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.

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<td>Annette Brewer</td>
<td>(410) 786-6580</td>
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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

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

BILLING CODE 4120-01-P
Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: 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 an FDL. Contact any library to locate the nearest FDL. This information is available at http://www.gpo.gov/libraries/

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most Federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the Medicare National Coverage Determination 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.

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**Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)**

None

**Medicare End-Stage Renal Disease Network Organizations (CMS Pub 100-14)**

None

**Medicare Managed Care (CMS-Pub. 100-16)**

Chapter 5, “Quality Improvement Program”
Overview of Quality Improvement (QI) Program Requirements Definitions Quality Data Reporting Requirements Quality Improvement (QI) Program QI Program Requirements Chronic Care Improvement Program (CCIP) Types of CCIPs Evaluation of CCIPs and Scoring Criteria CCIP Compliance Indicator 1- Target Population and Method of Identifying Eligible Enrollees CCIP Compliance Indicator 2- Method for Enrolling Participants and Participation Rates CCIP Compliance Indicator 3- Whether the CCIP is Designed to Improve Health Outcomes CCIP Compliance Indicator 4- Data Sources Used to Identify the Need for a CCIP CCIP Compliance Indicator 5- Intervention CCIP Compliance Indicator 6- Program Monitoring and Delegation Oversight CCIP Compliance Indicator 7- Outcome Measures Quality Improvement Projects (QIPs) Characteristics of QIPs Evaluation of QIPs and Scoring Criteria QIP Compliance Indicator 1- Target Population QIP Compliance Indicator 2- Topic Focus and Relevance to the Medicare Population QIP Compliance Indicator 3- QI Indicators, Data Sources and Collection Methodology QIP Compliance Indicator 4- Participation QIP Compliance Indicator 5- Results QIP Compliance Indicator 6- Intervention CMS and Department of Health and Human Services (DHHS) QI Initiatives General CMS Directed Special Projects QI Program Health Information Systems QI Program Remedial Action QI Program Requirements for MAOs Using Physician Incentive Plans (PIPs) QI Program Requirements for Medicare Advantage Regional and Local

**Transmittal Number**

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<th>Transmittal Number</th>
<th>Manual/Subject/Publication Number</th>
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<td></td>
<td>Preferred Provider Organizations (PPOs) QI Program Requirements for Private Fee-For-Service (PFFS) and Medicare Medical Savings Account (MSA) Plans QI Program Requirements for Special Needs Plans (SNPs) Additional SNP QI Program Requirements Additional SNP QI Program Requirements SNP Quality Data Reporting Requirements General SNP Reporting Measures Requirements SNP Structure and Process Measures SNP- Specific Medicare HOS Requirements SNP- Specific Medicare CAHPS® Requirements Medicare and Medicaid Quality Reporting Requirements for D-SNPs Quality Improvement Organizations (QIOs) Medicare Advantage (MA) Deeming Program Deeming Requirements Obligations of Deemed MAOs General Deemed Status and CMS Surveys Removal of an MAOs Deemed Status Removal of an MAOs Deemed Status CMS’ Role in Deeming Oversight of AOs Equivalency Review Validation Review Onsite Observation of an AO Enforcement Authority Notice of Intent to Withdraw Approval Obligations of AOs with Deeming Authority Application Requirements Application Notices Withdrawing an Application Reporting Requirements Reconsideration of Application Denials, Removal of Approval of Deeming Authority and Non-Renewals of Deeming Authority Informal Hearing Procedures Informal Hearing Findings Final Reconsideration Determinations Standard Reporting Requirements for MAOs for HEDIS®, HOS and CAHPS® General HEDIS® Reporting Requirements Additional Information Regarding HEDIS® HEDIS® Submission Requirements Summary and Patient- Level Data HEDIS® Compliance Audit Requirements Final Audit Reports, Use and Release Medicare HOS Requirements HOS Survey Process Requirements HOS Modified HOS Data Feedback Medicare CAHPS® Requirements Information Regarding the CAHPS® Satisfaction Survey</td>
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<td>11</td>
<td>CMS Business Partners Systems Security Manual/Subject/Publication Number Demonstration (CMS-Pub. 100-19)</td>
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<td>74</td>
<td>Affordable Care Act – Section 3113 – Laboratory Demonstration for Certain Complex Diagnostic Tests (This CR Fully Rescinds and Replaces CR 7278)</td>
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<td>75</td>
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<td>76</td>
<td>None</td>
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<td>77</td>
<td>Method of Cost Settlement for inpatient Services for Rural Hospitals Participating Under Demonstrations Authorized by Section 410A of the Medicare Modernization Act. Sections 3123 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 is an extension of CR 5020 for additional 5-year period.</td>
</tr>
<tr>
<td>78</td>
<td>Affordable Care Act - Section 3113 - Laboratory Demonstration for Certain Complex Diagnostic Tests (This CR fully Rescinds and Replaces CR 7413)</td>
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<td>79</td>
<td>Implementation Support and Payment Processing for the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration</td>
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<td>80</td>
<td>Implementation Support and Payment Processing for the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration</td>
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<td>910</td>
<td>VMS Utility Run for DME MACs identification of edits for ICD-10</td>
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<td>911</td>
<td>Implementing the Recompetition Award for the Jurisdiction D DME Medicare Administrative Contractor (MAC) Workload</td>
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<td>Durable Medical Equipment National Competitive Bidding: Correction to Permit Payment for Certain Grandfathered Accessories and Supplies</td>
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<td>Issued to specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction</td>
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<td>Issued to specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction</td>
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<td>915</td>
<td>Additional Healthcare Common Procedure Coding System (HCPCS) Codes Subject to Clinical Laboratory Improvement Amendments (CLIA) Edits</td>
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<td>918</td>
<td>HIPAA 5010 National Testing Day and Week</td>
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<td>919</td>
<td>Add Patient Status Codes to Bypass DAM2 Edit in Common Working File (CWF)</td>
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<td>920</td>
<td>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.</td>
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<tr>
<td>921</td>
<td>Common Edits and Enhancements Modules (CEM) Code Set Update</td>
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<td>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</td>
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<td>924</td>
<td>Implementing the Recompetition Award for the Jurisdiction A Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Workload</td>
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<td>Issued to specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction</td>
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<td>926</td>
<td>Medicare Remit Easy Print (MREP) and PC Print User Guide Update for Implementation of version 5010A1</td>
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<td>927</td>
<td>Populating REF Segment - Other Claim Related Adjustment - for Healthcare Claim Payment/Advice or Transaction 835 Version 5010A1</td>
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<td>928</td>
<td>Systems Analysis of New Medicare Summary Notice (MSN) Design</td>
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<td>929</td>
<td>Discontinuation of FISS Data Feed to Legacy Provider Statistical and Reimbursement (PSandR) System</td>
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<td>931</td>
<td>Health Insurance Portability and Accountability Act (HIPAA) 5010 837 Institutional (837I) Edits and 5010 837 Professional (837P) Edits – January 2012 Version</td>
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<td>932</td>
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<td>933</td>
<td>Health Insurance Portability and Accountability (HIPAA) 5010/D.0 Fixes – January 2012</td>
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<td>934</td>
<td>Issued to specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction</td>
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<td>935</td>
<td>Analysis CR - The Inclusion of Veterans Administration (VA) Skilled Nursing Facility (SNF) claims to the VA Medicare Remittance Advice (eMRA) Process</td>
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<td>936</td>
<td>Expand the Expert Claims Processing System (ECPS) for the Fiscal Intermediary Shared System (FISS) to accommodate ICD-10</td>
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<td>Issued to specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction</td>
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<td>939</td>
<td>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)</td>
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<td>940</td>
<td>Reporting of Recoupment for Overpayment on the Remittance Advice (RA) with Patient Control Number</td>
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<td>Common Working File (CWF) Editing Update for Pulmonary Rehabilitation Services (PR) and Cardiac and Intensive Cardiac Rehabilitation Services</td>
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<td>942</td>
<td>Instructions to Accept and Process All Ambulance Transportation Healthcare Common Procedure Coding System (HCPCS) Codes</td>
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<td>943</td>
<td>Issued to specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction</td>
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<td>944</td>
<td>Conference Calls and Research Hours to Identify an Automated Solution for Tracking and Reporting Recovery Auditor Reopening and Appeals throughout the Medicare Appeals Process Unit</td>
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<td>946</td>
<td>Implementation of the HIPAA Version 5010 276/277 Claim Status Edits January 2012 Release</td>
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<td>947</td>
<td>Revisions to Change Request 7362: “Integrated Data Repository (IDR) Claims Sourcing from Shared Systems – Implementation” to Require Transmission of CMN History Data</td>
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<td>948</td>
<td>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</td>
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<td>949</td>
<td>Medicare Fee-For-Service Claims Processing Guidance for Implementing International Classification of Diseases, 10th Edition (ICD-10)</td>
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<tr>
<td>950</td>
<td>Medicare Fee-For-Service Claims Processing Guidance for Implementing International Classification of Diseases, 10th Edition (ICD-10)</td>
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<tr>
<td>951</td>
<td>HITECH - Annual 1099 Address File – Requirements for Submitting Updated Address, TIN</td>
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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 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/CMSSR/list.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).

<table>
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<th>Title</th>
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<th>Transmittal Number</th>
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<th>Effective Date</th>
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<td>Magnetic Resonance Imaging (MRI) in Medicare Beneficiaries with Implanted (PMs) or ICDs</td>
<td>220.1</td>
<td>R134NCD</td>
<td>07/07/2011</td>
<td>08/26/2011</td>
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<td>Autologous Cellular Immunotherapy for Prostate Cancer</td>
<td>110.22</td>
<td>R133NCD</td>
<td>07/08/2011</td>
<td>06/30/2011</td>
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<td>Magnetic Resonance Imaging (MRI) in Medicare Beneficiaries with Implanted (PMs) or ICDs</td>
<td>220.1</td>
<td>R135NCD</td>
<td>08/26/2011</td>
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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

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<tr>
<td>G110107</td>
<td>DexCom G4 Continuous Glucose Monitoring System</td>
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<td>G110008</td>
<td>Sonalleve MR-HIFU Fibroid Therapy System</td>
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<td>G110064</td>
<td>Flexion Atrial Flutter Study with the Therapy CoolFlex ablation Catheter</td>
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<td>G110061</td>
<td>CELT ACD Vascular Closure Device</td>
<td>07/19/11</td>
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<td>BB14735</td>
<td>Magnetic-Activated Cell Sorter (CliniMACS, Miltenyi)</td>
<td>07/19/11</td>
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<td>G110091</td>
<td>Absolute Pro and Absolute Pro LL Self-Expanding Peripheral Stent Systems</td>
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<td>G110089</td>
<td>Essure Permanent Birth Control System</td>
<td>07/28/11</td>
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<tr>
<td>G110092</td>
<td>OMEGA Monorail Coronary Stent System</td>
<td>07/03/11</td>
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<td>G110009</td>
<td>Biomet Stimulator System</td>
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<td>G090229</td>
<td>Glaukos Suprachoroidal Stent Model G3</td>
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<td>G110053</td>
<td>Venous Window Needle Guide (VWNG)</td>
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<td>G080199</td>
<td>Coscal Adhesion Prevention Device</td>
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<td>G110032</td>
<td>Glaukos Trabecular Micro-bypass Stent Injector System, Model G2-M-LS(iith GT400 stent)</td>
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<td>G110030</td>
<td>XIENCE PRIME AND XIENCE PRIME LL Everolimus Eluting Coronary Stent System, XIENCE V Everolimus Eluting Coronary Stent System for EXCEL Clinical Trial</td>
<td>08/12/11</td>
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<td>G110100</td>
<td>ViKY UP - Uterine Positioner</td>
<td>08/24/11</td>
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<td>G110132</td>
<td>Ex-vivo Perfusion and Ventilation of Lungs Recovered from Non-Heart-Beating Donors to Assess Transplant Suitability</td>
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<td>G110067</td>
<td>Endoloxix Fenestrated Stent Graft System</td>
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<td>G110133</td>
<td>Iowa Cochlear Implant Clinical Research Center Hybrid L24 and Standard Cochlear Implants in Profoundly Deaf Infants</td>
<td>08/26/11</td>
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<td>BB14795</td>
<td>Miltenyi CliniMACS cell selection device</td>
<td>08/31/11</td>
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<td>G110035</td>
<td>Viper System Fenestrated Polyaxial Screw Fixation Augmented with the Confidence Spinal Cement System</td>
<td>09/01/11</td>
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<td>BB14796</td>
<td>ACP Double Syringe System</td>
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<td>G110103</td>
<td>EXPERT CTO Clinical Trial - Evaluation of the Xience Coronary Stent, Performance and Technique in Chronic Total Occlusions Clinical Trial</td>
<td>09/02/11</td>
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<tr>
<td>G110157</td>
<td>Exalizer Breath System</td>
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<td>G110150</td>
<td>TECNIS Toric 1-Piece Intraocular Lens (IOL) Model ZCT100</td>
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<td>G110153</td>
<td>Sirtex Technology Pty Ltd/Radioactive Ytrrium Microspheres</td>
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<td>G110080</td>
<td>Endovent Pulmonary Catheter Kit</td>
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<td>G110012</td>
<td>Biomet Stimulator System</td>
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<td>G110158</td>
<td>Lifecell Tissue Matrix</td>
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<td>G110101</td>
<td>Zenith p-Branch Endovascular Graft</td>
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**Addendum VI: Approval Numbers for Collections of Information (July through September 2011)**

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](http://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/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage). For questions or additional information, contact Sarah J. McClain (410-786-2294).
Facility Name | Provider Number | Effective Date | State | Other Information
--- | --- | --- | --- | ---
St. Petersburg, FL 33707 | 1679632137 | 08/04/2011 | GA |
EHCA – Emory Johns Creek Hospital 6325 Hospital Parkway Johns Creek, GA 30097 | 1700861580 | 08/04/2011 | WA |
UW Medicine – Northwest Hospital 1550 North 115th Street Seattle, WA 98133 | 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 | 09/15/2011 | TX |
Columbia Hospital 2201 45th Street West Palm Beach, FL 33407 | 100234 | 09/23/2011 | FL |
University Hospital and Medical Center 7201 North University Drive Tamarac, FL 33321 | 100224 | 09/23/2011 | 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 To: Capital Health Medical Center Hopewell One Capital Way Pennington, NJ 08534 | 1073516183 | 09/28/2009 | NJ |

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 (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).

<table>
<thead>
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<th>Facility Name</th>
<th>Address 1</th>
<th>City</th>
<th>State</th>
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<tbody>
<tr>
<td>Advocate Trinity Hospital</td>
<td>2320 E. 93 Street</td>
<td>Chicago</td>
<td>IL</td>
<td>60617</td>
</tr>
<tr>
<td>Beth Israel Medical Center</td>
<td>First Avenue @ East 16th Street</td>
<td>New York</td>
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<td>Central Michigan Community Hospital</td>
<td>1221 South Drive</td>
<td>Mount Pleasant</td>
<td>MI</td>
<td>48858</td>
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<td>Children’s Hospital and Medical Center</td>
<td>8200 Dodge Street</td>
<td>Omaha</td>
<td>NE</td>
<td>68114</td>
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<tr>
<td>Franciscan Healthcare</td>
<td>700 West Avenue S.</td>
<td>La Crosse</td>
<td>WI</td>
<td>54601</td>
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<tr>
<td>Horizon Medical Center</td>
<td>111 Highway 70E</td>
<td>Dickson</td>
<td>TN</td>
<td>37055</td>
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<tr>
<td>Indian River Surgery Center</td>
<td>1200 37th Street</td>
<td>Vero Beach</td>
<td>FL</td>
<td>32960</td>
</tr>
<tr>
<td>Indiana University Health West Hospital</td>
<td>1111 North Ronald Reagan Parkway</td>
<td>Avon</td>
<td>IN</td>
<td>46123</td>
</tr>
<tr>
<td>Kalispell Regional Medical Center</td>
<td>310 Sunnyview Lane</td>
<td>Kalispell</td>
<td>MT</td>
<td>59901</td>
</tr>
</tbody>
</table>
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/med/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.

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/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage.

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

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (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 Name, Provider Number, Date Approved, State Other Information

#### The following are new listings for this quarter.

<table>
<thead>
<tr>
<th>Facility Name</th>
<th>Provider Number</th>
<th>Date Approved</th>
<th>State</th>
<th>Other Information</th>
</tr>
</thead>
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<tr>
<td>Piedmont Hospital</td>
<td>110083</td>
<td>06/09/2011</td>
<td>GA</td>
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<tr>
<td>Albert Einstein Medical Center</td>
<td>390142</td>
<td>10/07/2011</td>
<td>PA</td>
<td></td>
</tr>
</tbody>
</table>

#### 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

#### 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 ASBS 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
--- | --- | --- | --- | ---
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
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 77524 | 450795 | 03/18/09 | TX | ASMBS

Editorial changes (shown in bold) were made to the facilities listed below.

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/MedicareApprovedFacilities/PETDT/list.asp#TopOfPage.

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