marketing rights to a generic carisoprodol product that was recently approved by the FDA. Once it begins marketing generic carisoprodol, Mylan likely would have been the third supplier of generic carisoprodol tablets. Mylan is one of a limited number of suppliers capable of entering the United States market in the near future.

II. Entry

Entry into the three relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed acquisition. The combination of drug development times and regulatory requirements, including approval by the United States Food and Drug Administration (''FDA''), is costly and lengthy.

III. Effects

The proposed acquisition likely would cause significant anticompetitive harm to consumers by eliminating competition between Mylan and Meda in the markets for 400 mg and 600 mg generic felbamate tablets. Market participants characterize generic felbamate tablets as commodity products, and prices are inversely correlated with the number of competitors in each market. As the number of suppliers offering a therapeutically equivalent drug increases, the price for that drug generally decreases due to the direct competition between the existing suppliers and each additional supplier. The proposed acquisition would combine two of three companies offering the 400 mg and 600 mg strengths of generic felbamate tablets, likely leading consumers to pay higher prices.

In addition, the proposed acquisition likely would cause significant anticompetitive harm to consumers by eliminating future competition that would otherwise have occurred in the 250 mg generic carisoprodol market if Mylan and Meda remained independent. The evidence shows that anticompetitive effects are likely to result from the proposed acquisition due to the elimination of an additional independent entrant in the market for 250 mg generic carisoprodol. Customers expect that the price of this pharmaceutical product will decrease with new entry by Mylan. Thus, absent a remedy, the proposed acquisition will likely cause U.S. consumers to pay significantly higher prices for 250 mg generic carisoprodol tablets.

IV. The Consent Agreement

The proposed Consent Agreement remedies the competitive concerns raised by the acquisition in the markets at issue by requiring Mylan to divest all its rights and assets relating to 400 mg and 600 mg generic felbamate tablets to Alvogen. Founded in 2009, Alvogen is an international pharmaceutical company with commercial operations in thirty-four countries. In addition, the proposed Consent Agreement requires Mylan to return its rights to market generic carisoprodol tablets in the United States to Indicus, the abbreviated new drug application owner for this product.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the proposed acquisition. If the Commission determines that Alvogen is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires Mylan to unwind the sale of rights to Alvogen and then divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The proposed Consent Agreement and Order contain several provisions to help ensure that the divestitures are successful. The proposed Order requires that Mylan transfer its manufacturing technology for felbamate to Alvogen and provide transitional services to assist Alvogen in establishing its manufacturing capabilities and securing all of the necessary FDA approvals. The transitional services include technical assistance to manufacture the product in substantially the same manner and quality employed or achieved by Mylan, and advice and training from knowledgeable employees of Mylan. In addition, Mylan must supply Alvogen with 400 mg and 600 mg generic felbamate tablets until Alvogen is able to manufacture generic felbamate successfully in commercial quantities.

To remedy competitive concerns raised by the acquisition in the market for generic 250 mg carisoprodol tablets, the proposed Order requires Mylan to terminate its agreement with Indicus that gives Mylan the exclusive right to market and sell in the United States all strengths of carisoprodol tablets manufactured by Indicus. Indicus has existing relationships with suppliers of generic drugs that it can and expects to use to replace Mylan as its marketing partner for its carisoprodol products.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–18563 Filed 8–4–16; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9098–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—April Through June 2016

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 April through June 2016, 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, MPA	(410) 786–7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786–6877

Addenda	Contact	Phone number
VI Collections of Information	Mitch Bryman	(410) 786–5258
VII Medicare-Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786–2749
VIII American College of Cardiology—National Cardiovascular Data Registry Sites	Sarah Fulton, MHS	(410) 786–2749
IX Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin, MS	(410) 786–7205
X One-Time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786–7205
XI National Oncologic Positron Emission Tomography Registry Sites	Stuart Caplan, RN, MAS	(410) 786–8564
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	Linda Gousis, JD	(410) 786–8616
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786–2749
XIV Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786–2749
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	Stuart Caplan, RN, MAS	(410) 786–8564
All Other Information	Annette Brewer	(410) 786–6580

SUPPLEMENTARY INFORMATION:

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS Web site or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the Web site list provides more timely access for beneficiaries, providers, and suppliers. We also believe the Web site offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and ''real time'' accessibility. In addition, many of the Web sites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the Web site. These listservs avoid the need to check the Web site, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a Web site proves to be difficult, the contact person listed can provide information.

III. How To Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at *http://www.cms.gov/manuals*.

Dated: July 27, 2016.

Kathleen Cantwell,

Director, Office of Strategic Operations and Regulatory Affairs.

BILLING CODE 4120–01–P

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: August 3, 2015 (80 FR 45980) November 13, 2015 (80 FR 70218), February 4, 2016 (81 FR 6009) and May 9, 2016 (81 FR 28072). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (April through June 2016)

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

How to Obtain Manuals

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

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

How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at http://www.gpo.gov/libraries/

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual for Medicare Internet Only Manual Publication 100-04 Chapter 26 – Completing and Processing Form CMS-1500 Data Set (CMS-Pub. 100-04) Transmittal No. 3490.

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

Transmittal Number	Manual/Subject/Publication Number
Medicare General Information (CMS-Pub. 100-01)	
99	Medicare Fee-for-Service Change Request Correction and Rescind Process
100	Medicare Fee-for-Service Change Request Correction and Rescind Process Change Management Process (Electronic Change Information Management Portal
Medicare Benefit Policy (CMS-Pub. 100-02)	
222	Revisions to Private Contracting/Opt-Out Manual Sections Due to the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Nonparticipating Physicians or Practitioners Who Opt-Out of Medicare Physicians or Practitioners Who Choose to Opt-Out of Medicare Opt-Out Relationship to Noncovered Services Maintaining Information on Opt-Out Physicians Informing Medicare Managed Care Plans of the Identity of the Opt-Out Physicians or Practitioners Emergency and Urgent Care Situations Mandatory Claims Submission Cancellation of Opt-Out

	Early Termination of Opt-Out Appeal Claims Denial Notices to Opt-Out Physicians and Practitioners
223	Clarification of Inpatient Psychiatric Facilities (IPF) Requirements for Certification, Recertification and Delayed/Lapsed Certification and Recertification
224	Update to Pub. 100-02, Chapter 11 End-Stage Renal Disease (ESRD) for Calendar Year (CY) 2016
Medicare National Coverage Determination (CMS-Pub. 100-03)	
191	Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, Sickle Cell Disease, and Myelodysplastic Syndromes
192	Percutaneous Left Atrial Appendage Closure (LAAC)
193	Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, Sickle Cell Disease, and Myelodysplastic Syndromes Stem Cell Transplantation9Formerly 110.8.1)(Various Effective Dates Below)
Medicare Claims Processing (CMS-Pub. 100-04)	
3490	Medicare Internet Only Manual Publication 100-04 Chapter 26 – Completing and Processing Form CMS-1500 Data Set
3491	Payment for Purchased Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Furnished to Medicare Beneficiaries Residing Outside the U.S. - Expatriate Beneficiaries
3492	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3493	Payment Change for Group 3 Complex Rehabilitative Power Wheelchair Accessories and Seat and Back Cushions under Section 2 of the Patient Access and Medicare Protection Act (PAMPA)
3494	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity Instruction
3495	Indian Health Services (IHS) Hospital Payment Rates for Calendar Year 2016
3496	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3497	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3498	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3499	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3500	Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP): Additional Instructions for the Implementation of Round 2 Recompete of the DMEPOS CBP and National Mail Order (NMO) Recompete Payment of a Part of a DMEPOS Item Payment for Capped Rental Items Payment for Inexpensive or Routinely Purchased Items Payment for Repair and Replacement of Beneficiary-Owned Equipment
3501	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3502	Making Principal Diagnosis Codes Mandatory for Notice of Election (NOE) to be Accepted Completing the Uniform (Institutional Provider) Bill (Form CMS 1450) for Hospice Election Service Intensity Add-on (SIA) Payments Frequency of Billing and Same Day Billing
3503	Billing of Vaccine Services on Hospice Claims Payer Only Codes Utilized by Medicare Hospice Claims for Vaccine Services Billing Requirements Claims Submitted to MACs Using Institutional Formats Payment for Pneumococcal Pneumonia Virus, Influenza Virus, and Hepatitis B Virus Vaccines and Their Administration on Institutional Claims Institutional Claims Submitted by Home Health Agencies and Hospice Payment Procedures for Renal Dialysis Facilities (RDF)
3504	Revision of the Method to Calculate the Length of Stay (LOS) Edit for Continuous Invasive Mechanical Ventilation for Greater than 96 Consecutive Hours Medicare Code Editor (MCE)
3505	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3506	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3507	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3508	JW Modifier: Drug amount discarded/not administered to any patient Discarded Drugs and Biologicals
3509	Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, Sickle Cell Disease, and Myelodysplastic Syndromes Stem Cell Transplantation Billing for Stem Cell Transplantation Billing for Autologous Stem Cell Transplants Billing for Allogeneic Stem Cell Transplants Stem Cell Transplantation
3510	Updates to Pub. 100-04, Chapters 1 and 16 to Correct Remittance Advice Messages Claims Processing Instructions for Payment Jurisdiction An A/B MAC (B) Receives a Claim for Services that are in Another A/B MAC (B)'s Payment Jurisdiction An A/B MAC (B) Receives a Claim for Services that are in a DME Payment Jurisdiction A DME MAC Receives a Claim for Services that are in an A/B MAC (B) Payment Jurisdiction An A/B MAC (B) Receives a Claim for an RRB Beneficiary An A/B MAC (B) or DME MAC Receives a Claim for a UMWA Beneficiary A DME MAC receives a Paper Claim with Items or Services that are in Another DME MAC's Payment Jurisdiction Deported Medicare Beneficiaries Processing Claims for Services of Participating Physicians or Suppliers Charges for Missed Appointments

	Coding That Results from Processing Noncovered Charges Handling Incomplete or Invalid Claims A/B MAC (B) Data Element Requirements Conditional Data Element Requirements for A/B MACs and DMEMACs A/B MAC (B) Specific Requirements for Certain Specialties/Services General Explanation of Payment Assignment Required Physician Notification of Denials Reasons for Denial - Physician Office Laboratories Out-of-Compliance
3511	Changes to the Fiscal Intermediary Shared System (FISS) Inpatient Provider Specific File (PSF) for Low-Volume Hospital Payment Adjustment Factor and New Inpatient Prospective Payment System (IPPS) Pricer Output Field for Islet Isolation Add-on Payment A/Provider Specific File Procedure for Medicare Contractors to Perform and Record Outlier Reconciliation Adjustments
3512	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3513	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3514	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3515	Percutaneous Left Atrial Appendage Closure (LAAC)
3516	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3517	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity Instruction
3518	Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - July 2016 Update
3519	Corrections to Chapter 1 of the Medicare Claims Processing Manual Claims Submitted for Items or Services Furnished to Medicare Beneficiaries in State or Local Custody Under a Penal Authority Application to Special Claim Type Payer Only Codes Utilized by Medicare
3520	2016 Durable Medical Equipment Prosthetics, Orthotics, and Supplies Healthcare Common Procedure Coding System (HCPCS) Code Jurisdiction List
3521	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3522	Update to Internet-Only-Manual Publication 100-04, Chapter 18, Section 30.6 Screening Pap Smears: Diagnoses Codes
3523	July 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS) Billing Instructions for IMRT Planning and Delivery
3524	July 2016 Integrated Outpatient Code Editor (I/OCE) Specifications Version 17.2
3525	Common Edits and Enhancements Modules (CEM) Code Set Update
3526	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3527	Claim Status Category and Claim Status Codes Update
3528	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - July CY 2016 Update
3529	Instructions for Downloading the Medicare ZIP Code File for October 2016
3530	JW Modifier: Drug amount discarded/not administered to any patient Discarded Drugs and Biologicals
3531	July 2016 Update of the Ambulatory Surgical Center (ASC) Payment System
3532	Annual Update of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)
3533	Payments to Home Health Agencies That Do Not Submit Required Quality Data
3534	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3535	Payment Change for Group 3 Complex Rehabilitative Power Wheelchairs Accessories and Seat and Back Cushions under Section 2 of the Patient Access and Medicare Protection Act (PAMPA)
3536	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
3537	Corrections to Chapter 1 of the Medicare Claims Processing Manual Claims Submitted for Items or Services Furnished to Medicare Beneficiaries in State or Local Custody Under a Penal Authority Application to Special Claim Types Payer Only Codes Utilized by Medicare
3538	JW Modifier: Drug amount discarded/not administered to any patient Discarded Drugs and Biologicals
3539	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3540	Billing of Vaccine Services on Hospice Claims Hospice Claims for Vaccine Services Billing Requirements Claims Submitted to MACs Using Institutional Formats Payment for Pneumococcal Pneumonia Virus, Influenza Virus, and Hepatitis B Virus Vaccines and Their Administration on Institutional Claims Institutional Claims Submitted by Home Health Agencies and Hospices Payment Procedures for Renal Dialysis Facilities (RDF)
3541	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3542	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3543	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3544	New Physician Specialty Code for Dentist Physician Specialty Codes
3545	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3546	October Quarterly Update to 2016 Annual Update of HCPCS Codes Used for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Enforcement
3547	New Physician Specialty Code for Dentist
3548	Issued to a specific audience, not posted to Internet/Intranet due to

	Confidentiality of Instruction
3549	Pub. 100-04, Chapter 29 – Appeals of Claims Decisions Update: Revisions to Timeliness Requirements for Forwarding Misfiled Appeal Requests, Reconsideration Request Form, and Guidelines for Writing Appeals Correspondence Glossary CMS Decisions Subject to the Administrative Appeals Process Who May Appeal Steps in the Appeals Process: Overview Where to Appeal Conditions and Examples That May Establish Good Cause for Late Filing by Beneficiaries Amount in Controversy General Requirements Principles for Determining Amount in Controversy Parties to an Appeal How to Make and Revoke an Appointment Appeals of Claims Involving Excluded Providers, Physicians, or Other Suppliers Reading Levels General Information Filing a Request for Redetermination Time Limit for Filing a Request for Redetermination The Redetermination The Redetermination Decision Dismissals Medicare Redetermination Notice (For Partly or Fully Unfavorable Redeterminations Filing a Request for a Reconsideration Time Limit for Filing a Request for a Reconsideration Contractor Responsibilities - General QIC Jurisdictions Tracking Cases Requests for an ALJ Hearing
3550	New Waived Tests
3551	July Quarterly Update for 2016 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
3552	July 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS)
3553	New Condition Code for Reporting Home Health Episodes With No Skilled Visits
3554	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - October 2016
3555	Medicare Part A Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Pricer Update FY 2017

Medicare Secondary Payer (CMS-Pub. 100-05)	
117	None Remote Identity Proofing (RIDP) and Multi-Factor Authentication (MFA) for Electronic Correspondence Referral System (ECRS) Web Users
118	Individuals Not Subject to the Limitation on Medicare Secondary Payment (MSP)
Medicare Financial Management (CMS-Pub. 100-06)	
266	Notice of New Interest Rate for Medicare Overpayments and Underpayments -3rd Qtr Notification for FY 2016
267	Notice of New Interest Rate for Medicare Overpayments and Underpayments -3rd Qtr Notification for FY 2016
268	New Physician Specialty Code for Dentist
269	New Physician Specialty Code for Dentist Physician/Limited License Physician Specialty Codes
Medicare State Operations Manual (CMS-Pub. 100-07)	
154	Revisions to the State Operations Manual (SOM) – Chapter 2 Exit Conference A Introductory Remarks B Ground Rules C Presentation of Finding D Closure Limitations on Technical Assistance Afforded by Surveyors
155	Revisions to the State Operations Manual (SOM) –Chapter 5 Survey Exit Conference and Report to the Provider/Supplier Task 7: Exit Conference
156	Post-Survey Certification Actions for Nursing Homes Survey Protocol for Long Term Care Facilities - Part I/IV Deficiency Categorization/E. Psychosocial Outcome Severity Guide
157	Revisions to the State Operations Manual (SOM) - Appendix PP – Guidance to Surveyors for Long Term Care Facilities
Medicare Program Integrity (CMS-Pub. 100-08)	
643	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
644	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
645	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
646	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
647	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
648	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
649	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
650	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
651	Medical Review of Skilled Nursing Facility Prospective Payment System (SNF PPS) Bills
652	Issued to a specific audience, not posted to Internet/Intranet due to

	Confidentiality of Instruction
653	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
654	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
	None
Medicare Quality Improvement Organization (CMS- Pub. 100-10)	
25	QIO Manual Chapter 11 - Hospital Payment Monitoring Program (HPMP)
26	QIO Manual Chapter 2 – Eligibility
27	QIO Manual Chapter 12 "Communications, Outreach, and Program-related Information Activities"
Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)	
	None
Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)	
	None
Medicare Managed Care (CMS-Pub. 100-16)	
121	Chapter 4, Benefits and Beneficiary Protections General Requirements Basic Rule Exceptions to Requirements for MA plans to Cover FFS Benefits Types of Benefits Hospice Coverage Uniformity Anti-Discrimination Review for Discrimination and Steering Confidentiality Multiple Plan Offerings and Benefit Caps Payment for Investigational Device Exemption (IDE) Studies Return to Enrollee's Home Skilled Nursing Facility (SNF) Therapy Caps and Exceptions
122	Chapter 14, Contract Determinations and Appeals
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
	None
Demonstrations (CMS-Pub. 100-19)	
142	Affordable Care Act Bundled Payments for Care Improvement Initiative - Recurring File Updates Models 2 and 4 July 2016 Updates
143	Implementing Payment Changes for FCIIIP (Frontier Community Health Integration Project), Mandated by Section 123 of MIPPA 2008 and as Amended by Section 3126 of the ACA of 2010 (This CR Rescinds and Replaces CR8683)
144	Issued to a specific audience, not posted to Internet/ Intranet to Confidentiality of Instruction
145	Update to the Common Working File Edits for G9678 - Oncology Care Model Service
146	Oncology Care Model (OCM) Monthly Enhanced Oncology Services (MEOS) Payment Implementation
147	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
148	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
149	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
One Time Notification (CMS-Pub. 100-20)	
1641	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
1642	Implementation of the Award for Jurisdiction A Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Workload
1643	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
1644	Reclassification of Certain Durable Medical Equipment HCPCS Codes Included in Competitive Bidding Programs (CBP) from the Inexpensive and Routinely Purchased Payment Category to the Capped Rental Payment Category
1645	Analysis of the Combined Common Edits/Enhancements Module (CCEM) 3rd Party Software
1646	Upgrade (Jaspersoft) reporting software for the Combined Common Edits/Enhancement Module (CCEM)
1647	Payment Change for Group 3 Complex Rehabilitative Power Wheelchairs Accessories and Seat and Back Cushions under Section 2 of the Patient Access and Medicare Protection Act (PAMPA) for Home Health Claims
1648	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
1649	Phase 2 of Updating the Fiscal Intermediary Shared System (FISS) to Make Payment for Drugs and Biologicals Services for Outpatient Prospective Payment System (OPPS) Providers
1650	Shared System Enhancement 2015: Archive/Remove Inactive Medicare Demonstration Projects
1651	National Provider Identifier Crosswalk System (NPICS) Retirement Analysis Only - Engage Shared Systems Maintainers and Medicare Administrative Contractors (MACs) in Meetings and Correspondence Related to the NPICS Retirement with the Stakeholders
1652	Analysis Only: To Obtain a Rough Order of Magnitude (ROM) from Durable Medical Equipment Medicare Administrative Contractors (DME MACs), GDIT/VMS, the National Supplier Clearinghouse (NSC) and the Common Electronic Data Interchange (CEDI) Contractor to Develop and Implement a Process for DME MAC Provider Self-Service Internet Portal Authentication of Medicare Providers Using EDI Enrollment Data Elements
1653	New State Code for AZ, ID, NY, and WV
1654	System Changes to Implement Section 231 of the Consolidated Appropriations Act, 2016, Temporary Exception for Certain Severe Wound Discharges From Certain Long-Term Care Hospitals (LTCHs)
1655	Recurring calls with the Fiscal Intermediary Shared System (FISS) for any in-depth discussions
1656	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
1657	Issuing Continuing Compliance Letters to Specific Providers and Suppliers
1658	Coding Revisions to National Coverage Determinations
1659	Convert Assembler Code to COBOL or Best Coding Language to Improve

	MCS System Maintainability and Sustainability, Analysis only.
1660	Shared Savings Program (SSP) Accountable Care Organization (ACO) Qualifying Stay Edits
1661	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
1662	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
1663	Issued to a specific audience, not posted to Internet/ Intranet to Confidentiality of Instruction
1664	Reporting Medicare Administrative Contractor (MAC) Provider Education Website Analytic Data to the Provider Customer Service Program Contractor Information Database (PCID)
1665	Coding Revisions to National Coverage Determinations (NCDs)
1666	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
1667	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
1668	National Provider Identifier Crosswalk System (NPICS) Retirement Analysis Only - Engage Shared Systems Maintainers and Medicare Administrative Contractors (MACs) in Meetings and Correspondence Related to the NPICS Retirement with the Stakeholders
1669	Guidance on Implementing System Edits for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)
1670	Shared System Enhancement 2014 – Identification of Fiscal Intermediary Standard System (FISS) Obsolete Reports – Analysis Only
Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)	
57	Payments to Home Health Agencies That Do Not Submit Required Quality Data
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
	None

Addendum II: Regulation Documents Published in the Federal Register (April through June 2016)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register,** contact GPO at www.gpo.gov/fdsys. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at http://www.gpoaccess.gov/fr/index.html. The following website http://www.archives.gov/federal-register/ provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our website at: http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-2Q16QPU.pdf

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

Addendum III: CMS Rulings (April through June 2016)

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

The rulings can be accessed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

Addendum IV: Medicare National Coverage Determinations (April through June 2016)

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

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Percutaneous Left Atrial Appendage Closure (LAAC)	NCD 20.34	R192	05/06/2016	02/08/2016
Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, Sickle Cell Disease, and Myelodysplastic Syndromes	NCD 110.23	R191	04/29/2016	01/27/2016

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (April through June 2016)

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
G160051	Brainsway Deep TMS System utilizing the H2-coil	04/13/2016
G160053	Closing the Loop on Tremor: A Responsive Deep Brain Stimulator for the Treatment of Essential Tremor	04/14/2016
G160058	True Beam, True Beam STx, Edge	04/14/2016
G160056	Allurion Elipse Device	04/15/2016
G160054	Repetitive Transcanial Magnetic Stimulation (rTMS) for Obsessive-Compulsive Disorder	04/20/2016
G160061	Spatz3 Adjustable Balloon System	04/20/2016
G160065	iNod Biopsy Needle, iNod Ultrasound Catheter, iNod Ultrasound Imaging System, iNod Motor Drive Unit, iNod Sled	04/21/2016
G160063	HEMOBLAST Bellows Hemostatic Agent	04/22/2016
G160064	Sight Sciences VISCO 360 Viscosurgical System	04/22/2016
G160074	MADIT S-ICD Clinical Study	04/26/2016
G160067	NeoChord Artificial Chordae Delivery System, Model DS1000	04/27/2016
G140102	ThermoCool SmartTouch SF Catheter	04/27/2016
G160066	Embosphere Microspheres	04/27/2016
G160071	NeuroBlate System	04/29/2016
G160072	Influence of Cooling duration on Efficacy in Cardiac Arrest Patients (ICECAP) trial	04/29/2016
G160073	MED-EL Synchrony cochlear implant with the FLEX28 electrode array	04/29/2016
G160077	Orbera Intragastric Balloon	05/04/2016
G160078	SJM MRI Diagnostic Imaging Registry	05/05/2016
G160081	WIRION Embolic Protection System (EPS)	05/06/2016
BB16430	DryThaw-MTS1-C	05/08/2016
G120246	Exablate Transcranial MRGFUS Thalmotomy Treatment	05/13/2016
G150199	Model SC9 Posterior Chamber Intraocular Lens	05/13/2016
G160082	DBS Leads, Activa PC Stimulator, DBS Extension	05/14/2016
G160084	Revanesse Ultra+ (with lidocaine)	05/17/2016
G040175	Relay Thoracic Stend Graft with Transport Delivery System	05/20/2016

IDE	Device	Start Date
	for treatment of thoracic aortic aneurysms.	
G160087	Aspen System	05/25/2016
G150241	Ellipse ICD and Durata and Optisure high voltage lead system	05/25/2016
G160013	Bio Ventrix Revivent TC System	05/25/2016
G160089	NovoTTF-100M System	05/26/2016
G160092	Bioness StimRouter Neuromodulation System, StimRouter Lead Kit, StimRouter Surgical Tool Kit, StimRouter Clinician Kit, StimRouter User Kit	06/01/2016
G160093	OVT	06/01/2016
G160094	TSolution One TKA	06/01/2016
G160049	EnligHTN Renal Denervation System	06/02/2016
G160001	Covera Vascular Covered Stent	06/03/2016
G160107	ZiftLift System	06/14/2016
G160105	therascreen BRAF V600E RGQ PCR Kit	06/15/2016
G160109	Covera Vascular Covered Stent	06/22/2016
G160111	MET Exon 14 Skipping Test	06/22/2016
G150137	JUVEDERM VOLUMA XC	06/22/2016
G160060	ClariCore Biopsy System	06/22/2016
G160110	TIVUS System, Multidirectional TIVUS Catheter (also referred as TIVUS Catheter), TIVUS Console	06/23/2016
G160113	SAFE - PCI in STEMI for Seniors	06/24/2016

Addendum VI: Approval Numbers for Collections of Information (April through June 2016)

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

Addendum VII: Medicare-Approved Carotid Stent Facilities, (April through June 2016)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Effective Date	State
The following facilities are new listings for this quarter.			
South Georgia Medical Center 2501 N. Patterson Street Valdosta, GA 31602	1306896253	04/12/2016	GA
Baptist Memorial Hospital – North Mississippi (Baptist North Mississippi) 2301 South Lamar Boulevard Oxford, MS 38655	250034	04/12/2016	MS
Aurora Medical Center - Oshkosh 855 North Westhaven Drive Oshkosh, WI 54904	060112	04/21/2016	WI
The following facility has editorial changes (in bold).			
FROM: Mercy General Health Partners **TO: Mercy Health Partners** 1500 East Sherman Boulevard Muskegon, MI 49444	23-0066	12/21/2005	MI

Addendum VIII: American College of Cardiology's National Cardiovascular Data Registry Sites (April through June 2016)

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

Effective January 27, 2005, to obtain reimbursement, Medicare NCD policy requires that providers implanting ICDs for primary prevention clinical indications (that is, patients without a history of cardiac arrest or spontaneous arrhythmia) report data on each primary prevention ICD procedure. Details of the clinical indications that are covered by Medicare

and their respective data reporting requirements are available in the Medicare NCD Manual, which is on the CMS website at http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961

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

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available by accessing our website and clicking on the link for the

American College of Cardiology's National Cardiovascular Data Registry at: www.ncdr.com/webncdr/common. For questions or additional information, contact Sarah Fulton, MHS (410 786 2749).

Facility	City	State
The following facilities are new listings for this quarter.		
Memorial Hermann Sugar Land	Sugar Land	TX
Tennova-North Knoxville Medical Center	Powell	TN
Wichita Ambulatory Surgery Center	Wichita	KS
Alexandria Ambulatory Surgery Center	Alexandria	LA
Baytown Ambulatory Surgery Center	Baytown	TX
Watertown Medical Center, LLC	Watertown	WI
Nason Medical Center, LLC	Roaring Spring	PA
Trios Health	Kennewick	WA
Memorial Hermann Pearland	Pearland	TX
North Metro Medical Center	Jacksonville	AZ
Ohio Valley General Hospital	McKees Rocks	PA
HHC ASC, LLC	St. Louis	MO
St. Bernard Parish Hospital	Chalmette	LA
Palms of Pasadena Hospital	St. Petersburg	FL
Melrose-Wakefield Hospital	Melrose	MA
Saint Anne's Hospital	Fall River	MA
United Hospital System	Kenosha	WI
Watsonville Community Hospital	Watsonville	CA
Bristol Regional Medical Center	Bristol	TN
UPMC McKeesport	McKeesport	PA
Lafayette General Southwest	Lafayette	LA

Addendum IX: Active CMS Coverage-Related Guidance Documents (April through June 2016)

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

Addendum X: List of Special One-Time Notices Regarding National Coverage Provisions (April through June 2016)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at www.cms.hhs.gov/coverage. For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

Addendum XI: National Oncologic PET Registry (NOPR) (April through June 2016)

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

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. 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 (April through June 2016)

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.

We are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage. For questions or additional information, contact Linda Gousis, JD, (410-786-8616).

Facility	Provider Number	Date Approved	State
The following facilities are new listings for this quarter.			
Saint Cloud Hospital 1406 Sixth Avenue North Saint Cloud, MN 56303	240036	04/13/2016	MN
Lubbock County Hospital District 602 Indiana Avenue Lubbock, TX 79415	450686	06/17/2016	TX
Fresno Community Hospital and Medical Center 2823 Fresno Street Fresno, CA 93721	1104906569	11/05/2014	CA
The following facility is being removed as of this quarter.			
Albany Medical Center Hospital 43 New Scotland Avenue Albany, NY	33-0013	11/06/2013	NY

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (April through June 2016)

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 Commision on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. There were no updates to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (April through June 2016)

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

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS's minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (April through June 2016)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

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

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BILLING CODE 4120–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10243]

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

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by September 6, 2016.

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

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

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

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

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

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Testing Experience and Functional Tools: Functional Assessment Standardized Items (FASI) Based on the CARE Tool; *Use:* In 2012, CMS funded a project entitled, Technical Assistance to States for Testing Experience and Functional Tools (TEFT) Grants. One component of this demonstration is to amend and test the reliability of a setting-agnostic, interoperable set of data elements, called ''items,'' that can support standardized assessment of individuals across the continuum of care. Items that were created for use in post-acute care settings using the Continuity Assessment Record and Evaluation (CARE) tool have been adopted, modified, or supplemented for use in community-based long-term services and supports (CB–LTSS) programs. This project will test the reliability and validity of the function-related assessment items, now referred to as Functional Assessment Standardized Items (FASI), when applied in community settings, and in various populations: Elders (65 years and older); younger adults (18–64) with physical disabilities; and adults of any age with intellectual or developmental disabilities, with severe mental illness, or with traumatic brain injury.

Individual-level data will be collected two times using the TEFT FASI Item Set. The first data collection effort will collect data that can be analyzed to evaluate the reliability and validity of the FASI items when used with the five waiver populations. Assessors will conduct functional assessments in client homes using the TEFT FASI Item Set. Changes may be recommended to individual TEFT FASI items, to be made prior to releasing the TEFT FASI items for use by the states. The FASI Field Test Report will be released to the public.

The second data collection will be conducted by the states to demonstrate their use of the FASI data elements. The assessment data could be used by the states for multiple purposes. They may use the standardized items to determine individual eligibility for state programs, or to help determine levels of care within which people can receive services, or other purposes. In the second round of data collection, states will demonstrate their proposed uses, manage their FASI data collection and conduct their own analysis, to the extent they propose to do such tasks. The states have been funded under the demonstration grant to conduct the round 2 data collection and analysis. These states will submit reports to CMS describing their experience in the Round 2 data collection, including the items they collected, how they planned to use the data, and the types of challenges and successes they encountered in doing so. The reports may be used by CMS in their evaluation of the TEFT grants.

Subsequent to the publication of our 60-day **Federal Register** notice (May 2, 2016; 81 FR 26235), we have made several minor modifications to the form. The changes are intended to further protect participant identification and improve the response efficiency by removing several checkboxes that we were using for item screening purposes. The instructions were revised accordingly. The revisions have no impact on our 60-day burden estimates. *Form Number:* CMS–10243 (OMB control number: 0938–1037); *Frequency:* On occasion; *Affected Public:* Individuals and Households; *Number of Respondents:* 5,650; *Total Annual Responses:* 5,650; *Total Annual Hours:* 2,825. (For policy questions regarding this collection contact Allison Weaver at 410–786–4924.)