crosswalk to include comparable standards to require disclosure of the names and addresses of the facility's owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest.

- Section 485.645(a)(2): Updated its crosswalk to include the correct regulatory language to require that the facility limits inpatient beds to no more than 25 and is verified on all surveys.
- Section 488.5(a)(4)(vii): Updated its policies and review process to ensure that approved plans of correction fully address all non-compliant practices identified during the survey; that appropriate policy changes have been made to ensure compliance; and that plans of correction identify the responsible party for ensuring corrective actions are implemented within the CAH and contain a description of how the CAH will monitor and evaluate the effectiveness of the corrective actions, analyze the data, and report findings to the senior leadership and governing body to ensure continued regulatory compliance.
- Section 488.5(a)(12): Provided CMS with assurance that its procedures for responding to, and investigating complaints against accredited facilities are fully implemented and followed.
- Section 488.26(b): Revised surveyor documentation to include appropriately detailed deficiency statements that clearly support the determination of noncompliance and appropriate level of deficiency.

TJC revised its survey policy and procedure to clearly delineate that a survey will not occur until after the applicable Regional Office has made a determination of the CAH's compliance with location and distance requirements.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that TJC's CAH program requirements meet or exceed our requirements, and its survey processes are comparable to ours. Therefore, we approve TJC as a national accreditation organization for critical access hospitals that request participation in the Medicare program, effective November 21, 2017 through November 21, 2023.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: *October 16, 2017.*

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2017–23449 Filed 10–26–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9105–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July Through September 2017

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 2017, 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.

BILLING CODE 4120–01–P

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
VI Collections of Information	William Parham	(410) 786-4669
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

BILLING CODE 4120–01–C

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: October 20, 2017.

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 2016 (81 FR 79489, February 23, 2017 (82 FR 11456), May 5, 2017 (82 FR 21241) and August 4, 2017 (82 FR 36404). 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 2017)

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 Update to the National Correct Coding Initiative (NCCI) Procedure to Procedure (PTP) Edits, Version 23.3, Effective October 1, 2017 use (CMS-Pub. 100-04) Transmittal No. 3807.

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)
106	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
107	Affordable Care Act Bundled Payments for Care Improvement Initiative – Recurring File Updates Models 2 and 4 January 2018 Updates
	Medicare Benefit Policy (CMS-Pub. 100-02)
	None
	Medicare National Coverage Determination (CMS-Pub. 100-03)
199	Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)(Various Effective Dates Below) (Rev.)
200	Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) Spinal Stenosis (LSS)(Various Effective Dates Below)
201	National Coverage Determination (NCD20.8.4): Leadless Pacemakers Leadless Pacemakers

202	Updates to Pub. 100-04, Chapter 18 Preventive and Screening Services and Chapter 32 Billing Requirements for Special Services and Publication 100-03, Chapter 1 Coverage Determinations Part 4
Medicare Claims Processing (CMS-Pub. 100-04)	
3805	Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) Claims Processing Requirements for Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) on Professional Claims
3806	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3807	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure to Procedure (PTP) Edits, Version 23.3, Effective October 1, 2017
3808	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3809	October 2017 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
3810	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3811	Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)
3812	New Waived Tests
3813	Accepting Hospice Notices of Election via Electronic Data Interchange Procedures for Hospice Election and Related Transactions Notice of Election (NOE) Notice of Termination/Revocation (NOTR) Change of Provider/Transfer Notice Cancellation of an Election Change of Ownership Notice Data Required on the Institutional Claim to A/B MAC (HHH) Independent Attending Physician Services
3814	Updated Editing of Always Therapy Services – MCS Claims Processing Requirements for Financial Limitations
3815	National Coverage Determination (NCD20.8.4): Leadless Pacemakers Leadless Pacemaker Leadless Pacemaker Coding and Billing Requirements for Professional Claims Leadless Pacemaker Place of Service Restrictions Leadless Pacemaker Modifier Leadless Pacemaker Additional Claim of Billing Information Leadless Pacemaker Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Medicare Summary Notice (MSN) Messages
3816	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3817	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3818	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3819	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3820	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3821	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3822	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3823	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3824	July Quarterly Update for 2017 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule
3825	October Quarterly Update to 2017 Annual Update of HCPCS Codes Used for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Enforcement
3826	Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) Fiscal Year (FY) Annual Update
3827	Quarterly Influenza Virus Vaccine Code Update - January 2018 Table of Preventive and Screening Services Healthcare Common Procedure Coding System (HCPCS) and Diagnosis Codes CWF Edits on A/B MAC (A) Claims CWF Edits on A/B MAC (B) Claims CWF Crossover Edits for A/B MAC (B) Claims
3828	Update to Hospice Payment Rates, Hospice Cap, Hospice Wage Index and Hospice Pricer for FY 2017
3829	Revisions to the Home Health Pricer to Support Value-Based Purchasing and Payment Standardization
3830	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3831	Screening for Hepatitis B Virus (HBV) Institutional Billing Requirements Professional Billing Requirements Diagnosis Code Reporting Requirements Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages
3832	Fiscal Year (FY) 2017 Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) PPS Changes
3833	Quarterly Update to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)
3834	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3835	Screening for the Human Immunodeficiency Virus (HIV) Infection Healthcare Common Procedure Coding System (HCPCS) for HIV Screening Tests Billing Requirements Payment Method Types of Bill (TOBs) and Revenue Codes Diagnosis Code Reporting

	Medicare Summary Notice (MSN) and Claim Adjustment Reason Codes (CARCs)
3836	Home Health Value-Based Purchasing Implementation
3837	Influenza Vaccine Payment Allowances - Annual Update for 2017-2018 Season
3838	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October 2017 Update
3839	Claim Status Category and Claim Status Codes Update
3840	Common Edits and Enhancements Modules (CEM) Code Set Update
3841	Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): CORE 360 Uniform Use of Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Claim Adjustment Group Code (CAGC) Rule - Update from Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE)
3842	Healthcare Provider Taxonomy Codes (HPTCs) October 2017 Code Set Update
3843	2018 Healthcare Common Procedure Coding System (HCPCS) Annual Update Reminder
3844	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3845	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3846	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3847	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3848	Updates to Pub. 100-04, Chapter 18 Preventive and Screening Services and Chapter 32 Billing Requirements for Special Services and Publication 100-03, Chapter 1 Coverage Determinations Part 4
3849	Inpatient Rehabilitation Facility (IRF) Annual Update: Prospective Payment System (PPS) Pricer Changes for FY 2018
3850	Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - October 2017 Update
3851	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
3852	October 2017 Integrated Outpatient Code Editor (I/OCE) Specifications Version 18.3
3853	October 2017 Update of the Hospital Outpatient Prospective Payment System (OPPS)
3854	October 2017 Update of the Ambulatory Surgical Center (ASC) Payment System
3855	Internet Only Manual (IOM) Update to Pub. 100-04, Chapter 15 – Ambulance, to Restore Multiple Patients on One Trip Instructions
3856	Clarification of the Billing of Immunosuppressive Drugs Billing for Immunosuppressive Drugs
3857	2018 Annual Update of Healthcare Common Procedure Coding System (HCPCS) Codes for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Update
3858	Fiscal Year (FY) 2018 Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) PPS Changes
3859	October Quarterly Update for 2017 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule
3860	Instructions for Downloading the Medicare ZIP Code File for January 2018
3861	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) – January 2018
3862	Annual Clotting Factor Furnishing Fee Update 2018 Clotting Factor Furnishing Fee (Chapter 17 - Drugs and Biologicals 80.4.1)
3863	Updated Editing of Always Therapy Services – MCS Claims Processing Requirements for Financial Limitations
3864	October 2017 Update of the Hospital Outpatient Prospective Payment System (OPPS)
3865	Instructions for Retrieving the 2018 Pricing and HCPCS Data Files through CMS' Mainframe Telecommunications Systems
3866	Accepting Hospice Notices of Election via Electronic Data Interchange Procedures for Hospice Election and Related Transactions Notice of Election (NOE) Notice of Termination/Revocation (NOTR) Change of Provider/Transfer Notice Cancellation of an Election Change of Ownership Notice Data Required on the Institutional Claim to A/B MAC (HHH Independent Attending Physician Services
3867	New Waived Tests
3868	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3869	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 24.0, Effective January 1, 2018
3870	Annual Update for the Health Professional Shortage Area (HPSA) Bonus Payments
3871	Revisions to Medicare Claims Processing Manual for Foreign, Emergency and Shipboard Claims
Medicare Secondary Payer (CMS-Pub. 100-05)	
120	Electronic Correspondence Referral System (ECRS) User Guide Medicare Beneficiary Identifier (MBI) Modifications including Updated Enterprise Identity Management (EIDM) Multi-Factor Authentication (MFA)/Remote Identity Proofing (RIDP) Screen Shots ECRS Web User Guide ECRS Quick Reference Card
Medicare Financial Management (CMS-Pub. 100-06)	
288	Pub. 100-6, Chapter 3 and 4 Revisions Determining Liability and Waiver of Recovery for Overpayments Determination – Limitation of Liability Determination Determination – Waiver of Recovery of an Overpayment Overpayments Discovered Subsequent to the Third Year How to Determine the Third Calendar Year After the Payment was

	Approved Recovery of Overpayment Due to Cost Report Termination of Collection Action Termination of Collection Action – Provider Overpayments Termination of Collection Action- Beneficiary Overpayments Requirements for Collecting Part A and B Provider Non-MSP Overpayments Debt Ineligible for Referral Intent to Refer Letter Response to Intent to Refer Letter Intermediary Claims Accounts Receivable (Debts RTA by Treasury as Dispute Response not Received Timely (RX) Debts RTA by Treasury as a Miscellaneous Dispute, a Manual RTA, Complaint or as Recall Approved (RD Intent to Refer Letter
289	Notice of New Interest Rate for Medicare Overpayments and Underpayments -4th Qtr Notification for FY 2017
290	New Specialty Code for Pharmacy Non-Physician Practitioner/Supplier Specialty Codes
291	Notice of New Interest Rate for Medicare Overpayments and Underpayments -4th Qtr Notification for FY 2017
292	Revision to Publication 100-06, Chapter 3, Medicare Overpayment Manual, Section 200, Limitation on Recoupment Section 935 of the Medicare Modernization Act (MMA) - Limitation on Recoupment Overpayments Limitation on Recoupment Section 935(f)(2) Eligibility Overpayments Subject to Limitation on Recoupment Overpayments Not Subject to Limitation on Recoupment Adjustment of the Fee-For-Service Claims The Rebuttal Process and the Limitation on Recoupment Extrapolated 935 Overpayments Medicare Secondary Payer (MSP) Provider Duplicate Primary Payment (DPP) Immediate Recoupment Requirements for 935 Overpayments Requirements for All Initial Demand Letters (Manual or Electronic) Initial Demand
293	Revision to Publication 100-06, Chapter 3, Medicare Overpayment Manual, Section 200, Limitation on Recoupment
Medicare State Operations Manual (CMS-Pub. 100-07)	
170	Revisions to the State Operations Manual (SOM) Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals
Medicare Program Integrity (CMS-Pub. 100-08)	
733	Clarification of Certificate of Medical Necessity (CMN) and Durable Medical Equipment Information Forms (DIFs)
734	Update to Reporting Requirements Reconsideration Requests – Non-certified Providers/Suppliers External Reporting Requirements
735	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
736	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
737	Credentials of Reviewers Complex Medical Review
738	Provider Error Rate Formula Provider Error Rate
739	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
740	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
741	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
742	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
743	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
744	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
745	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
746	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)	
37	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
38	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
39	Updates to Pub. 100-09, Chapter 6 Beneficiary and Provider Communications Manual, Chapter 6, Provider Customer Service Program Provider Claims Payment Alerts
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)	
13	IOM 100-17 Update Additional Requirements for MACs CMS Contracting Officer's Representative (COR) Principal Systems Security Officer (SSO CMS Business Owners CMS System Maintainers/Developers Personnel Security/Suitability Control Components Reporting Requirements System Security Plan (SSP) Risk Assessment (RA) Contingency Planning Compliance Annual FISMA Assessment (FA) Plan of Action and Milestones (POA&M) Background POA&M Package Components/Submission Format Security Incident Reporting and Response Authorization To Operate Patch Management Security Configuration Management Security Technical Implementation Guides (STIG End of Life Technology Components Cloud Computing Minimum System Security Requirements—HIGH Encryption Requirements for Data Leaving Data Centers Internet Security
Demonstrations (CMS-Pub. 100-19)	
176	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
177	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
178	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
179	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
One Time Notification (CMS-Pub. 100-20)	
1864	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1865	Health Insurance Portability and Accountability Act (HIPAA) Electronic Data Interchange (EDI) Front End Updates for January 2018
1866	National Provider Identification Crosswalk System (NPICS) Retirement Analysis Only - Engage Shared Systems Maintainers (SSMs) and Medicare Administrative Contractors (MACs) in Meetings and Correspondence Related to the NPICS Retirement with the Integrated Data Repository (IDR) Team
1867	Renovate MCS Correspondence Entry Driver Program H99P1C00
1868	Fee For Service (FFS) Applications Upgrade Customer Information Control System (CICS) to Transaction Server (TS) v5.2
1869	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1870	Correcting Payment of Inpatient Prospective Payment System (IPPS) Transfer Claims Assigned to Medicare Severity-Diagnosis Related Group (MS DRG) 385 and Allowing Part A Deductible on Medicare Secondary Payer (MSP) Same Day Transfer Inpatient Claims
1871	FISS Process Enhancements – Analysis Only
1872	Common Working File (CWF) to Add User Identification (ID) Information to CWF Provider Queries Audit File(s)
1873	Line Level versus Claim Level Reporting – Analysis Only
1874	Implementation CR: Integrating NLR into the HQR system
1875	ICD-10 Coding Revisions to National Coverage Determinations (NCDs)
1876	Modifications to the National Coordination of Benefits Agreement (COBA) Crossover Process
1877	Common Working File (CWF) to Modify CWF Provider Queries to Only Accept National Provider Identifier (NPI) as valid Provider Number
1878	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1879	Common Working File (CWF) to Increase the Next Eligible Date Occurrences for Preventive Services to 99 Occurrences – Analysis
1880	Shared Savings Program (SSP) Demonstration Code 77 Modification
1881	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1882	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1883	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1884	Analysis Only- Medicare Reporting on the Return of Self-Identified Overpayments
1885	Shared System Maintainers (SSMs) Standardized Release Identification (ID) Format Analysis and Design
1886	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1887	Shared System Enhancement 2015: Identify Inactive Medicare Demonstration Projects Within the Common Working File (CWF)
1888	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1889	Implementation of the Transitional Drug Add-On Payment Adjustment
1890	CICS Region Merge(s) for A/B MACs - Analysis Only
1891	Automating the HCPCS Load Process
1892	Shared System Enhancement 2015: Identify Inactive Medicare Demonstration Projects within the Fiscal Intermediary Shared System
1893	Combined Common Edits/Enhancements Module (CCEM) Updates to Business and Holiday Tables
1894	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1895	System Changes to Implement Section 15010 of the 21st Century Cures Act, Temporary Exception for Certain Severe Wound Discharges from Certain Long-Term Care Hospitals (LTCHs)

1896	Shared System Enhancement 2015: Identify Inactive Medicare Demonstration Projects within the Fiscal Intermediary Shared System - (Removing/Archiving demonstration codes 03, 04 and 15)
1897	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1898	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1899	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1900	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1901	Automating the HCPCS Load Process
1902	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1903	Implement Changes to Effect the Functionality of Combination Force Codes in the ViPS Medicare System (VMS)
1904	Multi-Carrier System (MCS), Fiscal Intermediary Shared System (FISS) and VIPS Medicare Shared System (VMS) Automation of Prior Authorization (PA) Requests/Pre-Claim Reviews (PCR) and their Responses with Multiple Services (for programs like Home Health (HH)) via the Electronic Submission of Medical Documentation (esMD) System
1905	Modify VMS Accreditation Logic to Accept Additional Modifiers
1906	Out-of-Jurisdiction Providers (OJP) and Qualified Chain Providers (QCP) Move to Correct A/B MAC Jurisdiction - Analysis CR Only
1907	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1908	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1909	Implementation of Section 1557 for Medicare Redetermination Notices (MRNs) by Adding a Notice and Tagline Sheet
1910	Guidance on Implementing System Edits for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)
1911	Part B Detail Line Expansion - Common Working File (CWF)
1912	HIGLAS Enhancement Required for Implementation of Overpayment based Denials
1913	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1914	Shared System Enhancement 2014 – Identification of Fiscal Intermediary Shared System (FISS) Obsolete On-Request Jobs - Analysis Only
1915	Medicare Administrative Contractor (MAC) and Pricing, Data Analysis and Coding (PDAC) Contractor Implementation of the New Medicare Card Project
1916	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1917	Shared System Enhancement 2014 – Identification of Fiscal Intermediary Standard System (FISS) Obsolete Reports - Analysis Only
1918	Correcting Payment of Inpatient Prospective Payment System (IPPS) Transfer Claims Assigned to Medicare Severity-Diagnosis Related Group (MS DRG) 385 and Allowing Part A Deductible on Medicare Secondary Payer (MSP) Same Day Transfer Inpatient Claims
1919	Targeted Probe and Educate
1920	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1921	Implementation of Section 1557 for Medicare Redetermination Notices (MRNs) by Adding a Notice and Tagline Sheet
1922	Shared System Enhancement 2014: Implementation of Fiscal Intermediary Shared System (FISS) Obsolete Financial and Expert Claims Processing System (ECPS) Reports
1923	Calculating Interim Rates for Graduate Medical Education (GME) Payments to New Teaching Hospitals
1924	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1925	Guidance on Implementing System Edits for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)
1926	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1927	Shared System Enhancement 2014: Implementation of Fiscal Intermediary Shared System (FISS) Obsolete Core Reports
Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)	
367	Fiscal Year 2018 and After Payments to Skilled Nursing Facilities (SNFs) That Do Not Submit Required Quality Data
368	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
369	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
3	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction

Addendum II: Regulation Documents Published in the Federal Register (July through September 2017)

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-3Q17QPU.pdf

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

Addendum III: CMS Rulings (July through September 2017)

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 2017)

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
National Coverage Determination (NCD20.8.4): Leadless Pacemakers	20.8.4	201	07/28/2017	01/18/2017

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (July through September 2017)

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
BB17544	Magnetic-Activated Cell Sorter (CliniMACS, Miltenyi) TCR alpha/beta and CD19 T-cell depletion PBSC; conditioning	07/03/2017
BB17595	CliniMACS® TCRaß/CD19 Combined Depletion System	08/09/2017
BB17601	Hemanext Red Blood Cell Processing System	08/16/2017
BB17615	The Tissue Genesis Icellator Cell Isolation System (Icellator)	08/17/2017
G140210	LABS ADHESION BARRIER	09/01/2017
G170039	Vas Q Device	08/01/2017
G170063	Vercise PC Deep Brain Stimulation System	07/21/2017
G170080	ZOLL Proteus Intravascular Temperature Management (IVTM) System	07/20/2017
G170086	AGNES	07/21/2017
G170104	Eximo Medical B-Laser Hybrid Atherectomy System	07/11/2017
G170106	EndoRotor	08/25/2017
G170113	Coherex WaveCrest Left Atrial Appendage Occlusion System	09/08/2017

IDE	Device	Start Date
G170122	DCB Drug Coated Balloon Catheter	08/24/2017
G170123	Medrobotics Flex System	07/28/2017
G170136	The Sprinter Over-the-Wire Semicompliant Balloon Dilatation Catheter	08/22/2017
G170145	novottf-200A	08/11/2017
G170149	SPRINT PNS System	07/03/2017
G170151	Bovie Ultimate Electrosurgical Generator; Bovie Ultimate Electrosurgical Generator; Bovie J-Plasma Precise Open handpieces; Bovie J-Plasma Precise Open handpieces	07/13/2017
G170153	JUVEDERM VOLUMA XC with cannula	07/12/2017
G170154	Randomized Trial of Hybrid Coronary Revascularization versus Percutaneous Coronary Intervention	07/14/2017
G170157	Theranova 400 Dialyzer	07/14/2017
G170160	Exablate Model 4000 Type-2 for Blood-Brain Barrier Disruption (BBBD)	09/29/2017
G170161	Chronic Venous Thrombosis: Relief with Adjunctive Catheter-Directed Therapy (C-TRACT) Trial	07/21/2017
G170162	Clotbust ER (Sonolysis Headframe System) Model 3.0C	09/17/2017
G170164	BOND MSLN (5B2) assay	07/20/2017
G170166	PASCAL Transcatheter Mitral Valve Repair System	07/25/2017
G170169	DISCSS Spinal Cord SCS System	07/28/2017
G170172	AcrySof IQ PanOptix Intraocular Lens	07/28/2017
G170173	LUM Imaging System	07/28/2017
G170174	Cartiva Synthetic Cartilage Implant for CMC	08/03/2017
G170175	AcrySof IQ Extended Depth of Focus (EDF) Intraocular Lens (IOL)	08/02/2017
G170184	Orion Visual Cortical Prothesis System	08/16/2017
G170185	NeuroStar TMS System	08/24/2017
G170191	LFP Beta aDBS System	08/24/2017
G170192	BabyGentleStick	08/30/2017
G170193	TULA System	08/30/2017
G170194	Model 1000C Generator; Model 3000C Programmer	09/01/2017
G170195	Oxiplex	08/31/2017
G170196	Valiant PS-IDE Stent Graft System with Captiva Delivery System	08/31/2017
G170197	LC Bead LUMI (BTG-004387)	08/31/2017
G170198	Exatherm TBH	08/23/2017
G170200	The Bidirectional Neural Bypass System	08/31/2017
G170202	ProSpace System	09/07/2017
G170208	ExAblate Model 4000 Type-1 ("ExAblate Neuro") System	09/15/2017
G170211	Belotero Balance Dermal Filler	09/15/2017
G170212	NeuroStar Transcranial Magnetic Stimulation (TMS) Therapy System	09/16/2017
G170221	FLExAbility Sensor Enabled Substrate Targeted Ablation for Reduction of VT (LESS-VT) Study	09/29/2017
G170222	Therasphere	09/27/2017
G170224	VENTANA HER2neu (4B5) IUO Assay; INFORM HER2	09/29/2017
	Dual ISH DNA Probe Cocktail IUO Assay	

Addendum VI: Approval Numbers for Collections of Information (July through September 2017)

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 William Parham (410-786-4669).

Addendum VII: Medicare-Approved Carotid Stent Facilities, (July through September 2017)

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.			
Good Samaritan Hospital MultiCare Health System 401 15th Ave SE Puyallup, WA 98372	1841231461	07/13/2017	WA
UPMC Altoona 620 Howard Avenue Altoona, PA 16601-4899	1649278730	07/18/2017	PA
Chippenham and Johnston Willis Medical Center 7101 Jahnke Road Richmond, VA 23225	490112	08/15/2017	VA
St. Helena Hospital – Napa Valley 10 Woodland Road St. Helena, CA 94574	050013	08/15/2017	CA
Glens Falls Hospital	1871606764	08/15/2017	NY

Facility	Provider Number	Effective Date	State
100 Park Street Glens Falls, NY 12801			
Memorial Hospital West 703 North Flamingo Road Pembroke Pines, FL 33028	100281	08/15/2017	FL
The following facilities have editorial changes (in bold).			
FROM: Shands Hospital at the University of Florida **TO: UF Health Shands Hospital** 1600 SW Archer Road Gainesville, FL 32610	100113	06/29/2005	FL
Poplar Bluff Regional Medical Center **3100 Oak Grove Road** Poplar Bluff, MO 63901	260119	08/23/2005	MO
Mercy Hospital Joplin **100 Mercy Way** **Joplin, MO 64804-4524**	260001	04/19/2005	MO

Addendum VIII: American College of Cardiology's National Cardiovascular Data Registry Sites (July through September 2017)

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 terminations for this quarter.		
Gulf Pointe Surgery Center Termination date: 9/22/17. See case 00368616. They no longer perform these procedures.	Port Charlotte	FL
Lake Area Medical Center Termination date: 9/28/17. Please see case 00363080. They would like to terminate CathPCI and ICD because cardiology services at their facility were discontinued effective 7/1/17.	Lake Charles	LA
Doctor's Same Day Surgery Center Termination date: 9/20/17. See case 00368426. Providers no longer perform procedures.	Sarasota	FL

Addendum IX: Active CMS Coverage-Related Guidance Documents (July through September 2017)

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 (July through September 2017)

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) (July through September 2017)

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 2017)

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 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.			
Beth Israel Deaconess Medical Center 330 Brookline Avenue Boston, MA 02215	22-0086	6/23/2107	MA
Mission Hospital 509 Biltmore Avenue Asheville, NC 28801-4690	34-0002	06/09/2016	NC
University Health Care System 1350 Walton Way Augusta, GA 30901	110028	08/16/2017	GA
Baystate Medical Center 759 Chestnut Street Springfield, MA 01199	22-0077	08/07/2017	MA

Facility	Provider Number	Date Approved	State
The following facilities have editorial changes (in bold).			
Fresno Community Hospital and Medical Center 2823 Fresno Street Fresno, CA 93721	**50060**	**12/14/2016**	CA
Maine Medical Center 22 Bramhall Street Portland, ME 04102	200009	**09/28/2016**	TX
Hackensack University Medical Center 30 Prospect Avenue Hackensack, NJ 07601	310001	**09/20/2017**	NJ
FROM : Banner Good Samaritan Medical Center **TO: Banner – University Medical Center Phoenix** 1111 East McDowell Road Phoenix, AZ 85006	030002	**07/26/2017**	AZ

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (July through September 2017)

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 (July through September 2017)

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 (July through September 2017)

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. 2017–23447 Filed 10–26–17; 8:45 am]
BILLING CODE 4120–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1076]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection in the guidance on ''Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice.''

DATES: Submit either electronic or written comments on the collection of information by December 26, 2017.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 26, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of December 26, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–N–1076 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the 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. ''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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites