

B. Federal Reserve Bank of San Francisco (Applications and Enforcement Section) 101 Market Street, San Francisco, California 94105–1579:

1. *GUVJEC Investment Corporation, Baltimore, Maryland*; to become a bank holding company by acquiring Farmington Bancorp, Bothell, Washington, and thereby indirectly acquire Farmington State Bank, Farmington, Washington.

Board of Governors of the Federal Reserve System, February 10, 2020.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2020–02921 Filed 2–12–20; 8:45 am]

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FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may

express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than March 3, 2020.

A. Federal Reserve Bank of Atlanta (Kathryn Haney, Assistant Vice President) 1000 Peachtree Street, NE, Atlanta, Georgia 30309. Comments can also be sent electronically to Applications.Comments@atl.frb.org:

1. *The Persons Family Trust, Macon Georgia, George Ogden Persons, III, Macon, Georgia, Jim Gillis Persons, Atlanta, Georgia, and Katherine Persons Kelly, Richmond, Virginia, as co-trustees; together with George Ogden Persons, III, Jim Gillis Persons, Katherine Persons Kelly, Mary K. Persons, Macon, Georgia, James G. Persons, Jr., Atlanta, Georgia, and Robert P. Persons and Harper Lee Kelly, both of Richmond, Virginia; as members of a group acting in concert to retain voting shares of Persons Banking Co., Inc., Macon, Georgia, and thereby indirectly retain voting shares of Persons Banking Company, Forsyth, Georgia.*

Board of Governors of the Federal Reserve System, February 10, 2020.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2020–02922 Filed 2–12–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9120–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—October Through December 2019

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 October through December 2019, 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 No.
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	David Dolan, MBA	(410) 786–3365
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	David Dolan, MBA	(410) 786–3365
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	David Dolan, MBA	(410) 786–3365
All Other Information	Annette Brewer	(410) 786–6580

SUPPLEMENTARY INFORMATION:

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination

and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective

communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners

(NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

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

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website 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 website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website 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 websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the

need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website 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: January 30, 2020.

Kathleen Cantwell

Director, Office of Strategic Operations and Regulatory Affairs.

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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: February 19, 2019 (84 FR 4805), April 29, 2019 (84 FR 18040), August 9, 2019 (84 FR 39323) and November 6, 2019 (84 FR 59815). 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 1: Medicare and Medicaid Manual Instructions (October through December 2019)

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 Updates to Publication (Pub.) 100-01, Manual Updates for CR11152 Implementation of the Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPM), use (CMS-Pub. 100-01) Transmittal No. 126.

Addendum 1 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)	
126	Manual Updates for CR11152 Implementation of the Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPM)
127	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
128	Internet Only Manual (IOM) - Update to General Information, Eligibility, and Entitlement, Chapter 7 - Contract Administrative Requirements, Section 40.2 - Shared System Maintainer Responsibilities for Systems Releases
129	Update to Medicare Deductible, Coinsurance and Premium Rates for Calendar Year (CY) 2020
Medicare Benefit Policy (CMS-Pub. 100-02)	
261	Manual Updates for CR11152 Implementation of the Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPM) Benefit Period (Spell of Illness) Inpatient Benefit Days Medicare SNF PPS Overview Three-Day Prior Hospitalization

	Transition Claims Default Billing	
4410	October 2019 Update of the Ambulatory Surgical Center (ASC) Payment System	
4411	October 2019 Update of the Hospital Outpatient Prospective Payment System (OPPS)	
4412	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions	
4413	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions	
4414	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions	
4415	Medicare Administrative Contractor (MAC) Guidance Related to Use of Adjustment Codes on Adjustment Claims	
4416	MAC Guidance Related to Use of Adjustment Codes on Adjustment Claims	
4417	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
4418	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
4419	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions	
4420	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
4421	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions	
4422	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to- Procedure (PTP) Edits, Version 26.0, Effective January 1, 2020	
4423	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to- Procedure (P/P) Edits, Version 26.0, Effective January 1, 2020	
4424	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2020	
4425	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions	
4426	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions	
4427	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
4428	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
4429	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
4430	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
4431	Health Professional Shortage Area (HPSA) Bonus Payments for All Mental Health Specialties HPSA Designations Services Eligible for HPSA and Physician Scarcity Bonus Payments	

	Three-Day Prior Hospitalization - Foreign Hospital Administrative Level of Care Presumption Services Provided on an Inpatient Basis as a "Practical Matter" The Availability of Alternative Facilities or Services Whether Available Alternatives Are More Economical in the Individual Case Who May Sign the Certification or Recertification for Extended Care Services Services Furnished Under Arrangements	
262	Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2020	
263	Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Medicare Benefit Policy Manual Chapter 13 Update	
264	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction	
	Medicare National Coverage Determination (CMS-Pub. 100-03)	
	None	
	Medicare Claims Processing (CMS-Pub. 100-04)	
4405	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
4406	Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) Updates for Fiscal Year (FY) 2020 Annual Update Wage Index Determining the Cost-to-Charge Ratio	
4407	Ambulance Inflation Factor for Calendar Year (CY) 2020 and Productivity Adjustment Ambulance Inflation Factor (AIF)	
4408	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions	
4409	Manual Updates for CR11152 Implementation of the Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPM) Inpatient Part A Billing and SNF Consolidated Billing/Requirement for SNFs Types of Facilities Subject to the Consolidated Billing Requirement for SNFs Physician's Services and Other Professional Services Excluded From Part A PPS Payment and the Consolidated Billing Requirement Other Excluded Services Beyond the Scope of the SNF Part A Benefit Other Services Excluded from SNF PPS and Consolidated Billing Input/Output Record Layout Decision Logic Used by the Pricer on Claims SNF Spell of Illness Quick Reference Chart Retrospective Removal of Sanctions Swing Bed Services Not Included in the Part A PPS Rate Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPM) HIPPS Updates and Structure Changes Interrupted Stay Policy Variable Per Diem (VPD) Adjustment AIDS Adjustments	

	For Use in the National Coordination of Benefits Agreement (COBA)
4455	Crossover Process
4456	Calendar Year (CY) 2020 Participation Enrollment and Medicare Participating Physicians and Suppliers Directory (MEDPARD) Procedures Combined Common Edits/Enhancements Modules (CCEM) Code Set Update
4457	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
4458	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
4459	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4460	Claim Status Category and Claim Status Codes Update
4461	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
4462	Instructions for Downloading the Medicare ZIP Code Files for April 2020
4463	Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): Committee on Operating Rules for Information Exchange (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) CORE
4464	Instructions for Retrieving the 2020 Pricing and Healthcare Common Procedure Coding System (HCPCS) Data Files through CMS' Mainframe Telecommunications Systems
4465	Medicare Claims Processing Manual Chapter 23 - Fee Schedule Administration and Coding Requirements
4466	Home Health Prospective Payment System (HH PPS) Rate Update for Calendar Year (CY) 2020
4467	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4468	Summary of Policies in the Calendar Year (CY) 2020 Medicare Physician Fee Schedule (MPFS) Final Rule, Telehealth Originating Site Facility Fee Payment Amount and Telehealth Services List, CT Modifier Reduction List, and Preventive Services List
4469	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4470	CY 2020 Update for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
4471	April 2020 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder
4472	New Medicare Provider Specialty Code (D5) and Billing Codes for Opioid Treatment Programs and New Place of Service Code 58
4473	Update to Medicare Claims Processing Manual, Chapters 1, 23 and 35
4474	Updates to the Coordination of Benefits Agreement Insurance File (COIF) For Use in the National Coordination of Benefits Agreement (COBA)
4475	Crossover Process
	Changes to the Laboratory National Coverage Determination (NCD) Edit

	Post-payment Review
4432	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4433	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
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4441	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4442	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4443	Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - October 2019 Update
4444	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4445	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4446	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
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4450	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4451	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4452	Home Health (HH) Patient-Driven Groupings Model (PDGM) - Revised and Additional Manual Instructions Discharge and Readmission Situation Under HH PPS - Payment Effects Request for Anticipated Payment (RAP)
4453	HH PPS Claims
	Home Health Prospective Payment System (HH PPS) Rate Update for Calendar Year (CY) 2020
4454	Updates to the Coordination of Benefits Agreement Insurance File (COIF)

	Weakness Material Weaknesses Identified During the Reporting Period Statement on Standards for Attestation Engagements (SSAE) Number 18, (SSAE 18) Reporting on Controls at Service Providers List of Complementary User Entity Controls (CUECs) Information Systems Claims Processing Medical Review (MR) Medicare Secondary Payer (MSP) Provider Audit Financial Financial (Non-HIGLAS) Financial (HIGLAS) Debt Referral (MSP and Non-MSP) Debt Referral (MSP and Non-MSP) (Non-HIGLAS) Debt Referral (MSP and Non-MSP) (HIGLAS) Non-MSP Debt Collection Corrective Action Plan (CAP) Reports CMS Finding Numbers Initial CAP Report Quarterly CAP Report CMS Initial and Quarterly CAP Report Template B Controls – Claims Process Controls – Provider Audit Controls – Debt Referral (MSP and Non-MSP) List of Commonly Used Acronyms
332	New Medicare Provider Specialty Code (D5) and Billing Codes for Opioid Treatment Programs and New Place of Service Code 58
333	New Medicare Provider Specialty Code (D5) and Billing Codes for Opioid Treatment Programs and New Place of Service Code 58
Medicare State Operations Manual (CMS-Pub. 100-07)	
194	Revisions to State Operations Manual (SOM) Appendix G, Guidance for Surveyors: Rural Health Clinics
195	Revisions to State Operations Manual (SOM) Chapter 6 - Special Procedures for Laboratories and Chapter 9 Exhibits
Medicare Program Integrity (CMS-Pub. 100-08)	
907	Update to Chapter 3, Section 3.2.3.1 Additional Documentation Requests (ADR) of Publication (Pub) 100-08
908	The Medicare Fee-for-Service Recovery Audit Program The Medicare Fee-for-Service (FFS) Recovery Audit Program Medicare FFS Recovery Audit Program Communication with Recovery Audit Contractors (RACs) RAC Points of Contact Applications to Assist Communication RAC/MAC Communication Referral to the UPIC Joint Operating Agreement Provider Information Overview of the RAC Process Inputting Suppression and Exclusion Cases to the RACDW

	Software for April 2020
4476	Calendar Year (CY) 2020 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
4477	Update Inpatient Prospective Payment System (IPPS) Pricer and Related Claims Reprocessing
4478	Manual Update to Publication (Pub.) 100-04, Chapter 20, to Revise the Subsection 10 - Where to Bill Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Parenteral and Enteral Nutrition (PEN) Items and Services
4479	Internet Only Manual Update to Add New and Revise Sections of Publication 100-04, Chapter 16
4480	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
4481	Internet Only Manual Update to Pub 100-04, Chapter 16, Section 40.8 - Laboratory Date of Service Policy
4482	Home Health (HH) Patient-Driven Groupings Model (PDGM) - Split Implementation
4483	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
4484	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4485	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
4486	New Medicare Provider Specialty Code (D5) and Billing Codes for Opioid Treatment Programs and New Place of Service Code 58
4487	CY 2020 Update for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
Medicare Secondary Payer (CMS-Pub. 100-05)	
	None
Medicare Financial Management (CMS-Pub. 100-06)	
326	The Medicare Fee-for-Service Recovery Audit Program
327	Notice of New Interest Rate for Medicare Overpayments and Underpayments - 1st Qtr Notification for FY 2020
328	Updates to Medicare Financial Management Manual Chapter 4, Section 50-50.6 Extended Repayment Schedules
329	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
330	The Medicare Fee-for-Service Recovery Audit Program
331	FMFIA and the CMS Medicare Contractor Contract Standards for Internal Control Contractor Internal Control Review Process and Timeline Risk Assessment Certification Package for Internal Controls (CPIC) Requirements OMB Circular A-123, Appendix A: Internal Controls Over Financial Reporting (ICOFR) Certification Statement CPIC- Report of Material Weaknesses CPIC- Report of Internal Control Deficiencies Definitions of Control Deficiency, Significant Deficiency, and Material

	Adjusting the Claim Tracking Overpayments and Appeals Underpayment Error Files Closure/Retraction Files Extended Repayment Schedule Requests Received on a RAC Initiated Overpayment Appeals Resulting from RAC Initiated Denials Referrals to the Department of the Treasury Reporting Administrative Costs Directly Associated with the RAC Program Potential Fraud MAC Requirements Involving RAC Information Dissemination Voluntary Refund Working with RAC Support Contractors Receivables Initiated by the RAC as Independent Audit Accessible Information MAC Participation in the Review Approval Process
909	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
910	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
911	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
912	Medicare Administrative Contractor (MAC) Verification of Potential Errors and Corrective Actions Taken
913	Corrective Action Reporting Requirements
914	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
915	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
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919	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
920	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
921	The Medicare Fee-for-Service Recovery Audit Program The Medicare Fee-for-Service (FFS) Recovery Audit Program Medicare FFS Recovery Audit Program Communication with Recovery Audit Contractors (RACs) RAC Points of Contact Applications to Assist Communication RAC/MAC Communication

	Referral to the UPIC Joint Operating Agreement Provider Information Overview of the RAC Process Inputting Suppression and Exclusion Cases to the RACDW Adjusting the Claim Tracking Overpayments and Appeals Underpayment Error Files Closure/Retraction Files Extended Repayment Schedule Requests Received on a RAC Initiated Overpayment Appeals Resulting from RAC Initiated Denials Referrals to the Department of the Treasury Reporting Administrative Costs Directly Associated with the RAC Program Potential Fraud MAC Requirements Involving RAC Information Dissemination Voluntary Refund Working with RAC Support Contractors Receivables Initiated by the RAC as Independent Audit Accessible Information MAC Participation in the Review Approval Process
922	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
923	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
924	Updates to the Medical Review Instructions Related to Skilled Nursing Facilities (SNF)
925	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
926	Additional Guidance on Private Contracting/ Opting-out of Medicare and Entering) Opt-out Affidavit Records in the Provider Enrollment, Chain and Ownership System (PECOS)
927	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
928	Medicare Administrative Contractor (MAC) Verification of Potential Errors and Corrective Actions Taken
929	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
	Medicare Contractor, Beneficiary and Provider Communications (CMS-Pub. 100-09)
42	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
43	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
	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)

	Without Cost or With a Credit Policy
2382	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)—April 2020 Update
2383	User Change Request: Fiscal Intermediary Shared System (FISS) - Hook Option for National Provider Identifier (NPI) Does Not Select Claims
2384	User CR: ViPS Medicare System (VMS) - Increase Edit Code Maximum
2385	Medicare Shared Savings Program (SSP) Skilled Nursing Facility (SNF) Affiliates' Updated Qualifying Stay Edit
2386	ViPS Medicare System (VMS) Online and Print Reporting of Automated Claims Examination System (ACES) Statistics
2387	Positron Emission Tomography (PET) Scan - Allow Tracer Codes Q9982 and Q9983 in the Fiscal Intermediary Shared System (FISS)
2388	User Change Request (CR) - Adjustment Reason Code to Identify Office of the Inspector General (OIG) Initiated Overpayments and Healthcare Integrated General Ledger Accounting System (HIGLAS) Demand Letter Verbiage
2389	User CR: ViPS Medicare System (VMS) Increase Number of SuperOp Occurrences within a Value Set
2390	Enhance Maximum Claim Counter for Edits and Audits - Implementation
2391	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
2392	Refinement of the Transitional Drug Add-on Payment Adjustment (TDAPA)
2393	Mobile Personal Identity Verification (PIV) Station Installation
2394	Updating Fiscal Intermediary Shared System (FISS) Editing for Practice Locations to Bypass Mobile Facility and/or Portable Units and Services Rendered in the Patient's Home
2395	Implementation to Accept Document Codes and Include Appropriate Document Code(s) in the Pre-Pay Electronic Medical Documentation Requests (eMDR) to Participating Providers, via the Electronic Submission of Medical Documentation (esMD) System
2396	Create a New Standalone Health Insurance Master Record (HIMR) Application Analysis Only
2397	User CR: ViPS Medicare System (VMS) Updates to Entry Code (VEC9) Processing
2398	Updates to Bills Pending Report for the Fiscal Intermediary Shared System (FISS)
2399	User CR: ViPS Medicare System (VMS) Update to the Automated Paperless Exception System (APEX) Selection Process
2400	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
2401	Fiscal Intermediary Shared System (FISS) Reason Code Reports to Show Status for Active Reason Codes
2402	Implementation to Adopt the Document Codes into the Post-Pay Electronic Medical Documentation Requests (eMDR) to Participating Providers via the Electronic Submission of Medical Documentation (esMD) System
2403	Automation of Part B Underpayment Processing of Recovery Audit Contractor (RAC) Adjustments
2404	Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging -

	None
	Medicare Managed Care (CMS-Pub. 100-16)
	None
	Medicare Business Partners Systems Security (CMS-Pub. 100-17)
	None
	Medicare Prescription Drug Benefit (CMS-Pub. 100-18)
	None
	Demonstrations (CMS-Pub. 100-19)
230	Next Generation and Vermont ACO Model - AIPBP Reduction File and BE Modifications
231	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
232	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
233	Display PARHAM Claim Payment Amount
234	TVIG Demonstration: Payment Update for 2020
	One Time Notification (CMS-Pub. 100-20)
2366	Implementation of the Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPM)
2367	Implementation for First Coast Service Options (FCSO) and Novitas for the CMS Enterprise Identity Management OKTA/Saviynt Migration
2368	Reconciliation Effort Between Shared Systems and Provider Enrollment Chain and Ownership System (PECOS)
2369	Implementation for First Coast Service Options (FCSO) and Novitas for the CMS Enterprise Identity Management OKTA/Saviynt Migration
2370	Integrated Data Repository (IDR) Weekly Scheduled Full Provider Master File Extracts
2371	New Overpayment Field Established within the ViPS Medicare System (VMS) for Healthcare Integrated General Ledger Accounting System (HIGLAS) Reporting
2372	Add Dates of Service (DOS) for Pneumococcal Pneumonia Vaccination (PPV) Health Care Procedure Code System (HCPCS) Codes (90670, 90732), and remove Next eligible dates for PPV IICPCS
2373	Home Health Orders for Nurse Practitioners under the Maryland Total Cost of Care (TCOC) Model
2374	Updating Calendar Year (CY) 2020 Medicare Diabetes Prevention Program (MDPP) Payment Rates
2375	Advanced Provider Screening (APS) Phase 2 Go-Live
2376	User CR: MGS - Updates to Beneficiary Deliverable Logic for Internal/Clerk Duplicate Medicare Summary Notices (MSNs) and Temporary Addresses
2377	User Change Request: Analysis for Medicare Summary Notices (MSNs) without Beneficiary Address after Finalist
2378	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
2379	Updates to CR 11152 Implementation of the Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPM)
2380	Editing Update for Vaccine Services
2381	Addition of Medical Severity Diagnosis Related Groups (MS-DRG) Subject to Inpatient Prospective Payment System (IPPS) Replaced Devices Offered

	Educational and Operations Testing Period - Claims Processing Requirements
2405	Expand Other Amounts Indicator to Carry Additional Values
2406	Health Insurance Portability and Accountability Act (HIPAA) Electronic Data Interchange (EDI) Front End Updates for January 2020
2407	User Change Request: Enhancement to Update Electronic Funds Transfer (EFT) Process
2408	Add Dates of Service (DOS) for Pneumococcal Pneumonia Vaccination (PPV) Health Care Procedure Code System (HCPCS) Codes (90670, 90732), and remove Next eligible dates for PPV HCPCS.
2409	Medicare Shared Savings Program (SSP) Skilled Nursing Facility (SNF) Affiliates' Updated Qualifying Stay Edits
2410	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
2411	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
2412	Expand Narrative File Message Number Range Implementation
	Medicare Quality Reporting Incentive Programs (CMS Pub. 100-22)
	None
	Information Security Acceptable Risk Safeguards (CMS Pub. 100-25)
	None

Addendum II: Regulation Documents Published in the Federal Register (October through December 2019)

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:

<https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/QPUCOctoberDecember2019>

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

Addendum III: CMS Rulings (October through December 2019)

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 (October through December 2019)

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. There were no updates to national coverage determinations (NCDs), or reconsiderations of completed NCDs published 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).

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDES) (October through December 2019)

(Inclusion of this addenda is under discussion internally.)

Addendum VI: Approval Numbers for Collections of Information (October through December 2019)

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, (October through December 2019)

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/MedicareApprovedFacilities/CASE/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.			
California Pacific Medical Center – Davies Campus 601 Duboce Avenue San Francisco, CA 94117 – 3389 Other information: Sutter Bay Hospitals – dba California Pacific Medical Center (CPMC) – Davies	050008	10/08/2019	CA
Providence Park Hospital 47601 Grand River Novi, MI 48374	230019	10/08/2019	MI

Facility	Provider Number	Effective Date	State
Avera McKennan Hospital and University Health Center 1325 S. Cliff Avenue Sioux Falls, SD 57105	1568460772	10/29/2019	SD
Hackensack Meridian Health Mountainside Medical Center 1 Bay Avenue Montclair, NJ 07042	310054	11/05/2019	NJ
The following facilities have editorial changes (in bold).			
FROM: Mount Clemens General Hospital TO: McLaren Macomb Hospital 1000 Harrington Boulevard Mount Clemens, MI 48043	230227	10/11/2005	MI
FROM: Providence – Providence Park Hospital TO: Providence Hospital 16001 West Nine Mile Road Southfield, MI 48075	230019	06/27/2005	MI
FROM: Floyd Memorial Hospital and Health Services TO: Baptist Health Floyd 1850 State Street New Albany, IN 47150	1497798847	10/17/2013	IN
FROM: USC University Hospital TO: Keck Hospital of USC 1500 San Pablo Street Los Angeles, CA 90033	050696	10/24/2005	CA
FROM: St. Elizabeth Regional Health East TO: Franciscan Health Lafayette East 1701 S. Creasy Lane Lafayette, IN 47905	150109	01/03/2011	IN
FROM: Appleton Medical Center TO: ThedaCare Regional Medical Center-Appleton, Inc. 1818 N Meade Street Appleton WI 54911-3454	520160	06/14/2005	WI
FROM: Theda Clark Medical Center TO: ThedaCare Regional Medical Center-Neenah, Inc. 130 2nd Street Neenah, WI 54956-2883	520045	06/14/2005	WI

Addendum VIII:

American College of Cardiology's National Cardiovascular Data Registry Sites (October through December 2019)

The initial data collection requirement through the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) has served to develop and improve the evidence base for the use of ICDs in certain Medicare beneficiaries. The data collection requirement ended with the posting of the final decision memo for Implantable Cardioverter Defibrillators on February 15, 2018.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum IX: Active CMS Coverage-Related Guidance Documents (October through December 2019)

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 (October through December 2019)

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

Addendum XI: National Oncologic PET Registry (NOPR) (October through December 2019)

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/MedicareApprovedFacilities/NOPR/list.asp#TopOfPage>. For questions or additional information, contact David Dolan, MBA (410-786-3365).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (October through December 2019)

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/MedicareApprovedFacilities/VAD/list.asp#TopOfPage>.

For questions or additional information, contact David Dolan, MBA, (410-786-3365).

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
Old: Cedars-Sinai Medical Center New: Cedars-Sinai Health System 8700 Beverly Boulevard Los Angeles, CA 90048 Other information: Joint Commission ID # 9792 Previous Re-certification Dates: 2008-12-12; 2011-06-21; 2013-06-11; 2015-05-29; 2017-07-11	050625	12/29/2003	09/11/2019	CA
Banner-University Medical Center Tucson Campus 1625 North Campbell Tucson, AZ 85719 Other information: Joint Commission ID # 9514	030064	04/19/2017	07/12/2019	AZ
Banner – University Medical Center Phoenix 1111 East McDowell Road Phoenix, AZ 85006 Other information: Joint Commission ID # 9489	030002	07/26/2017	07/10/2019	AZ
FROM: Stanford University Hospital and Clinics TO: Stanford Health Care 300 Pasteur Drive Stanford, CA 94305 Other information: Joint Commission ID # 10010 Previous Re-certification Dates: 2010-11-24; 2012-12-12; 2014-12-09; 2017-03-14	050441	12/22/2003	08/28/2019	CA
Bryan Medical Center 1600 South 48th Street Lincoln, NE 68506 Other information: Joint Commission ID # 244330 Previous Re-certification Dates: 2013-03-05; 2015-02-12; 2017-04-18	280003	10/23/2003	07/17/2019	NE

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
The following facility is new for this quarter.				
Sunrise Hospital & Medical Center 3186 S. Maryland Parkway Las Vegas, NV 89109 Other information: DNV GL Certificate # 95992-2019-VAD	290003	09/10/2019		NV
The following facilities have editorial changes (in bold).				
FROM: University of Alabama at Birmingham Health System TO: University of Alabama at Birmingham 619 19TH S. South Birmingham, AL 35249-1900 Other information: Joint Commission ID # 2814 Previous Re-certification Dates: 2008-12-09; 2011-04-22; 2013-04-09; 2015-04-07; 2017-05-16	010033	10/29/2003	07/03/2019	AL
FROM: Memorial Hermann Hospital TO: Memorial Hermann – Texas Medical Center 6411 Fannin Street Houston, TX 77030-1501 Other information: Joint Commission ID # 9081 Previous Re-certification Dates: 2013-03-19; 2015-04-14; 2017-05-24	450068	04/10/2013	06/26/2019	TX

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
12-18				
FROM: Texas Heart Hospital of the Southwest DBA The Heart Hospital Baylor Plano TO: Texas Heart Hospital of the Southwest, LLP 1100 Allied Drive Plano, TX 75093 Other information: Joint Commission ID # 440319 Previous Re-certification Dates: 2013-07-09; 2015-07-14; 2017-08-22	670025	06/15/2011	09/07/2019	TX
FROM: Baptist Memorial Hospital TO: Baptist Memorial Hospital – Memphis 6019 Walnut Grove Road Memphis, TN 38120 Other information: Joint Commission ID # 7869 Previous Re-certification Dates: 2009-01-27; 2011-05-20; 2013-04-17; 2015-06-02; 2017-07-25	440048	04/07/2007	09/18/2019	TN
Baystate Medical Center 759 Chestnut Street Springfield, MA 01199 Other information: Joint Commission ID # 2768 Old: Jewish Hospital New: Jewish Hospital and St. Mary's Healthcare 200 Abraham Flexner Way Louisville, KY 40202 Other information: Joint Commission ID # 7765 Previous Re-certification Dates: 2008-11-14; 2011-03-22; 2013-02-26; 2015-03-24; 2017-05-23	220077	08/07/2017	09/11/2019	MA
	180040	11/10/2003	08/07/2019	KY

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
FROM: Spectrum Health – Butterworth Campus Hospitals TO: Spectrum Health 100 Michigan Street, NE Grand Rapids, MI 49503 Other information: Joint Commission ID # 277668 Previous Re-certification Dates: 2013-06-18; 2015-05-19; 2017-06-20	230038	06/17/2011	09/25/2019	MI
FROM: St. Vincent Hospital and Health Services TO: St. Vincent Hospital and Health Care Services, Inc. 2001 West 86th Street Indianapolis, IN 46260 Other information: Joint Commission ID # 7178 Previous Re-certification Dates: 2008-12-16; 2011-05-17; 2013-06-25; 2015-05-19; 2017-06-13	150084	01/05/2004	07/31/2019	IN
FROM: OSF St Francis Medical Center TO: OSF Saint Francis Medical Center 530 NE Glen Oak Avenue Peoria, IL 61637 Other information: DNV GL Certificate # 95663-2019-VAD Previously De-certified 2011-11-22	140067	08/31/2009	10/10/2019	IL
Rush University Medical Center 1653 West Congress Parkway Chicago, IL 60612 Other information: DNV GL Certificate # 167371-2019-VAD Previously De-certified 2014-	140119	07/19/2013	09/25/2019	IL

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/MedicareApprovedFacilities/LVRS/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (October through December 2019)

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' 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/MedicareApprovedFacilities/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 (October through December 2019)

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/MedicareApprovedFacilities/PETDT/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA (410-786-3365).

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
FROM: Tampa General Hospital TO: Florida Health Sciences Center Inc. 1 Tampa General Circle Tampa, FL 33606 Other information: Joint Commission ID # 6934 Previous Re-certification Dates: 2011-04-05; 2013-04-09; 2015-04-21; 2017-06-06 FROM: Swedish Medical Center Cherry Hill TO: Swedish Health Services d/b/a Swedish Medical Center Cherry Hill 500 17th Avenue Seattle, WA 98122 Other information: DNV GL Certificate # 528555-2019-VAD Previous Re-certification Dates: 2011-04-05; 2013-04-09; 2015-04-21; 2017-06-06	100128	12/19/2008	07/24/2019	FL
	500025	11/09/2016	10/15/2019	WA

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (October through December 2019)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery.

Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

[FR Doc. 2020-02845 Filed 2-12-20; 8:45 am]

BILLING CODE 4120-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-2494]

Peripheral Vascular Atherectomy Devices—Premarket Notification Submissions; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled “Peripheral Vascular Atherectomy Devices—Premarket Notification Submissions.” This guidance provides recommendations for premarket submissions for a new or modified peripheral vascular atherectomy device.

DATES: The announcement of the guidance is published in the **Federal Register** on February 13, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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 Docket No. FDA-2018-D-2494 for “Peripheral Vascular Atherectomy Devices—Premarket Notification [510(k)] Submissions.” Received comments 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.govinfo.gov/content/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Peripheral Vascular Atherectomy Devices—Premarket Notification [510(k)] Submissions” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Jhumur Banik, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2223, Silver Spring, MD 20993-0002, 240-402-5239.

SUPPLEMENTARY INFORMATION:

I. Background

Atherectomy is an interventional procedure performed to remove atherosclerotic plaque from diseased arteries. FDA has developed this guidance for members of industry who submit and FDA staff who review premarket submissions for atherectomy devices used in the peripheral vasculature. This guidance is intended to provide recommendations for information to include in premarket notifications (510(k)) for peripheral vascular atherectomy devices (e.g., descriptive characteristics, labeling, biocompatibility, sterility, non-clinical, animal, and clinical performance testing).

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of July 27, 2018 (83 FR 35658). FDA revised the guidance as appropriate in response to the comments.

II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Peripheral