentations will be considered public information and will be posted on the CMS Web site. Presenters should not send pictures of patients in any of the documents (unless their faces have been blocked out) or include any examples with patient identifiable information.

In order to consider presentation and/or comment requests, we will need to receive the following information:

1. A hardcopy of your presentation; only hardcopy comments and presentations can be reproduced for public dissemination. We note that all presentations are limited to 5 minutes per individual or organization.
2. An email copy of your presentations sent to the Panel mailbox, APCPanel.cms.hhs.gov or to the DFO, Paula.Smith@cms.hhs.gov.
3. Form CMS-20017 with complete contact information that includes name, address, phone, and email addresses for all presenters and a contact person that can answer any questions and or provide revisions that are requested for the presentation.

○ Presenters must clearly explain the actions that they are requesting CMS to take in the appropriate section of the form. A presenter's relationship to the organization that they represent must also be clearly listed.

○ The form is now available through the CMS Forms Web site. The Uniform Resource Locator (URL) for linking to this form is as follows: <http://www.cms.hhs.gov/cmsforms/downloads/cms20017.pdf>.

ADDRESSES: *Meeting Location:* The meeting will be held in the Auditorium, CMS Central Office, 7500 Security Boulevard, Woodlawn, Maryland 21244-1850.

FOR FURTHER INFORMATION CONTACT: For inquiries about the Panel, contact the Designated Federal Officer (DFO):

Paula Smith, 7500 Security Boulevard, Mail Stop C4-05-17, Woodlawn, MD 21244-1850. Phone: (410) 786-4709.

Mail hardcopies and email copies to the following addresses:

Paula Smith, DFO, CMS, CM, HAPC, DOC—HOPS Panel, 7500 Security Blvd., Woodlawn, MD 21244-1850, Mail Stop C4-05-17, Paula.Smith@cms.hhs.gov or APCPanel@cms.hhs.gov.

Note: We recommend that you advise couriers of the following information: When delivering hardcopies of presentations to CMS, if no one answers at the above phone number, call (410) 786-4532 or (410) 786-7267.

News media representatives must contact our Public Affairs Office at (202) 690-6145.

Advisory Committees' Information Lines: The phone numbers for the CMS Federal Advisory Committee Hotline are 1-(877) 449-5659 (toll free) and (410) 786-9379 (local).

Web Sites: For additional information on the Panel and updates to the Panel's activities, we are referring readers to view our Web site at the following: http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage. (Use control + click the mouse in order to access the previous URL.)

Note: There is an underscore after FACA/05 (like this_); there is no space.

You may also search information about the Panel and its membership in the FACA database at the following URL: <https://www.fido.gov/facadatabase/public.asp>.

SUPPLEMENTARY INFORMATION:**I. Background**

The Secretary of the Department of Health and Human Services (DHHS) (the Secretary) is required by section 1833(t)(9)(A) of the Social Security Act (the Act) and section 222 of the Public Health Service Act (PHS Act) to consult with an expert outside advisory panel regarding the clinical integrity of the Ambulatory Payment Classification (APC) groups and relative payment weights. The Hospital Outpatient Payment (HOP) Panel (which was formerly known as the Advisory Panel on Ambulatory Payment Classification Groups) 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.