• *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0053, Permits, Authorities, or Franchises''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0053, Permits, Authorities, or Franchises'' on your attached document.

• Mail: General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000–0053, Permits, Authorities, or Franchises.

Instructions: Please submit comments only and cite ''Information Collection 9000–0053, Permits, Authorities, or Franchises,'' in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Michael O. Jackson, Procurement Analyst, Office of Governmentwide Acquisition Policy, GSA 202–208–4949 or email *michaelo.jackson@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

The FAR requires insertion of clause 52.247–2, Permits, Authorities, or Franchises, when regulated transportation is involved. The clause requires the contractor to indicate whether it has the proper authorization from the Federal Highway Administration (or other cognizant regulatory body) to move material. The contractor may be required to provide copies of the authorization before moving material under the contract. The clause also requires the contractor, at its expense, to obtain and maintain any permits, franchises, licenses, and other authorities issued by State and local governments. The Government may request to review the documents to ensure that the contractor has complied with all regulatory requirements.

B. Annual Reporting Burden

Respondents: 255.
Responses per Respondent: 1.
Annual Responses: 255.
Hours per Response: 0.5.
Total Burden Hours: 128.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulations (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405 telephone 202–501–4755.

Please cite OMB Control No. 9000–0053, Permits, Authorities, or Franchises, in all correspondence.

Edward Loeb,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2015–28802 Filed 11–12–15; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9093–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July through September 2015

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 2015, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone Number
I CMS Manual Instructions	Ismael Torres	(410) 786-1864
II Regulation Documents Published in the **Federal Register**	Terri Plumb	(410) 786-4481
III CMS Rulings	Tiffany Lafferty	(410)786-7548
IV Medicare National Coverage Determinations	Wanda Belle	(410) 786-7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786-6877
VI Collections of Information	Mitch Bryman	(410) 786-5258
VII Medicare –Approved Carotid Stent Facilities	Lori Ashby	(410) 786-6322
VIII American College of Cardiology-National Cardiovascular Data Registry Sites	Marie Casey, BSN, MPH	(410) 786-7861
IX Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin	(410) 786-7205
X One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin	(410) 786-7205
XI National Oncologic Positron Emission Tomography Registry Sites	Stuart Caplan, RN, MAS	(410) 786-8564
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	Marie Casey, BSN, MPH	(410) 786-7861
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Marie Casey, BSN, MPH	(410) 786-7861
XIV Medicare-Approved Bariatric Surgery Facilities	Jamie Hermansen	(410) 786-2064
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	Stuart Caplan, RN, MAS	(410) 786-8564
All Other Information	Annette Brewer	(410) 786-6580

I. Background

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

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

II. Format for the Quarterly Issuance Notices

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

III. How to Use the Notice

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

Dated: November 6, 2015.

Kathleen Cantwell,

Director, Office of Strategic Operations and Regulatory Affairs.

BILLING CODE 4120–01–P

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: November 14, 2014 (79 FR 68253), February 2, 2015 (80 FR 5537), April 24, 2015 (80 FR 23013) and August 3, 2015 (80 FR 45980). For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (July through September 2015)

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 Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - October 2015 Update, use Medicare Claims Processing (CMS-Pub. 100-04)Transmittal No. 3304.

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)
93	Internet Only Manual (IOM) Publication 100-01 - General Information, Eligibility, and Entitlement, Chapter 7 - Contract Administrative Requirements, Section 40 – Shared System Maintainer Responsibilities for Systems Releases Shared System Maintainer and Part A/Part B (A/B)/Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) and the Shared System Maintainer and Part A/Part B (A/B)/Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) and the Single Testing Contractor (STC) Responsibilities for Systems Releases Standardized Terminology for Claims Processing Systems Standard Terminology Chart Release Software Implementing Validated Workarounds for Shared System Claims Processing by All Medicare DME MACs Next Generation Desktop (NGD) Requirements

	Shared System Testing Requirements for Shared System Maintainers Single Testing Contractor (STC), and DME MACs Minimum Testing Standards for Shared System Maintainers and the Single Testing Contractor (STC)/Beta Testers Testing Standards Applicable to all Beta Testers Part A/Part B (A/B) Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) (User) Testing Requirements Testing Requirements Applicable to all CWF Data Centers (Hosts) Timeframe Requirements for all Testing Entities Testing Documentation Requirements Definitions Test Case Specification Standard Shared System Testing Requirements for Shared System Maintainers, Single Testing Contractor (STC)/Beta Testers, and Part A/Part B (A/B) Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs)
Medicare Benefit Policy (CMS-Pub. 100-02)	
210	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
Medicare National Coverage Determination (CMS-Pub. 100-03)	
183	National Coverage Determination (NCD) for Screening for Colorectal Cancer Using Cologuard™ - A Multitarget Stool DNA Test National Coverage Determination (NCD) for Screening for Colorectal Cancer Using Cologuard™ - A Multitarget Stool DNA Test
184	Update to Pub. 100-03, National Coverage Determination Manual, Chapter 1, Part 1, Section 50.1 Speech Generating Device
185	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
Medicare Claims Processing (CMS-Pub. 100-04)	
3288	Medicare Internet Only Manual Publication 100-04 Chapter 22 Remittance Advice Background Remittance Balancing Electronic Remittance Advice - ERA or ASC X12 835 ASC X12 835 Medicare Standard Electronic PC-Print Software for Institutional Providers Medicare Remit Easy Print Software for Professional Providers and Suppliers Standard Paper Remittance Advice Claim Adjustment Reason Codes Remittance Advice Remark Codes Requests for Additional Codes The Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) Mandated Operating Rules Health Care Claim Payment/Advice (835) Infrastructure Rule Uniform Use of CARCs and RARCs Rule EFT Enrollment Data Rule ERA Enrollment Form
3289	Medicare Part A Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Pricer Update FY 2016
3290	October 2015 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
3291	Indian Health Services (IHS) Hospital Payment Rates for Calendar Year 2015
3292	Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - July 2015 Update Average Sales Price (ASP) Payment Methodology
3293	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3294	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3295	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3296	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3297	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3298	Remittance Advice Remark and Claims Adjustment Reason Code and Medicare Remit Easy Print and PC Print Update
3299	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3300	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3301	Claims Processing Instructions for Diagnostic Digital Breast Tomosynthesis Digital Breast Tomosynthesis Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages
3302	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3303	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3304	Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - October 2015 Update
3305	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3306	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3307	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3308	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) – October 2015
3309	Applying Therapy Caps to Maryland Hospitals Determining Payment Amounts – Institutional Claims Application of Financial Limitations Exceptions to Therapy Caps – General Exceptions Process Use of the KX Modifier for Therapy Cap Exceptions Therapy Cap Manual Review Threshold

	Identifying the Certifying Physician MSN Messages Regarding the Therapy Cap Part B Outpatient Rehabilitation and Comprehensive Outpatient Rehabilitation Facility (CORF) Services – General
3310	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3311	End Stage Renal Disease (ESRD) Home Dialysis Policy Guidelines for Physician or Practitioner Billing -- (Per Diem)
3312	None
3313	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3314	Procedure for Medicare Contractors to Perform and Record Outlier Reconciliation Adjustments
3315	New and Revised Place of Service Codes (POS) for Outpatient Hospital Part B Medicare Administrative Contractor (MAC) Instructions for Place of Service (POS) Codes Selection of Level of Evaluation and Management Service Payment for Office or Other Outpatient Evaluation and Management (E/M) Visits (Codes 99201 - 99215) Place of Service (POS) Instructions for the Professional Component (PC or Interpretation) and the Technical Component (TC) of Diagnostic Tests Professional Billing Requirements Items 14-33 - Provider of Service or Supplier Information Place of Service Codes (POS) and Definitions Site of Service Payment Differential
3316	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3317	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October CY 2015 Update
3318	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3319	National Coverage Determination (NCD) for Screening for Colorectal Cancer Using Cologuard™ - A Multitarget Stool DNA Test
3320	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3321	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3322	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3323	October Quarterly Update for 2015 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule
3324	Clarification of the Policy for Competitively-Bid Wheelchair Accessories Furnished with Non-Competitively Bid Wheelchair Base Equipment Exception for Wheelchair Accessories Furnished with Non-Competitively Bid Wheelchair Base Equipment
3325	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3326	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3327	New Waived Tests
3328	October 2015 Integrated Outpatient Code Editor (I/OCE) Specifications Version 16.3
3329	Update to Pub. 100-04, Chapter 18 to Provide Language-Only Changes for Updating ICD-10, the 02/12 version of the Form CMS-1500, and ASC X12 Healthcare Common Procedure Coding System (HCPCS) and Diagnosis Codes Roster Claims Submitted to A/B MACs (B) for Mass Immunization Centralized Billing for Influenza Virus and Pneumococcal Vaccines to Medicare A/B MACs (B) Claims Submitted to A/B MACs (A) for Mass Immunizations of Influenza Virus and Pneumococcal Vaccinations HCPCS and Diagnosis Codes for Mammography Services Billing Requirements – A/B MAC (B) Claims Remittance Advice Messages Pap Smears On and After July 1, 2001 HCPCS Codes for Billing Diagnoses Codes Remittance Advice Codes Screening Pelvic Examinations on and After July 1, 2001 Diagnoses Codes Revenue Code and HCPCS Codes for Billing Remittance Advice Codes Diagnosis Coding Remittance Advice Notices Payment Determining High Risk for Developing Colorectal Cancer Billing Requirements for Claims Submitted to A/B MACs Remittance Advice Notices Claims Submission Requirements and Applicable HCPCS Codes HCPCS and Diagnosis Coding Remittance Advice Notices A/B Medicare Administrative Contractor (MAC) (B) and Contractor Billing Requirements A/B MAC (B) Billing Requirements Modifier Requirements for Pre-diabetes A/B MAC (A) Billing Requirements Modifier Requirements for Pre-diabetes Diagnosis Code Reporting Medicare Summary Notices A/B MAC (B) Billing Requirements A/B MAC (A) Billing Requirements Diagnosis Code Reporting Medicare Summary Notice Billing Requirements Diagnosis Code Reporting Medicare Summary Notice (MSN) and Claim Adjustment Reason Codes (CARCs) Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RARCs), Claims Adjustment Reason Codes (CARCs), and Advance Beneficiary Notices (ABNs) Healthcare Common Procedure Coding System (HCPCS) and Diagnosis

	Coding Common Working File (CWF) Edits Diagnosis Code Reporting Billing Requirements Policy Professional Billing Requirements Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RARCs), Claims Adjustment Reason Codes (CARCs), and Group Codes
3330	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3331	Inpatient Rehabilitation Facility (IRF) Annual Update: Prospective Payment System (PPS) Pricer Changes for FY 2016
3332	Update-Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) Fiscal Year (FY) 2016 Annual Update
3333	October 2015 Update of the Hospital Outpatient Prospective Payment System (OPPS)
3334	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3335	Implement Operating Rules - Phase III ERA EFT: CORE 360 Uniform Use of Claim Adjustment Reason Codes (CARC) and Remittance Advice Remark Codes (RARC) Rule - Update from CAQH CORE
3336	Healthcare Provider Taxonomy Codes (HPTCs) October 2015 Code Set Update
3337	Instructions for Downloading the Medicare ZIP Code File for January 2016
3338	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3339	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3340	Annual Clotting Factor Furnishing Fee Update 2016
3341	Influenza Vaccine Payment Allowances - Annual Update for 2015-2016 Season
3342	Common Edits and Enhancements Modules (CEM) Code Set Update
3343	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3344	Claim Status Category and Claim Status Codes Update
3345	Update to Hospice Payment Rates, Hospice Cap, Hospice Wage Index and Hospice Pricer for FY 2016
3346	Removing References to Network Service Vendors from Chapter 24 of the Medicare Claims Processing Manual, Pub. 100-04
3347	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3348	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3349	2016 Annual Update of Healthcare Common Procedure Coding System (HCPCS) Codes for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Update
3350	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3351	Additional Fields Added to the Outlier Reconciliation Lump Sum Utility
3352	October 2015 Update of the Hospital Outpatient Prospective Payment System (OPPS)
3353	Quarterly Update to the Correct Coding Initiative (CCI) Edits, Version 22.0, Effective January 1, 2016
3354	January 2016 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
3355	Annual Medicare Physician Fee Schedule (MPFS) Files Delivery and Implementation Maintenance and Update of the Temporary Hook Created to Hold OPPS Claims that Include Certain Drug HCPCS Codes
3356	Maintenance and Update of the Temporary Hook Created to Hold OPPS Claims that Include Certain Drug HCPCS Codes
3357	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3358	Claims Processing Medicare Secondary Payer (MSP) Policy and Procedures Regarding Ongoing Responsibility for Medicals (ORM)
3359	October 2015 Integrated Outpatient Code Editor (I/OCE) Specifications Version 16.3
3360	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3361	October 2015 Update of the Ambulatory Surgical Center (ASC) Payment System
3362	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3363	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3364	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October CY 2015 Update
3365	2016 Healthcare Common Procedure Coding System (HCPCS) Annual Update Reminder
3366	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2016
Medicare Secondary Payer (CMS-Pub. 100-05)	
113	Instructions for the Shared Systems and Medicare Administrative Contractors (MACs) to follow when a Medicare Residual Payment must be Paid on Workers' Compensation Medicare Set-aside Arrangement (WCMSA) or for Ongoing Responsibility of Medicals (ORM) Non-Group Health Plan (NGHP) Medicare TOC Secondary Payer (MSP) Claims. MSP "W' Record and Accompanying Processes Medicare Residual Payments Due When On-going Responsibility for Medicals (ORM) Benefits Terminate, or Deplete, During a Beneficiary's Provider Facility Stay or Upon a Physician, or Supplier, Visit. Workers' Compensation (WC)
114	Claims Processing Medicare Secondary Payer (MSP) Policy and Procedures Regarding Ongoing Responsibility for Medicals (ORM)

	MSP Utilization Edits and Resolutions for Claims Submitted to CWF Identification of Liability and No-Fault Situations Identify Claims with Possible WC Coverage Identification of On-Going Responsibility for Medicals (ORM) in Liability, No-Fault, and Workers' Compensation Situations Background Regarding ORM for Contractors Policy Regarding ORM Operationalizing ORM for Liability, No-Fault, and Workers' Compensation Situations MSP Auxiliary File Errors Sources That May Identify Other Insurance Coverage
Medicare Financial Management (CMS-Pub. 100-06)	
251	Notice of New Interest Rate for Medicare Overpayments and Underpayments –4th Qtr. Notification for FY 2015
252	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
253	Update the Contractor Reporting of Operational and Workload Data (CROWD) CMS-2592 Report to Indicate Requests Received in Claims and Requests Received That Are Recovery Audit Related
Medicare State Operations Manual (CMS-Pub. 100-07)	
141	Revisions to the State Operations Manual (SOM), Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals
142	Revisions to State Operations Manual (SOM) Chapter 9 Exhibits
143	Revisions to State Operations Manual (SOM) Chapter 2, The Certification Process and Appendix W, Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs
144	Revisions to State Operations Manual (SOM) Appendix J, Part II – Interpretive Guidelines – Responsibilities of Intermediate Care Facilities for Individuals with Intellectual Disabilities
145	Revisions to Medicare State Operations Manual (SOM), Chapter 9 - Exhibits
146	State Operations Manual (SOM), Section 2185- Home Health Agencies (HHAs), Change of Address to a Medical Administrative Contractor (MAC) within 90 Days Home Health Agencies (HHAs)/2185-HHA Change of Address
Medicare Program Integrity (CMS-Pub. 100-08)	
600	Workload Reporting Prepay Complex Service Specific Review Prepay Complex Provider Specific Review
601	Review of Home Health Claims Home Health
602	Medical Review of Home Health Services Table of Contents Medical Review of Home Health Services Physician Certification of Patient Eligibility for the Medicare Home Health Benefit Certification Requirements Physician Recertification Recertification Elements The Use of the Patient's Medical Record Documentation to Support the Home Health Certification Coding Medical Necessity of Services Provided Examples of Sufficient Documentation Incorporated Into a Physician's Medical Record Medical Review of Home Health Demand Bills
603	Medical Review of Home Health Services Table of Contents Medical Review of Home Health Services Physician Certification of Patient Eligibility for the Medicare Home Health Benefit Certification Requirements Physician Recertification Recertification Elements The Use of the Patient's Medical Record Documentation to Support the Home Health Certification Coding Medical Necessity of Services Provided Examples of Sufficient Documentation Incorporated Into a Physician's Medical Record Medical Review of Home Health Demand Bills
604	Signature Requirements
605	Clarification Regarding the Processing of Certain Provider Enrollment-Related Transactions
606	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
607	Workload Reporting Prepay Complex Provider Specific Review
608	Update to Pub. 100-08 to Provide Language-Only Changes for Updating ICD-10 and ASC X12
609	Clarification Regarding the Processing of Certain Provider Enrollment-Related Transactions Denials Licenses and Certifications Final Adverse Action Supporting Documents Special Processing Guidelines for Form CMS-855A, Form CMS-855B, Form CMS-855I and Form CMS-855R Applications Sole Proprietorships CMHC 40 Percent Rule
610	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
611	Changes to Supplier Documentation and Evidence of Medical Necessity for 3 Oxygen Claims Supplier Documentation Evidence of Medical Necessity for the Oxygen Claims
612	Changes to Supplier Documentation and Evidence of Medical Necessity for Oxygen Claims Evidence of Medical Necessity for the Oxygen Claims
613	Postpayment Review Requirements Complex Medical Review

614	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
	None
Medicare Quality Improvement Organization (CMS- Pub. 100-10)	
	None
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)	
	None
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
	None
Demonstrations (CMS-Pub. 100-19)	
121	Medicare Care Choices Model (MCCM) - Per Beneficiary per Month Payment (PBPM) - Implementation
One Time Notification (CMS-Pub. 100-20)	
1514	Award of Medicare Administrative Contractor (MAC) Contract for Jurisdiction J
1515	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1516	Analysis and Design for Part B Detail Line Expansion
1517	Tester Resolution Reports for International Classification of Diseases, Tenth Revision (ICD-10) Limited End to End Testing with Submitters
1518	Contractor Reporting of Operational and Workload Data (CROWD) Form 5 Remittance Advice Reporting
1519	Medicare Appeals System (MAS) Upgrade
1520	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1521	CMS Information Security Acceptable Risk Safeguards Update - Multifactor Authentication
1522	Data Act Treasury Referral Timeframe and Reporting - DME MAC Changes
1523	Procedures for Processing Under Tolerance Part A 935, Part A-Other, Part A and B Healthcare Professional Shortage Area (HPSA), and Part A-Provider Recovery Audit Contractor (RAC) Identified debts in the Healthcare Integrated General Ledger Accounting System (HIGLAS)
1524	Medicare Remit Easy Print (MREP) Upgrade
1525	Add Original Common Working Files (CWF) Occurrence Number to the CWF Feed to MBD
1526	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1527	Update for Paper Claims Processing Under the Administrative Simplification Compliance Act (ASCA)
1528	Reporting of Anti-Cancer and Anti-Emetic Drugs
1529	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1530	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1531	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1532	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1533	Update Hard Coded Audit 205A MSP Return Code 3925 and Edit 152D
1534	Health Insurance Portability and Accountability Act (HIPAA) EDI Front End Updates for January 2016
1535	International Classification of Diseases, 10th Revision (ICD-10) Additional Acknowledgement Testing Reporting
1536	Increasing Tax Withholding to 100 Percent for Internal Revenue Service (IRS) Federal Payment Levy Program (FPLP)
1537	ICD-10 Conversion/Coding Infrastructure Revisions to National Coverage Determinations (NCDs)--3rd Maintenance CR
1538	Medicare Prior Authorization of Power Mobility Devices (PMDs) Demonstration: Advance Determination of Medicare Coverage (ADMC) Reviews for Beneficiaries Who Have Representative Payees
1539	Implementing the Insertion of a Sheet of Paper Promoting the Electronic Medicare Summary Notices (eMSNs) into Mailed Medicare Summary Notices (MSNs)
1540	Modification to the Telehealth Originating Site Facility Fee Billing Requirements for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)
1541	Health Insurance Portability and Accountability Act (HIPAA) EDI Front End Updates for October 2015
1542	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1543	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1544	Implementation of Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) Based on Specific Clinical Criteria
1545	Procedures for Processing Under Tolerance Part A 935, Part A-Other, Part A and B Healthcare Professional Shortage Area (HPSA), and Part A-Provider Recovery Audit Contractor (RAC) Identified debts in the Healthcare Integrated General
1546	Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction
Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)	
46	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
47	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
	None

Addendum II: Regulation Documents Published in the Federal Register (July through September 2015)

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-3Q15QPU.pdf

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

Addendum III: CMS Rulings

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

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

Addendum IV: Medicare National Coverage Determinations (July through September 2015)

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

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Medicare Coverage of Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)	NCD 210.14	R185	08/21/2015	02/05/2015
National Coverage Determination (NCD) for Screening for Colorectal Cancer Using Cologuard™ - A Multitarget Stool DNA Test	NCD 210.3	R183	08/06/2015	10/09/2014

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (July through September 2015)

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
G130235	ACTIGAIT IMPLANTABLE DROP FOOT STIMULATOR SYSTEM	09/18/15
G140192	Organ Care System (OCS) - Liver, Organ Care System (OCS) - Liver Console, OCS Liver Perfusion Set	07/09/15
G140202	AEQUALIS PYROCARBON HUMERALHEAD	08/26/15
G140221	Intergraft System	07/31/15
G140243	Organox Metra System	08/21/15
G150029	Tack Endovascular System	08/14/15
G150119	MagVenture MagProX100 with MagOption stimulator, C-B60 butterfly coil and MagPro Cool Coil B65 A/P	07/02/15
G150120	Pilot Study of Novottf - 100A System in Conjunction with Temozolomide Chemoradiation For Newly Diagnosed Glioblastoma	07/15/15
G150123	Argus II Retinal Prosthesis System	07/08/15
G150125	BreathID MCS System C-Methacetin Breath Test	07/31/15
G150127	SaluSTIM, a transcutaneous electrical nerve stimulation (TENS) device	07/10/15
G150131	Monovisc	07/16/15
G150132	University of Minnesota Medical School	08/11/15
G150134	HiResolution Bionic Ear System	07/16/15
G150136	Percutaneous Osseointegrated Prosthesis Implant	07/22/15
G150138	FLT3 Mutation Assay	07/23/15
G150140	CP810 Sound Processor	07/23/15
G150143	Juvederm Voluma XC For Chin Augmentation	07/31/15
G150145	Modulight Laser, Isotropic Probe, Cylindrical Light Diffuser, and Diffusing Balloon Catheter	07/31/15
G150147	SENTUS OTW QP L-75/ SENTUS OTW QP L-85/ SENTUS OTW QP L-95; SENTUS OTW QP S-75/ SENTUS OTW QP S-85/ SENTUS OTW QP S-95 MODEL 389 835/ 386 836/ 386 837/ 400 719/ 400 720/ 400 721	08/05/15
G150150	REPLICATE System	08/07/15
G150155	Osseointegrated Prostheses for the Rehabilitation of Amputees (OPRA)	08/14/15
G150161	Boston Scientific Vessix system	08/19/15
G150167	Medtronic Restore ULTRA 37712 spinal cord stimulator, Medtronic Specify 5-6-5, 16-electrode surgical lead	08/28/15
G150169	Visualase Thermal Therapy System	08/28/15
G150170	Mitralign Percutaneous Tricuspid Valve Annuloplasty System (PTVAS)	08/28/15
G150171	ELUVIA Drug-Eluting Vascular Stent System	09/02/15
G150173	MemoryGel Breast Implant UHP-L Smooth Round UHP-L Silicone Gel-Filled Breast Implant, MemoryGel Breast Implant UHP-L Siltex Round UHP-L Silicone Gel-Filled Breast Implant	09/03/15
G150174	Cutera Excel V	09/02/15
G150175	QUARTET MODEL 1457Q IDE STUDY	09/03/15
G150177	Cardiac Resynchronization Therapy Pacemakers	09/11/15
G150178	StimGuard Protect Chronic Tibial Nerve Stimulator (CTNS) System	09/18/15
G150179	SCD (Selective Cytopheretic Device)	09/17/15
G150180	Cook Antimicrobial Hernia Repair Device	09/17/15
G150182	VENTANA PD-L1 (SP142) CDx Assay	09/17/15
G150183	Cochlear Nucleus CI532 Cochlear Implant	09/18/15

Addendum VI: Approval Numbers for Collections of Information (July through September 2015)

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, (July through September 2015)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage For questions or additional information, contact Lori Ashby (410-786-6322).

Facility	Provider Number	Effective Date	State
The following facilities are new listings for this quarter.			
Pikeville Medical Center 911 Bypass Road Pikeville, KY 41501	180044	09/22/2015	KY
Truman Medical Center 2301 Holmes Street Kansas City, MO 64108	1467595793	09/22/2015	MO
Editorial changes (in bold) for this quarter.			
FROM: University Medical Center **TO: Banner University Medical Center Tucson** 1501 N. Campbell Avenue Tucson, AZ 85724	030064	06/01/2005	AZ
FROM: University Physicians Hospital **TO: Banner University Medical Center South** 2800 East Ajo Way Tucson, AZ 85713	030111	06/21/2012	AZ
FROM: Orlando Regional Healthcare System, Inc. **TO: Orlando Health** 52 West Underwood Street Orlando, FL 32806	100006	04/05/2006	FL
FROM: Medcenter One **TO: Sanford Health Bismarck** 300 North 7th Street Bismarck, ND 58506	350015	05/26/2005	ND

Addendum VIII: American College of Cardiology's National Cardiovascular Data Registry Sites (July through September 2015)

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

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

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

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available by accessing our website and clicking on the link for the American College of Cardiology's National Cardiovascular Data Registry at: www.ncdr.com/webncdr/common. For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

Facility	City	State
The following facilities are new listings for this quarter.		
Mountain Point Medical Center	Lehi	UT
University Health Conway	Monroe	LA
Sentara Albemarle Medical Center	Elizabeth City	NC
Fort Hamilton Hospital	Hamilton	OH
Piedmont Newnan Hospital	Newnan	GA
The following facilities are terminated as of this quarter.		
Baton Rouge General Medical Center (Mid City)	Baton Rouge	LA
Unity Medical and Surgical Hospital	Mishawaka	IN

Addendum IX: Active CMS Coverage-Related Guidance Documents (July through September 2015)

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 (410-786-7205).

Addendum X: List of Special One-Time Notices Regarding National Coverage Provisions (July through September 2015)

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 (410-786 7205).

Addendum XI: National Oncologic PET Registry (NOPR) (July through September 2015)

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 (July through September 2015)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred to the list of Medicare-approved facilities that meet our standards in the 3-month period. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage. For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

Facility	Provider Number	Date Approved	State
The following facilities are new listings for this quarter.			
Riverside Methodist Hospital 3535 Olentangy River Road Columbus, OH 43214	360006	8/11/2015	OH
Delray Medical Center, Inc 5352 Linton Boulevard Delray Beach, FL	100258	8/12/2015	FL
Editorial changes (in bold) for this quarter.			
TO: Keck Hospital of USC **FROM: USC University Hospital** 1500 San Pablo Street Los Angeles, CA 90033	050696	01/09/2004	CA

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (July through September 2015)

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 Marie Casey, BSN, MPH (410-786-7861).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (July through September 2015)

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 Jamie Hermansen (410-786-2064).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (July through September 2015)

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).

[FR Doc. 2015–28870 Filed 11–12–15; 8:45 am]
BILLING CODE 4120–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Head Start Family and Child Experiences Survey (FACES).

OMB No.: 0970–0151.

Description: The Office of Planning, Research and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data for a new round of the Head Start Family and Child Experiences Survey (FACES). Featuring a new ''Core Plus'' study design, FACES will provide data on a set of key indicators, including information for performance measures. The design allows for more rapid and frequent data reporting (Core studies) and serves as a vehicle for studying more complex issues and topics in greater detail and with increased efficiency (Plus studies).

The FACES Core study will assess the school readiness skills of Head Start children, survey their parents, and ask their Head Start teachers to rate children's social and emotional skills. In addition, FACES will include observations in Head Start classrooms, and program director, center director, and teacher surveys. FACES Plus studies include additional survey content of policy or programmatic interest, and may include additional programs or respondents beyond those participating in the Core FACES study.

Previous notices provided the opportunity for public comment on the proposed Head Start program recruitment and center selection process (FR V.78, pg. 75569 12/12/2013; FR V.79, pg. 8461 02/12/2014), the child-level data collection in fall 2014 and spring 2015(FR V. 79, pg. 11445 02/28/2014; FR V. 79; pg. 27620 5/14/2014), the program- and classroom-level spring 2015 data collection activities (FR v.79; pg. 73077 12/09/2014), and the American Indian and Alaska Native Head Start Family and Child Experiences Survey (AI/AN FACES) child-level data collection activities in fall 2015 and spring 2016 (FR V. 80, pg. 30250 08/07/2015). This 30-day notice describes the planned additional data collection activities for AI/AN FACES in spring 2016, including surveys with parents, teachers, program directors, and center directors.

AI/AN FACES spring 2016 data collection includes site visits to 37 centers in 22 Head Start programs. As in fall 2015, parents of sampled children will complete surveys on the Web or by telephone (or in person if needed) about their children, activities family members engage in with their children, and family and household background characteristics. Head Start teachers, program directors, and center directors will complete surveys about the Head Start classroom or program and their own background using the Web or paper-and-pencil forms.

The purpose of the Core data collection is to support the 2007 reauthorization of the Head Start program (Pub. L. 110–134), which calls for periodic assessments of Head Start's quality and effectiveness. As additional information collection activities are fully developed, in a manner consistent with the description provided in the 60-day notice (79 FR 11445) and prior to use, we will submit these materials for a 30-day public comment period under the Paperwork Reduction Act.

Respondents: Parents of Head Start children, Head Start teachers and Head Start staff.

ANNUAL BURDEN ESTIMATES—CURRENT INFORMATION COLLECTION REQUEST

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hour per response	Estimated annual burden hours
Head Start core parent survey for plus study (AI/AN FACES Spring 2016)	800	267	1	0.50	134
Head Start core teacher survey for plus study (AI/AN FACES)	80	27	1	0.58	16
Head Start program director core survey for plus study (AI/AN FACES)	22	7	1	0.33	2
Head Start center director core survey for plus study (AI/AN FACES)	37	12	1	0.33	4
Total					156

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov*.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

ACF Reports Clearance Officer.

[FR Doc. 2015–28815 Filed 11–12–15; 8:45 am]
BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: State Self-Assessment Review and Report.

OMB No.: 0970–0223.

Description: Section 454(15)(A) of the Social Security Act, as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, requires each State to annually assess